CREATING VALUE FOR INVESTORS
THROUGH OUR NEXT PHASE OF GROWTH

CAPITAL MARKETS DAY

23 NOVEMBER 2022

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AGENDA

Time	AGENDA
10:00 am	**Update on ROVI's strategy** Juan López-Belmonte, Chairman and CEO
10:30 am	**Update on R&D strategy** Ibón Gutierro, R&D Manager
10:50 am	**Financial results** Javier López-Belmonte, Deputy Chairman and CFO
11:00 am	**Q&A**
11:30 am	**Closure** Juan López-Belmonte, Chairman and CEO

Chair: Marta Campos, Head of Investor Relations

Update on ROVI's strategy

Juan López-Belmonte
Chairman and Chief Executive Officer

OVERVIEW

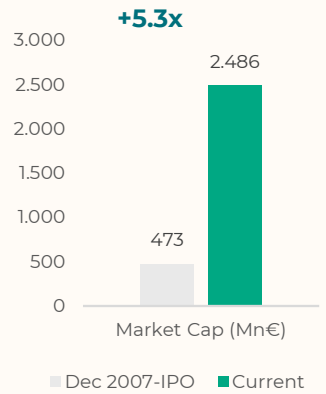
Madrid, Spain
Company HQ

1,751 Employees as of Dec 2021

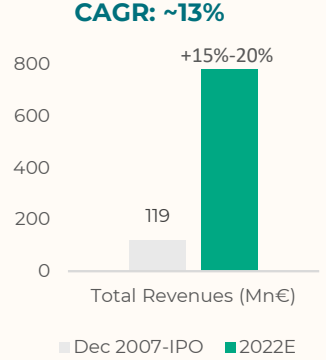
c.250 Specialty Pharma Sales Force

7 Fully Invested Manufacturing Facilities

MKT CAP (€M)[1]



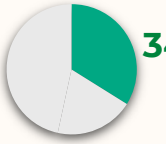
TOTAL REVENUES (€M)[2]

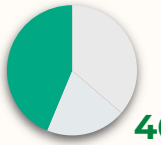


Solid specialty pharma growth story coupled with strong potential from the ISM® Platform

Leading Proprietary LMWH Franchise	• **Unparalleled know-how** of the Low Molecular Weight Heparin ("LMWH") market. • **2 in-house developed flagship products**: Bemiparin **Hibor®** ("Hibor®") and Enoxaparin biosimilar **Becat®** ("Becat®")
Leading Spanish Specialty Pharma Business	• Through its **large and specialized sales force** (c. 250 employees) ROVI distributes in Spain its proprietary products and third party products through in-license agreements • 15 new in-licensed products over the last 12 years
CMO	• Vertical integration and fully-invested production facilities allow ROVI to offer high-value-added injectable and oral forms CMO services • One of the global leaders in **pre-filled syringes** manufacturing[3]
ISM®[4] Technology Platform	• **Patent-protected, long-acting sustained-release injectable technology** provides versatile platform with wide applicability across multiple drug candidates - **Lead candidate Risperidone ISM®, a long acting injectable of risperidone** for schizophrenia. Approved for commercialization in Europe in Feb 2022 (launched in Germany in April, UK in July and Spain in September) and in approval process in USA since Nov 2020 - **A long-acting injectable of Letrozole** for hormone-dependent breast cancer that will start an efficacy clinical trial in 2H 2023

Revenue 9M 2022[2]





Approved in Europe and in approval process in the United Estates

Currently at Clinical Development Stage

1. CapIQ as of Oct 31, 2022.
2. Total revenues include sales from products and services, royalties and government grants.
3. In terms of annual number of units manufactured. Offers filling and finishing; does not manufacture the syringe itself.
4. ISM® stands for "In-Situ Microimplants" technology.
5. Includes revenues from Hibor®and Becat®.
6. Includes sales of goods excluding Hibor® and Becat®.
7. Includes sales of services.

ROVI under transformation

	ROVI today	Next Steps	ROVI in the future
Leading Proprietary Heparin Franchise	Presence in more than 70 countries	• New enoxaparin biosimilar launches	Potential presence in more than 110 countries
Leading Spanish Specialty Pharma Business	c. 250 specialty pharma sales force	• Specialized Psychiatric salesforce in Europe	Specialized psychiatric salesforce in Europe
CMO	7 fully invested manufacturing facilities	• Second API LMWH plant in Granada • Glicopeptón • Crude heparin plant • Moderna agreement	10 fully invested manufacturing facilities Manufacturing partner for Moderna outside USA
ISM® Technology Platform	3 key own products (Bemiparin, Enoxaparin biosimilar and Okedi®)	• Risvan® • Letrozole ISM® • Risperidone ISM® (quarterly)	At least 5 key own products (Bemiparin + Enoxaparin biosimilar + Risperidone ISM® + Letrozole ISM® + Risperidone ISM® (quarterly))

ROVI improves its ESG Rating in 2022

SUSTAINALYTICS

ROVI has obtained an **ESG Rating** 2022 of

17.3

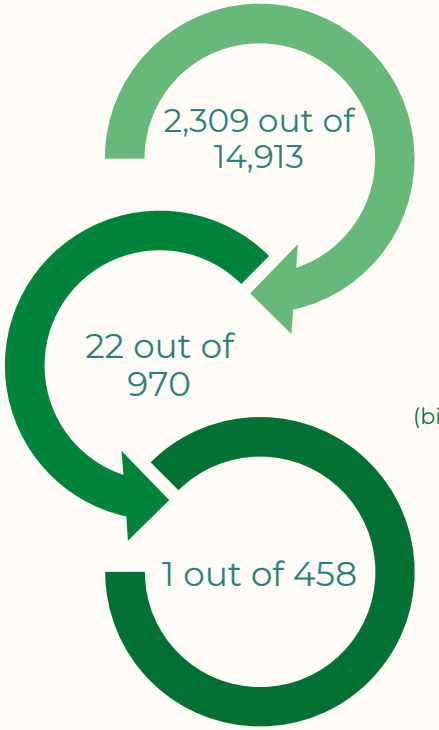
(low risk between 10 and 20)

United Nations Global Compact

- ROVI is a member of the **United Nations Global Compact**
- ROVI is a **carbon neutral** company

1st position out of 458 companies

(in the sub-industry "pharmaceuticals")



Global Universe

Industry Group
(biotech + laboratory equipment + pharma companies)

Subindustry
(pharma companies)

Key Company highlights

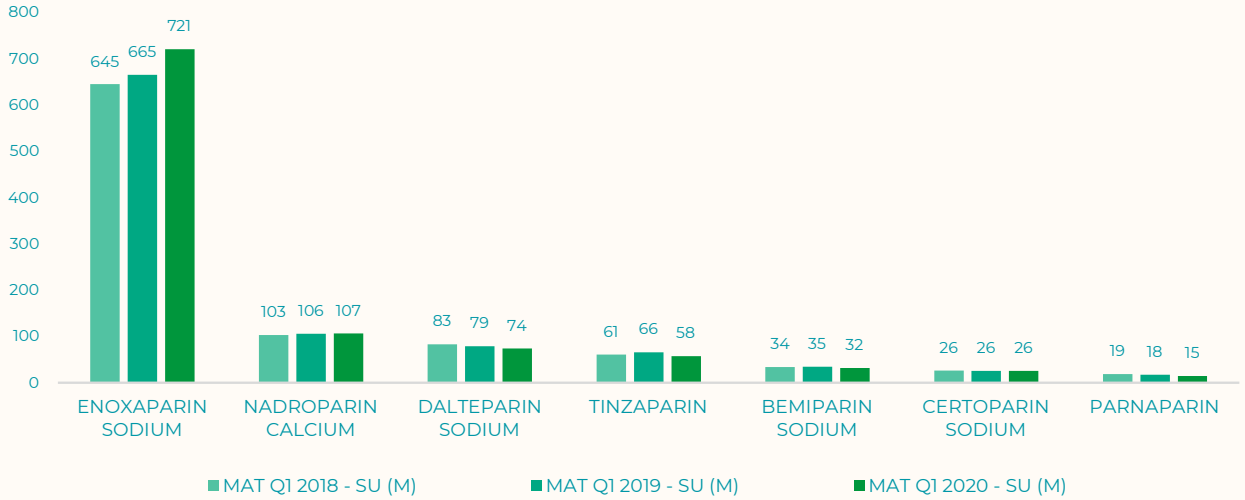
- Well-balanced pan-European specialty pharma business with 3 diversified growth drivers
- Unparalleled proprietary heparin franchise with strong European footprint
- Leading Spanish specialty pharma franchise
- High-value-added global CMO business with differentiated capabilities

- Proprietary ISM® Platform opens up new avenues of growth
- Ownership of technology and vertical integration enhance competitive position
- Potential wide applicability of ISM® technology to new chronic therapeutic areas

- Sound financial policy supported by strong track record

The LMWH market has increased by 3% over the period 2018-2020 (in units)

Market growth – Million units



Market growth

Enoxaparin is the main driver with an average growth of 5.7% in Q1 2018-Q1 2020 MAT to 721Mn units in Q1 2020 MAT

Market size

The size of the market is over €4Bn where EMA-ROW represent 83% of the market

Enoxaparin accounts for 63% of the market **(€2.6Bn)**

REGION (€Mn)	ENOXAPARIN SODIUM	NADROPARIN CALCIUM	DALTEPARIN SODIUM	TINZAPARIN	BEMIPARIN SODIUM	OTHERS	TOTAL
EMA	1,323.3	173.3	145.8	297.5	107.9	62.6	2,110.4
RoW	687.3	176.3	73.7	16.3	23.7	297	1,274.2
USA-CAN	547.5	0.0	68.5	22.0	0.0	0.0	637.9
Japan	8.5	0.0	13.2	0.0	0.0	11.1	32.8
Total	**2,566.5**	**349.7**	**301.2**	**335.8**	**131.6**	**370.6**	**4,055.3**

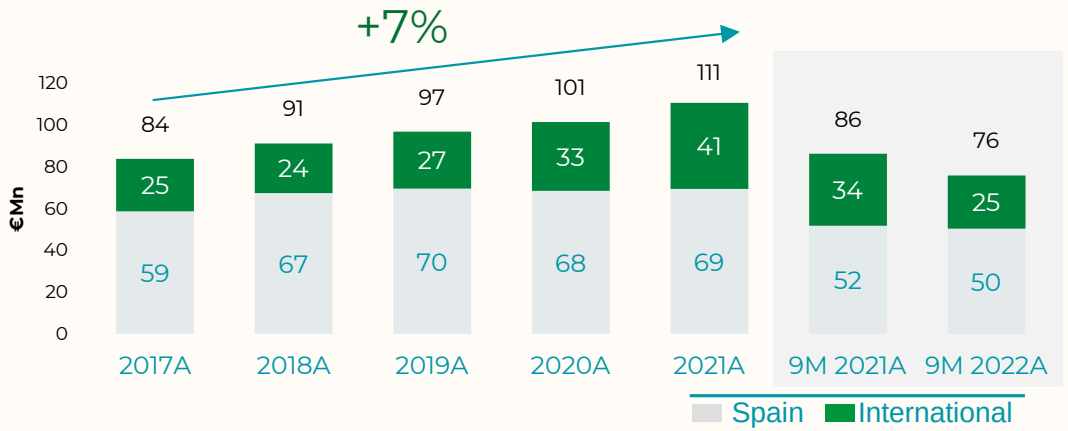
Source: IQVIA MIDAS Q1 2020

Bemiparin Hibor® is ROVI's first internally-developed flagship heparin product

Unparalleled Know-How of the Heparin Market

- ROVI has been engaged in the development of heparin-based drugs for **over 70 years**
- Bemiparin Hibor® is a **Low Molecular Weight Heparin** (LMWH)
  - **#1 market position in Spain** with a c.33% [1] market share and presence in 70 countries in total
  - Only 2nd generation LMWH; **clinically differentiated from other competitors (such as Sanofi's Clexane / Lovenox)**
- **Vertically integrated** structure with its own **LMWH manufacturing plant**

Bemiparin Hibor® Global Sales



Approved in **63** countries

Registration in process in **2** countries

Pending authorization in **5** countries

Bemiparin HIBOR® is the LMWH with the highest anti Xa/IIa ratio, which may lead to a higher antithrombotic activity without increasing the bleeding risk

More convenient treatment: 1 daily injection needed in comparison to Sanofi's (Clexane / Lovenox) treatment, which requires 2[2].

International network supported by long-term contracts with leading local pharma distributors

In-house legal team has achieved marketing authorisations worldwide

International Bemiparin sales are expected to decrease due to our focus on the enoxaparin biosimilar outside Spain

1. Iqvia Midas Sep 2022
2. Bemiparin, due to its superior pharmacological profile, is the only second-generation LMWH that guarantees an effective 24h coverage with an always once-daily dose in all patient profiles, regardless of their risk level.

Enoxaparin €2.6bn global market: an untapped opportunity for ROVI's biosimilar Becat®

European market represents an attractive opportunity

- **Enoxaparin** (such as Clexane / Lovenox) **is the world leading LMWH**
- **Europe** is the **largest Enoxaparin market** worldwide (>50%)[1]

€2.6Bn Global Sales[1]

721Mm units Global Sales[1]

+5.7% Global Q1 18- Q1 20 MAT CAGR[1]

€1.3Bn European Sales[1]

€0.7Bn Emerging Markets Sales[1]

European Competitive Landscape

Originator

CLEXANE / LOVENOX

- Originator product developed by Sanofi Aventis
- Patent expired in 2011 (high entry barriers: first biosimilar entered the market 6 years after patent expiry)

Biosimilar

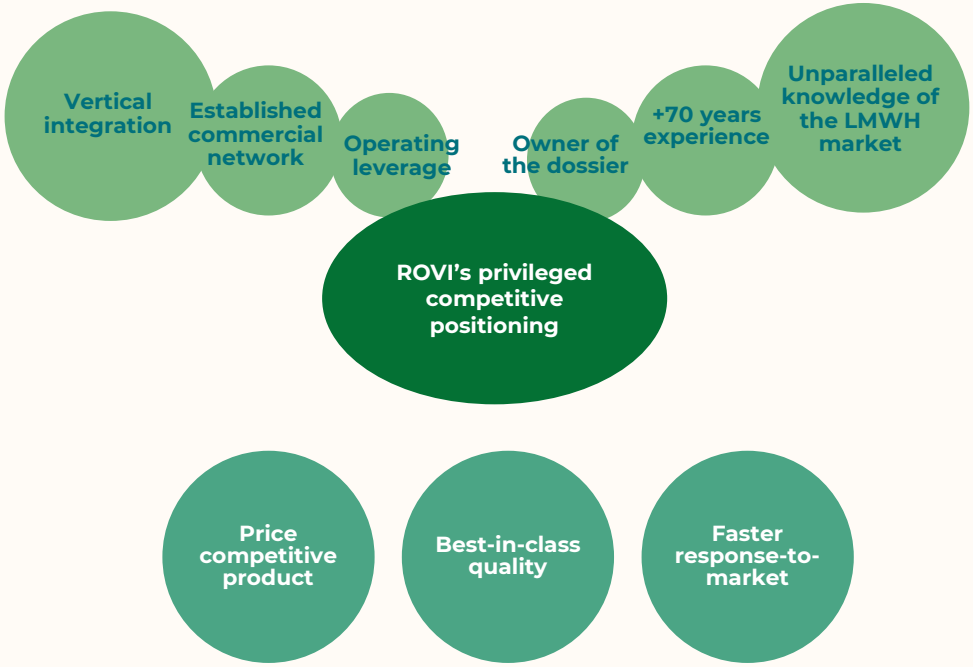
Enoxaparin biosimilar **Becat®**

- ROVI markets its internally-developed enoxaparin biosimilar
- Launched in Sep'17 with total sales of €124.0Mn in 2021 and €119.2Mn in 9M 2022

In the long term, biosimilars tend to reach a 50%-70% share of the reference product market[2]

Well-positioned for long-term leadership in LMWH

- ROVI aims to become one of **Europe's top players in a €1.3bn market**
- ROVI's **competitive advantages** within the LMWH market:



1. IQVIA MIDAS Q1 2020
2. Technavio 2016 biosimilars report

Strong growth potential of Enoxaparin Biosimilar Becat®

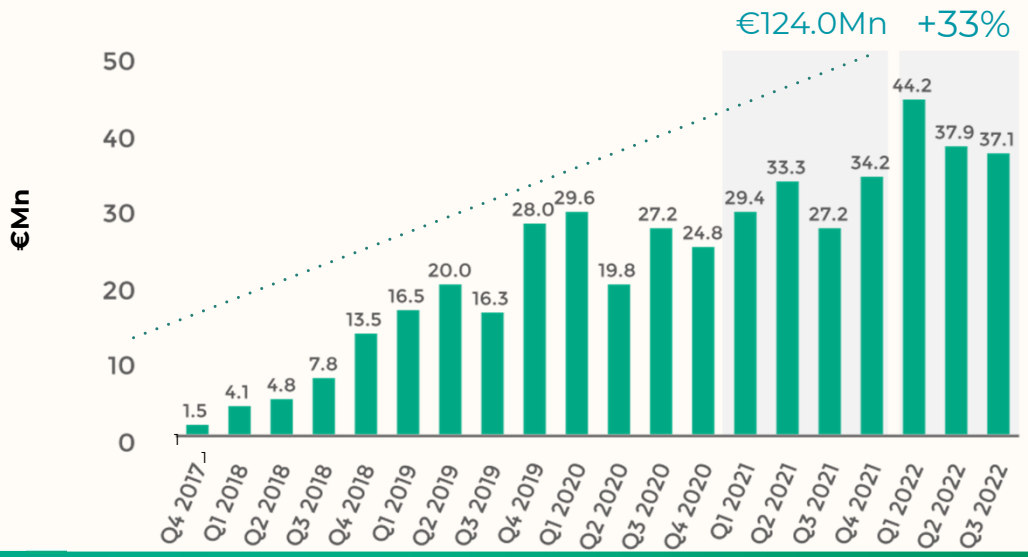
Well-established network to minimize time-to-market

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

Approved in **26 countries in Europe** and **31 in the Rest of the World**

Launched in **38 countries**

Enoxaparin Biosimilar Becat® sales ramp-up



Stage I of commercial strategy

...the largest enoxaparin market with **€1.3bn** sales[2]

ROVI directly markets enoxaparin biosimilar Becat® in 7 European countries...

...which account for c.75% of the European market[3]

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

50-70% Market Share[4]

...of the reference product market

Launches in 9M 2022

ROVI launched its enoxaparin biosimilar in 5 countries in 9M 2022: Brazil, Luxembourg, Colombia, Bosnia and Herzegovina and Kosovo.

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

€0.7bn Q1 2020 MAT Market Sales[2]

1. Becat® 4Q 2017 sales include sales in September. As the product was launched that month, sales were negligible.
2. IQVIA MIDAS Q1 2020
3. QuintilesIMS, 2015.
4. Technavio 2016 biosimilars report.

International growth potential of Enoxaparin Biosimilar Becat®

Stage II of commercial strategy

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

Out-Licensed agreements already signed: **81 Countries**

ROVI signed a licensing agreement with Sandoz to distribute the enoxaparin biosimilar Becat® in 14 countries/regions and with Hikma in 17 Middle East and North African countries.

€0.7Bn
Q1 2020 MAT Market Sales[1]

Agreements with international partners

teva · CABER Farmaceutici · Tzamal Medical Group · Gobbi Novag S.A. · Sandoz A Novartis Division · Norameda · hikma · Juno Pharmaceuticals · Avansor Pharma Oy · adcock ingram · achē · Dem İlaç

2022 [2]

- Brazil
- Luxembourg
- Colombia
- Bosnian
- Kosovo

2023 [2]

- Jordan
- Sri Lanka
- Montenegro
- Ecuador
- Lebanon
- New Zealand
- Paraguay
- Mexico

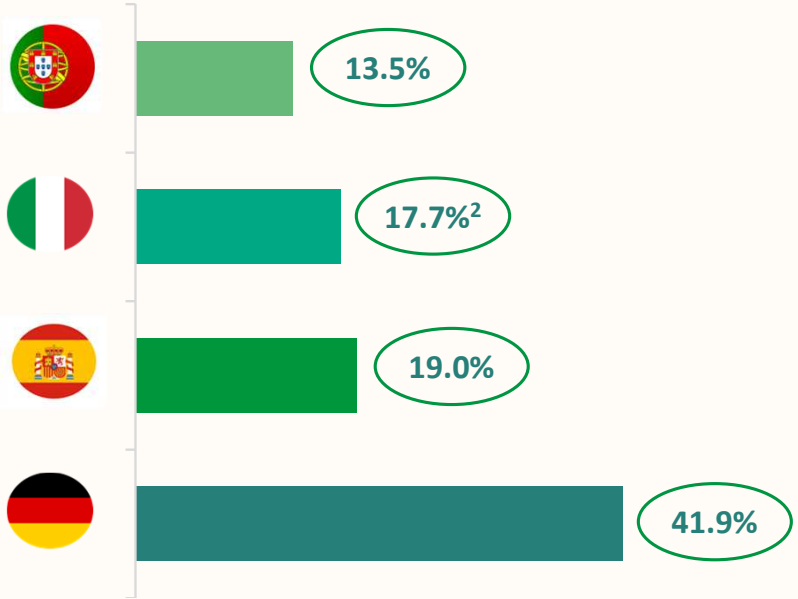
2024 [2]

- Argentina
- Vietnam
- Ukraine
- UAE[3]
- Kuwait
- Turkey
- Belarus
- Malta
- China

1. IQVIA MIDAS Q1 2020
2. Most important markets to be launched
3. United Arab Emirates

ROVI aims to become one of the leaders in the LMWH market

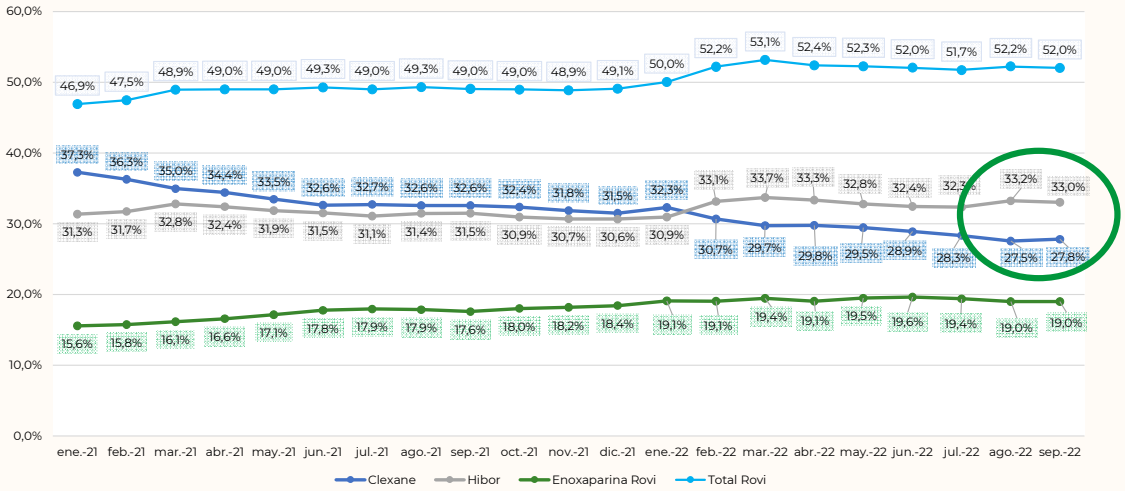
Enoxaparin market share ROVI[1]



Note: market shares correspond to the retail market except Italy (total market share) where the hospital market is more significant.

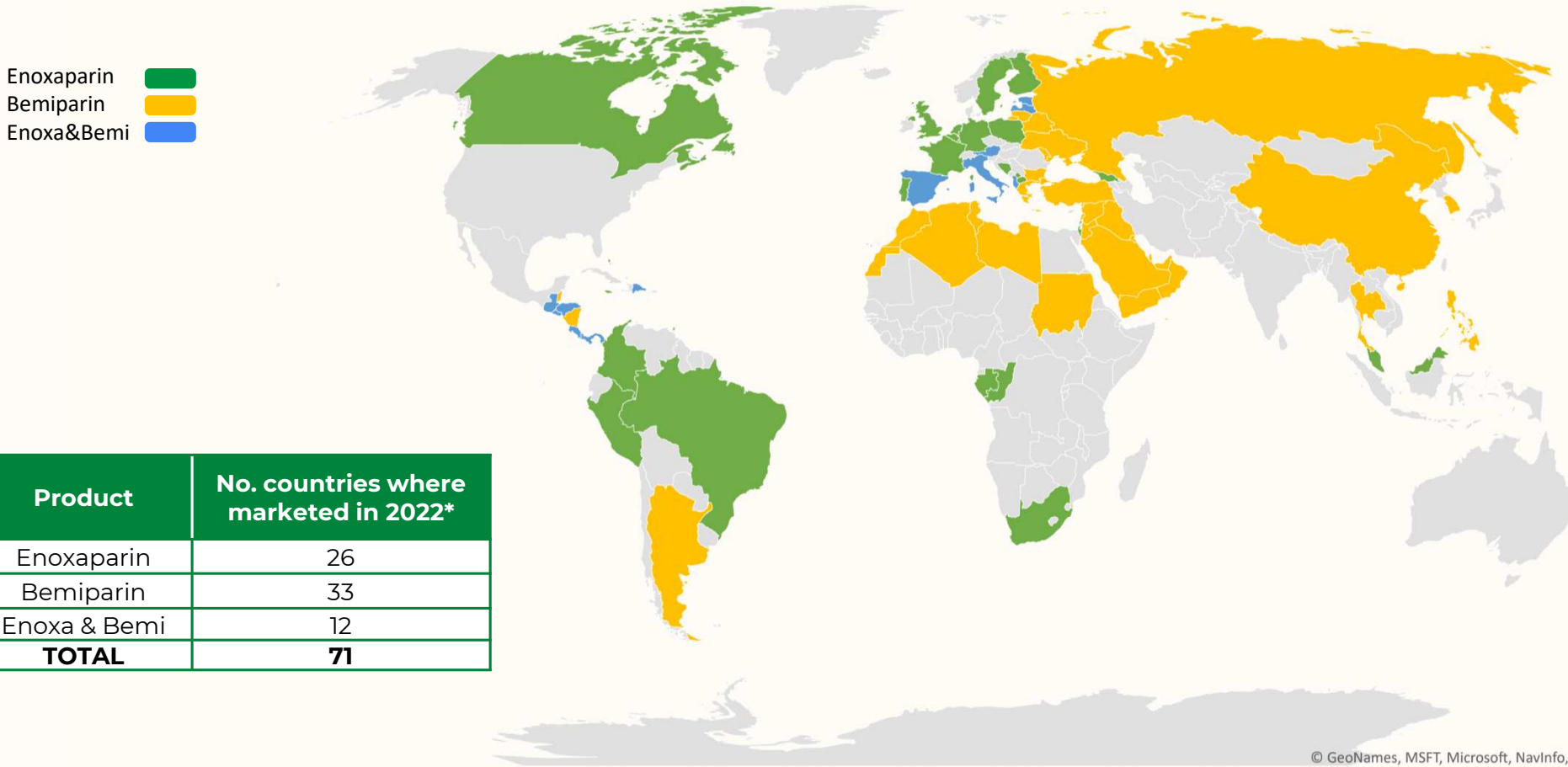
ROVI vs competitors: Spanish value market (%)[1]

Hibor® surpassed Clexane in February 2022



[1] IQVIA Sept 2022
[2] June 2022 data

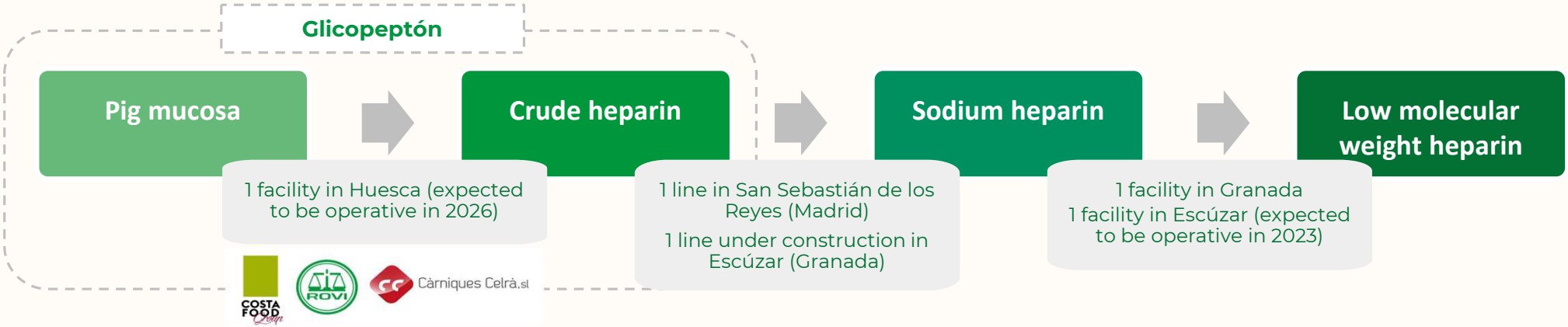
Bemiparin and the Enoxaparin biosimilar international presence



Product	No. countries where marketed in 2022*
Enoxaparin	26
Bemiparin	33
Enoxa & Bemi	12
TOTAL	**71**

*As of October 1, 2022

Fully vertically integrated in the heparin value chain



GOALS

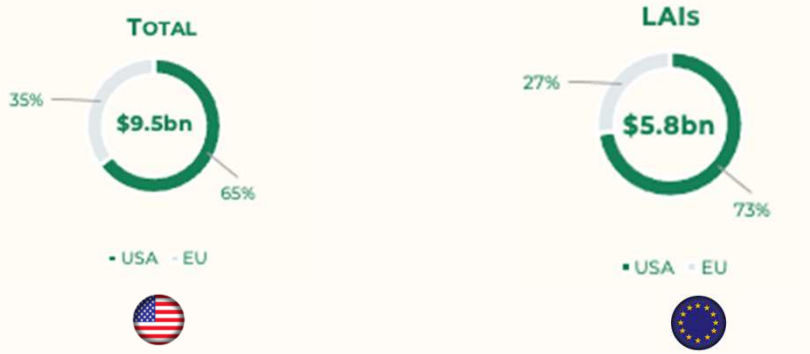
1. **Achieve further vertical integration**
2. **Less dependence on suppliers** (50% sodium heparin from ROVI (self-supply) and 50% sodium heparin purchased from suppliers)
3. **Reduce raw material price fluctuations**
4. **Improved product traceability**
5. **Improve gross margin**

Risperidone ISM®: Attractive schizophrenia market with strong growth prospects

Attractive Schizophrenia Market

- Chronic and progressive disease
- Affects 21Mn people worldwide with a relatively high lifetime prevalence[1]
- Strict compliance needed to avoid relapses
- LAIs[2] are becoming the gold standard for treatment, due to improved adherence and effectiveness

MAT Q3-19 Schizophrenia Market Value US & EU[3]



- Largest schizophrenia LAI market
- MAT Q3 2015 – MAT Q3 2019 CAGR of **20.0%**
- Higher prices than other markets
- LAIs penetration: **5.8%** (in monthly treatments)[4]

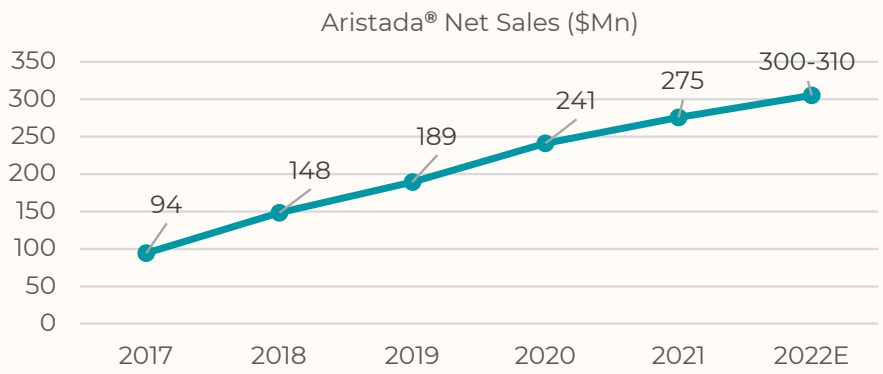
- Second largest schizophrenia LAI market
- MAT Q3 2015 – MAT Q3 2019 CAGR of **8.5%**
- Relatively low competition due to fewer drug options
- LAIs penetration: **8.4%** (in monthly treatments)[4]

Solid Grounds for Success for a Risperidone LAI

LAI schizophrenia market presents key features for a successful launch

- **High treatment switching rate**
- **Focused group of psychiatrists to target**
- **Increasing penetration of LAIs across treatment paradigm**

Ample Market with Room for New Entrants: Alkermes Success Story[5]



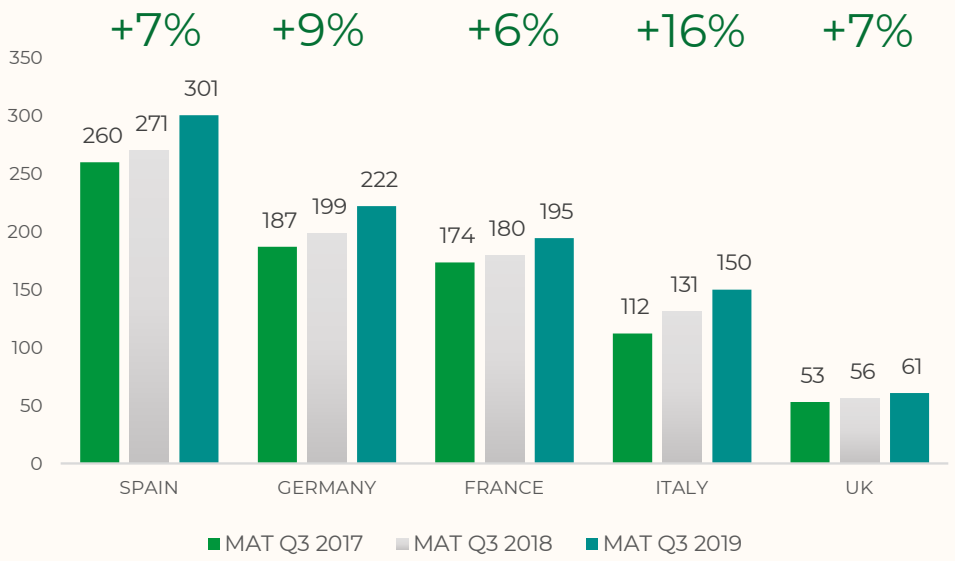
Due to current low penetration, schizophrenia LAI sales are expected to drive future market growth

1. Epidemiology data-Kantar Health Epi Database®.
2. LAIs stands for Long Acting Injectables.
3. Iqvia Midas MAT Q3 2019.
4. Iqvia Midas MAT Q3 2019 and Rovi's monthly treatments estimates.
5. Alkermes results.

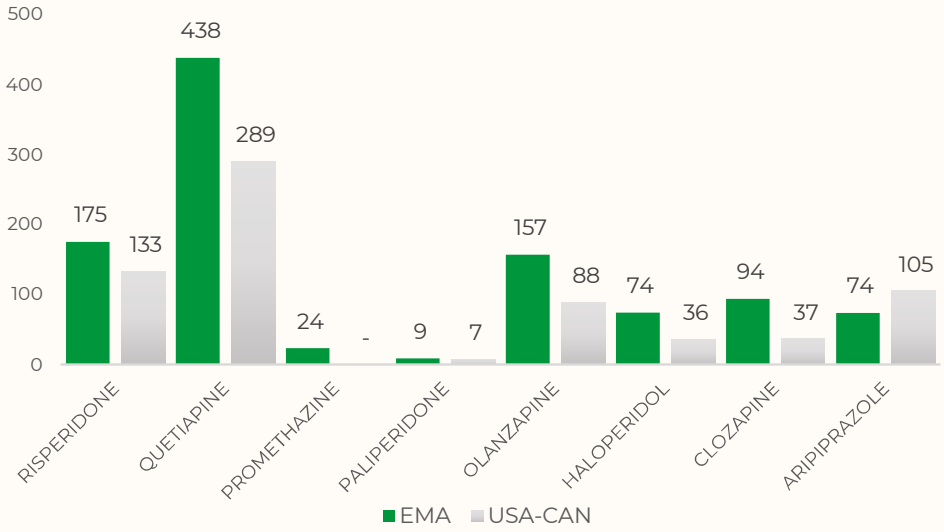
LAIs are becoming the gold standard for treatment in EU5

- LAI market grew by 9% from Q3 2017 (MAT) to Q3 2019 (MAT) in EU5
- Spain is the biggest market, representing 23% of European sales, and grew by 7% in the period Q3 2017-Q3 2019 (MAT)
- LAIs represent 57%[1] of the Spanish antipsychotic market
- Risperidone is the second preferred molecule in EMA and USA

Antipsychotic LAI sales – EU5 (€Mn)



Schizophrenia market (Standard units MAT Q3 2019)

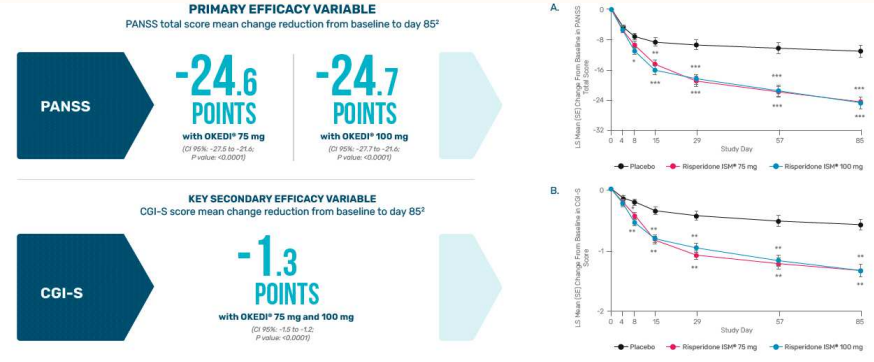


[1]Source: IQVIA Midas MAT Q3 2019

Main attributes of Okedi® that contribute to cover an unmet medical need

High efficacy of Okedi® in the short and long-term treatment of Schizophrenia

PRISMA-3 SHORT-TERM



- Okedi® achieves sustained therapeutic levels from DAY 1 providing a significant sympton reduction as early as **DAY 8**

PRISMA-3 LONG-TERM

OKEDI® has a low overall relapse rate of

10.7%

(95% CI, 6.9% to 15.6%)

in 12 months[4]

which demonstrates its extended effect in controlling psychotic symptoms in Schizophrenia disease[4]

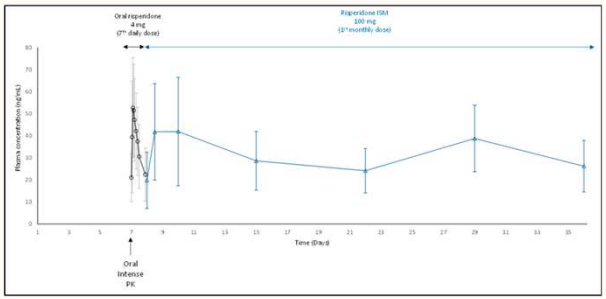
Only **9 out of 215** patients required re-hospitalization

4.2%

in 12 months[4]

Sustained therapeutic levels from DAY 1

BORIS STUDY



- Therapeutic plasma levels from **DAY 1** without the need of oral supplementation or loading doses
- As fast as oral risperidone

- Okedi® is the **only product** that can be used **for a wide range of adult patients with schizophrenia** without the need of using loading doses or concomitant oral antipsychotic medication

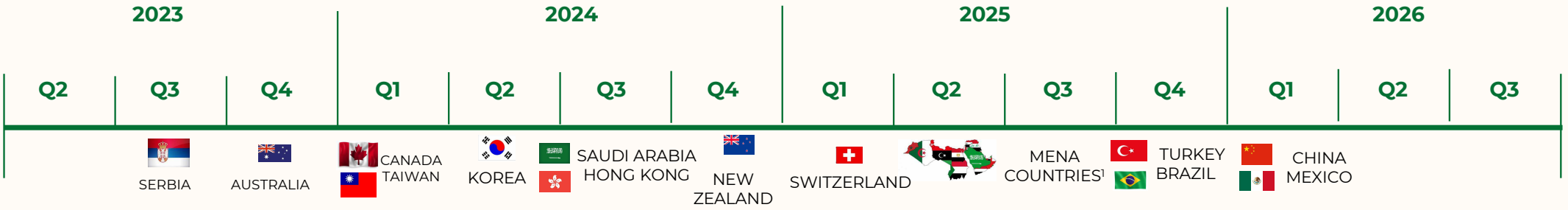
Okedi® launch plan in Europe

Data in €Mn	Q2 2022	Q3 2022	Q1 2023	Q2 2023	2023
Market size (MAT Q3 2019)	222	61 (UK) 301 (Spain)	39	150 (Italy) 195 (France)	Other European countries

Registration process in 5 countries (Canada, Australia, Serbia, Taiwan and Hong Kong)

Feedback	
Germany	• Access to doctors slightly lower than initially expected because of the Company's focus on the hospital psychiatrist, although the product is being received very positively in the medical education activities.
UK	• Product is in the introduction phase in the "trusts" (entities that manage the health areas). Subsequently, it will be introduced in the hospitals managed by each "trust" and become available soon in most hospital pharmacies.
Spain	• Introduction of the product in regions and hospitals progressing swiftly. By the end of October, the product was available in approximately 70% of the autonomous communities.

Okedi® Roll Out



[1] Middle East and North Africa (MENA) region

Spanish market leadership positions ROVI as the partner of choice for global pharma players in Spain

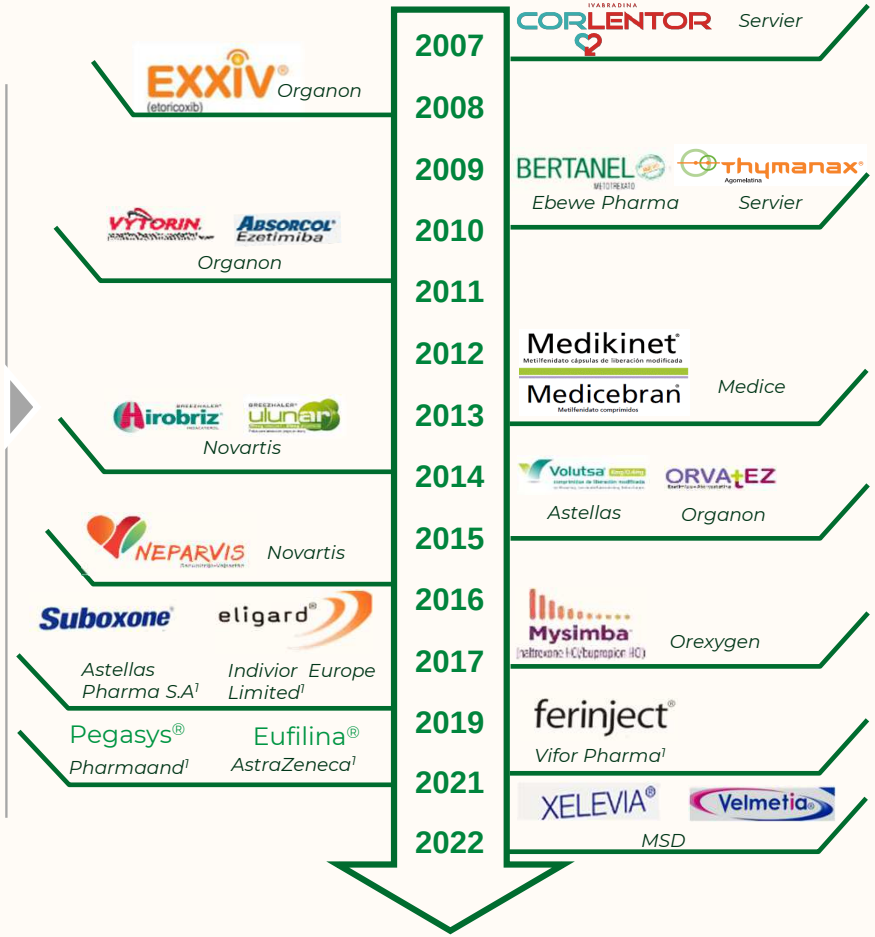
Our strong market leadership in Spain...

- Presence in the Spanish market since 1946
- Well-known proprietary portfolio driving strong leadership position
- Franchise focused business: 20 proprietary and 28 in-licensed products
- Multiple Strategic Alliances

NOVARTIS · astellas · BRACCO · MEDICE · MSD

- One of the largest specialty pharma sales forces in Spain with c.250 employees
- Strong knowledge of the Spanish regulatory framework

...allows us to be the partner of choice for global pharma players in Spain



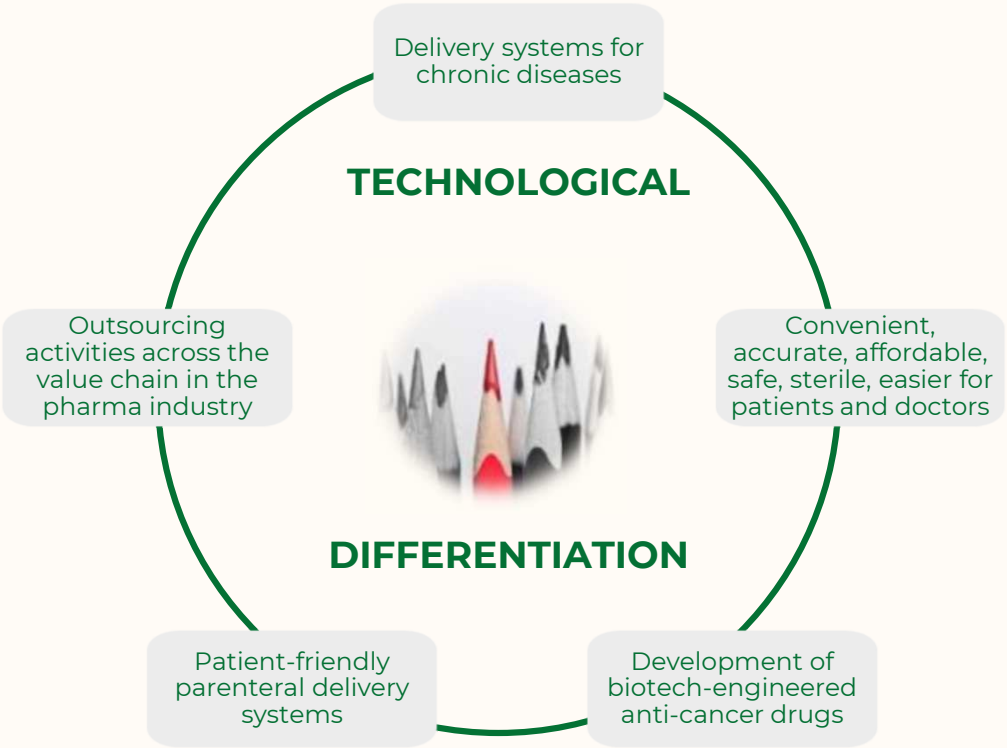
- Broad portfolio of innovative products
- Proven track record with 15 new products in the last 12 years
- Familiar with national regulatory phases, pricing and product reimbursement schemes
- Lengthy track record in strategic agreements, having an attractive portfolio of long-term contracts
- Long patent-protected portfolio

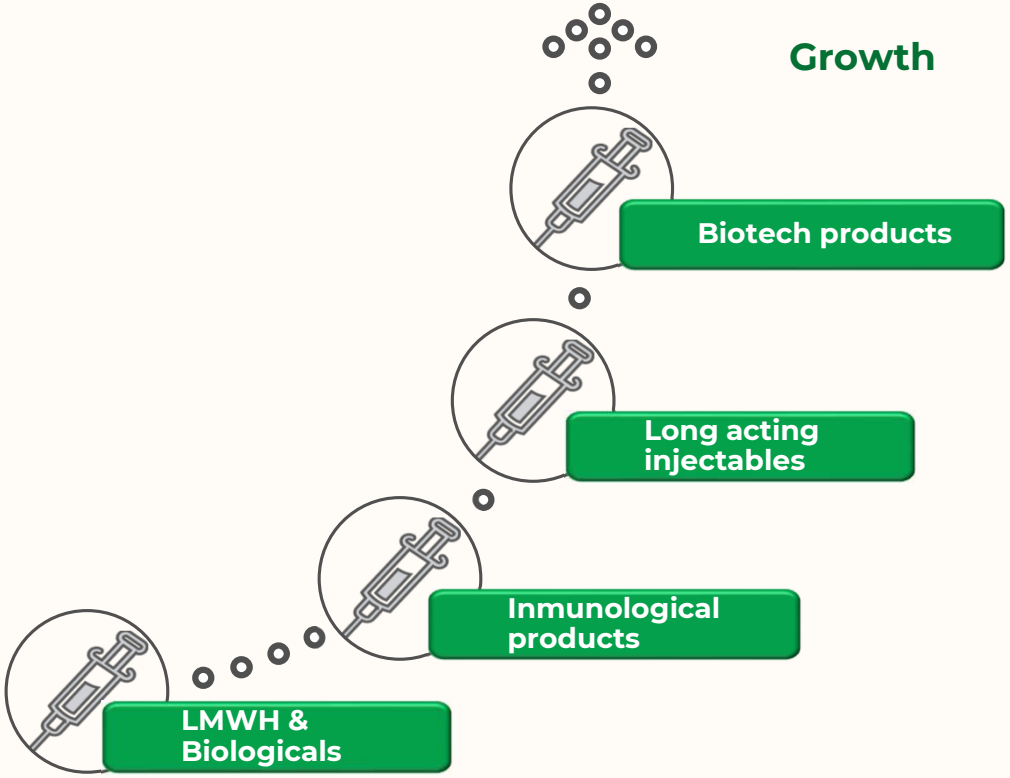
1. Co-promotion products

Key drivers for future growth

Pre-filled syringes are expected to drive the sterile injectable drugs market

The CMO market[1] is expected to grow 7% CAGR until 2027[1]





[1] GlobeNewswire, 27 April 2022

CMOs are consolidating as a means of enhancing profitability in the competitive market

1 **The market is growing due to the increasing tendency of pharmaceutical companies to outsource their production activities**

The Global Pharmaceutical Contract Manufacturing Organization (CMO) Market was valued at USD 134.12 billion in 2021, and it is expected to reach USD 204.14 billion by 2027, registering a CAGR of 7% from 2022 to 2027.

GlobeNewswire, April 27th, 2022

2 **Between 2018 and 2020, private equity firms increased their investment in the CMO industry with the acquisition of almost 70 CMOs**

Recipharm pci PHARMA SERVICES Cambrex

The company's report, "*M&A in the Contract Manufacturing Industry: Implications and Outlook – 2021 Edition*", explains that between 2018 and 2020, PE firms have shown a rapidly increasing level of investment in the CMO sector. PE firms acquired almost 70 pharmaceutical contract manufacturing companies, and PE-backed CMOs acquired eight during the 2018–2020-time frame. Private equity firms own many of the leading CMOs, including Recipharm, Cambrex Corp and PCI Pharma Services.

3 **Lonza enters the fill and finish sector for the first time, with a new plant that is expected to be completed in 2026 and an investment of CHF 500 million**

Lonza

Several other contract development and manufacturing organizations (CDMOs) have added dosage-form services as part of an overall strategy to serve drug makers with everything from process research to finished-product manufacturing.

4 **Moderna announces EUR 500 million investment in Spain to increase its manufacturing capacities**

moderna

"Spain is a key market in terms of access to talent, quality of infrastructure and innovation in the biotechnology industry. We at Moderna are therefore very proud to be able to strengthen our presence in Spain with a new investment of more than 500 million euros in 2022, which will among other things be destined to the construction of a new testing laboratory for mRNA vaccines."

Announcement of Gil Rubio, Moderna General Manager for Spain and Portugal

ROVI industrial footprint (1/2)

2 Crude Heparin plants

2 LMWH API plants

2 Filling&Inspection plants

1 Packaging center
1 Oral Compounds plant

2 ISM plants

ROVI industrial footprint (2/2)

2020

- **4 sites**
- 5 aseptic filling lines
- 11 packaging lines
- 190 Mn PFS cap.
- 20 Mn vials cap.

2022

- **7 sites**
- 8 aseptic filling lines
- 14 packaging lines
- 215 Mn PFS cap.
- 80 Mn vials cap.

Objective for 2024

- **10 sites**
- 11 aseptic filling lines
- 19 packaging lines
- 450-500Mn PFS cap.
- 120Mn vials cap.

COVID-19 endemic outlook

1. There's no sign the virus is going away anytime soon. New coronaviruses are bound to emerge.[1]
2. "With three coronavirus epidemics or pandemics already in the 21st century alone, it's fair to say coronaviruses are right up there with flu as having dangerous pandemic potential".[1]
3. The medical burden of endemic COVID is expected to be larger than flu.[2]
4. As COVID transitions to endemic, annual COVID booster volumes could approximate flu vaccine volumes over time.[2]

[1] Dr Melanie Saville, Executive Director of Vaccine Research and Development, CEPI. https://cepi.net/news_cepi/the-race-to-future-proof-coronavirus-vaccines/
[2] Moderna

ROVI strengthens its collaboration with Moderna (1/2)

Fill-Finish manufacturing

- Investment in 2 new lines for compounding, filling, automatic visual inspection and labeling at ROVI's San Sebastián de los Reyes (Madrid) facility
- These lines **more than double** the number of vials for which there is fill-finish capacity at this facility
- Supply to markets outside the United States

DARA 2

- Came into operation in Q4 2021

DARA 3

- Expected to come into operation in Q4 2022

Manufacture of the active substance

- Installation of a new line in Granada
- Production capacity equivalent to more than 100 million doses per year
- Greater vertical integration of the vaccine production process
- Supply to markets outside the United States

ROVI strengthens its collaboration with Moderna (2/2)

Moderna and ROVI expand long-term collaboration for the manufacture of mRNA medicines over the next 10 years

- 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 used to service future Moderna mRNA vaccine candidates.
- Investments related to lines already in operation are not included in this agreement.

Update on the R&D strategy

Ibón Gutierro
R&D Manager

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

Product	Potential Indication	Current Situation	Key Milestones
Risperidone ISM® Risperidone, monthly	**Schizophrenia**	Approved	Marketed in Europe and in approval process in USA
Letrozole ISM® Long acting Letrozole	**Breast Cancer**	Efficacy study in advanced breast cancer	Starting of efficacy clinical trial
Risperidone, quarterly	**Schizophrenia**	Preparing Phase I	
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 Clinical Program	Expected high success rate in Phase III in new developments
2 **Usability**	Improved stability	No cold chain needed
3 **Flexibility**	Selecting the most convenient posology depending on clinical needs	From 1 to 12-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 Microimplants*®.
2. PK stands for pharmacokinetic.

Risvan® regulatory process in USA – Where are we? (1/2)

ROVI submitted the dossier to the FDA[1] on 24 November 2020.

→

On 24 September 2021, ROVI received a Complete Response Letter (CRL) from the FDA with outstanding questions on the Risperidone ISM® dossier.

→

The Company submitted the responses to the outstanding questions on 17 January 2022.

New Goal Date was established by 19 July 2022.

↓

The FDA has already inspected the ROVI plant in the last two weeks of June 2022 and the Company is working on correcting some deficiencies that were noted.

Final responses to be submitted in February 2023.

→

A new CRL was received in Q3 2022 with outstanding issues:

- Questions to be addressed by ROVI
- Questions to be addressed by a supplier
- A pending inspection of a supplier

Responses to outstanding issues is expected by January 2023.

→

Marketing authorization is expected to be granted.

Potential New Goal Date: July 2023.

The indication pursued in the US is the same as all other LAIs[2] have, "Treatment of schizophrenia in adults"

1. FDA: Food and Drugs Administration
2. LAI: Long.-Acting Injectable

Risvan® regulatory process in USA – Where are we? (2/2)

Immediate steps

Questions to ROVI:

- A priori, not expected to risk approval
- Most of responses already prepared. Pending one that requires data collection and preliminary data suggest high visibility of success
- Expected to be submitted by January 2023

Pending inspection to a manufacturer:

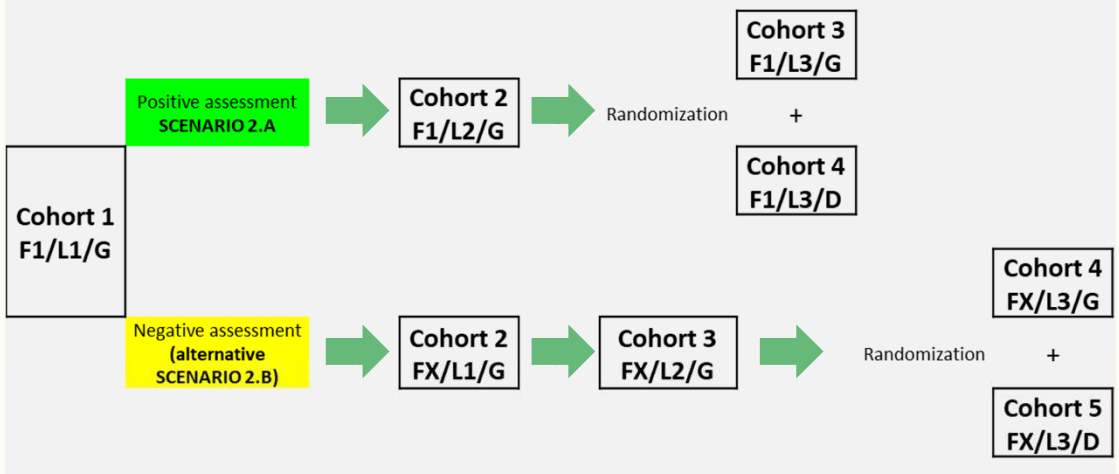
- Not related to our process but inspection is pending
- Date of FDA inspection not yet notified by FDA

Questions to a manufacturer on the restricted part of the dossier:

- Responses expected by January 2023
- The manufacturer has several FDA approved products manufactured in the same line

Quarterly Risperidone ISM®

Phase I Design



F1: Formulation 1
FX: alternative Formulation (2 or 3)
L1: dose Level 1 (= 225 mg)
L2: dose Level 2 (to be decided as similar to 4-weekly Risperidone ISM 75 mg)
L3: dose Level 3 (to be decided as similar to 4-weekly Risperidone ISM 100 mg)
G: gluteus injection
D: deltoid injection

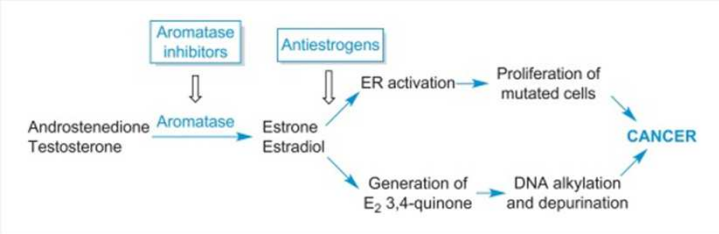
- Up to 3 prototypes will be tested in stable patients with schizophrenia to select the best profile.
- Then the dose corresponding to monthly 75 mg will be tested in gluteus and the dose corresponding to monthly 100 mg in gluteus and deltoid.
- **Expected to start in 2Q 2023.**
- Population PK model to be refined after this clinical trial, but PK/PD model is the same than the model for Okedi®.
- Once the trial is conducted, visibility on the range of plasma concentrations and the expected impact on PANSS is very high, and therefore, visibility on the overall success of the program will be very high.

Letrozole ISM®: Update of Phase I Trial

Overview

Hormone receptor-targeting drugs offer a unique opportunity to leverage ISM® technology. Aromatase Inhibitors (AI) Letrozole and Anastrozole are used in HR+ breast cancer as they block the production of estrogen in post-menopausal women.

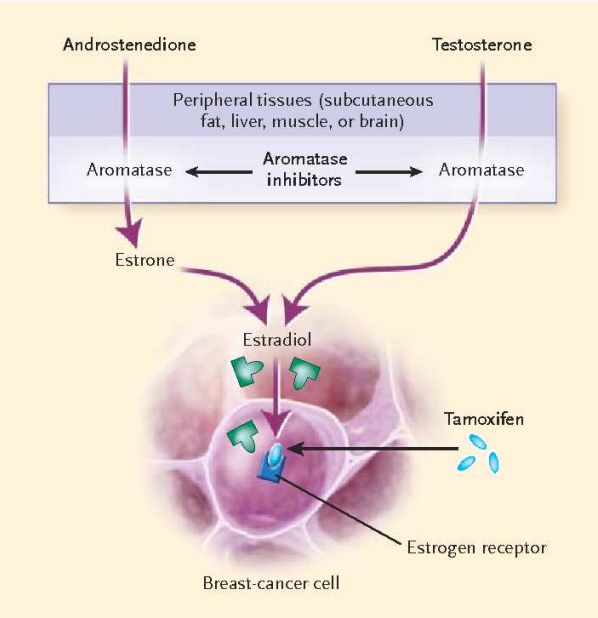
- **Oral Letrozole is the gold standard treatment** for HR+ breast cancer.
- Current posology of AIs is daily oral – potential for Letrozole ISM® **targeting a long-acting injection** to **meaningfully disrupt the market and improve patient outcomes.**
- Currently, there is no LAI approved for Letrozole in the market.



Patient Compliance is a real issue and the market is in high need of a LAI that ensures patient compliance:

- Literature evidence suggests[1] that after 6 months, 51% of EBC[2] patients under treatment with aromatase are not inhibited on Estradiol (E2).
- Lack of inhibition is linked with a significant increased risk of a breast cancer event and mortality.

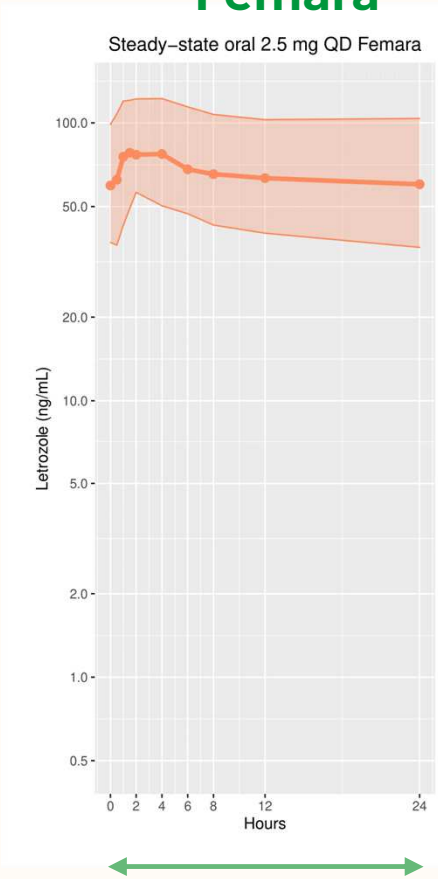
Mechanism of Action of Aromatase Inhibitors and Tamoxifen



1. Ingle et al. Clin Cancer Res. 2020 June 15; 26(12): 2986–2996. doi:10.1158/1078-0432.CCR-19-3091.
2. Early breast cancer

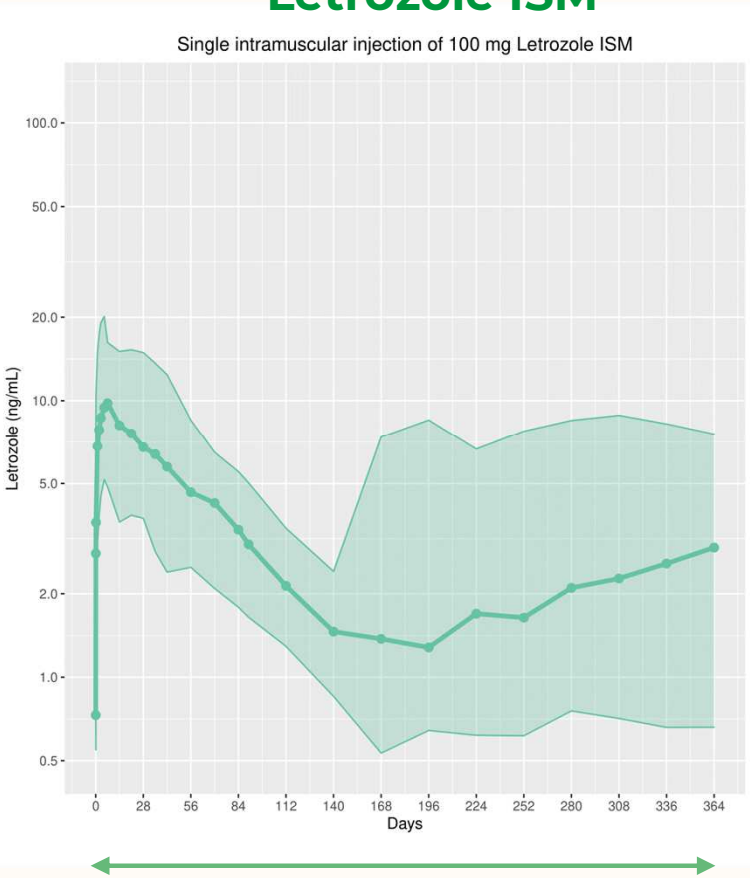
LISA-1 results: Drug levels are lower but much longer sustained for a single injection of Letrozole ISM® as compared to QD oral Femara®

Femara®



1 day

Letrozole ISM®



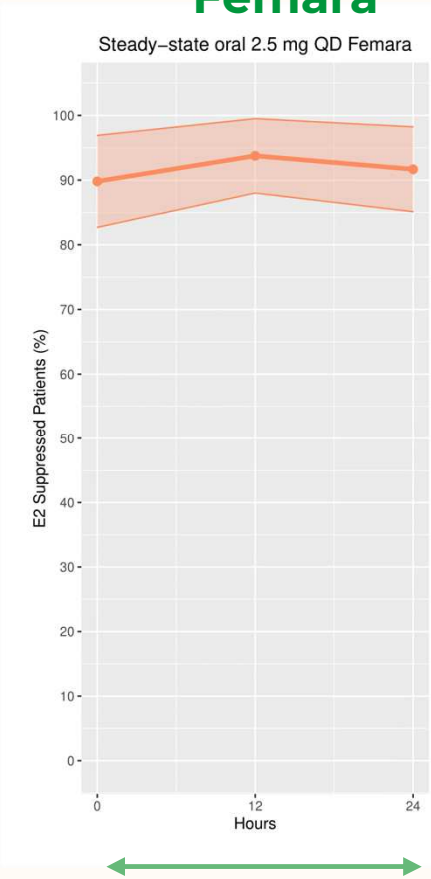
1 year

- **Formulation is expected to provide therapeutic plasma values for 1 year.**

1. ROVI data on file

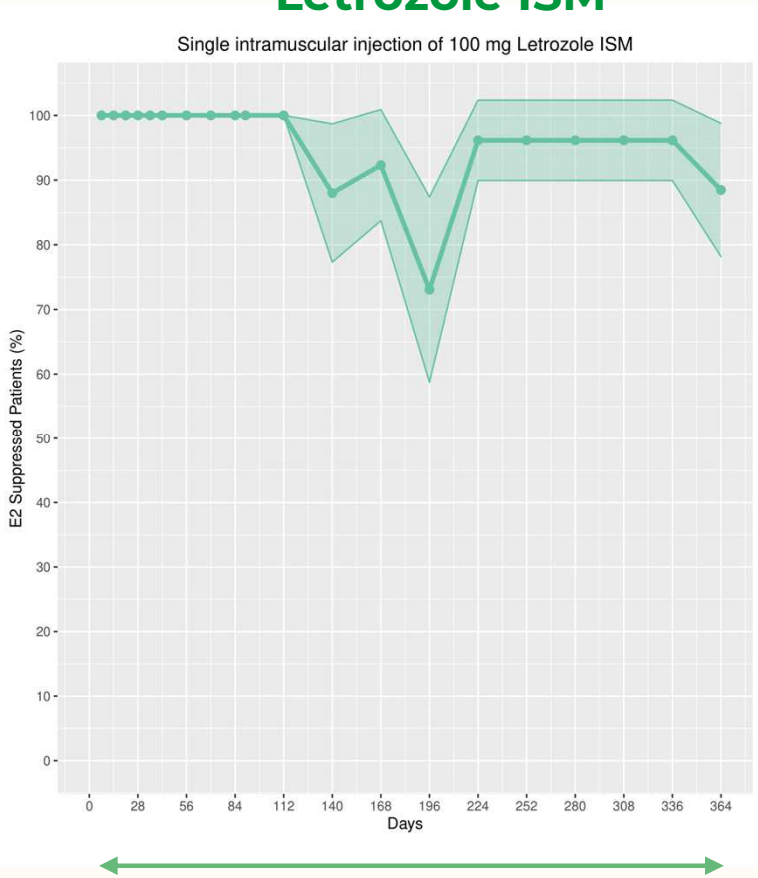
LISA-1 results: Despite the lower drug levels, comparative estrogen suppression is maintained for a long period of time after a single injection of Letrozole ISM®

Femara®



1 day

Letrozole ISM®



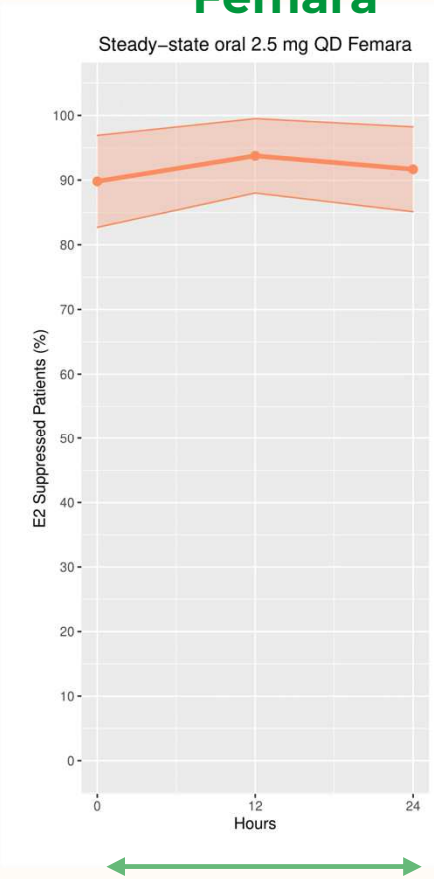
1 year

- A single dose of 100 mg provide a Deep and sustained suppression of estradiol and estrone for more than 1 year.
- Population pK/pD models have been developed and used to support the selected dosing in efficacy trials.
- The selected posology is 100 mg + 100 mg at week 8, then a single 100 mg injection every 52 weeks.
- FDA has reviewed and accepted the dose is justified to progress to Efficacy clinical trials.

1. ROVI data on file

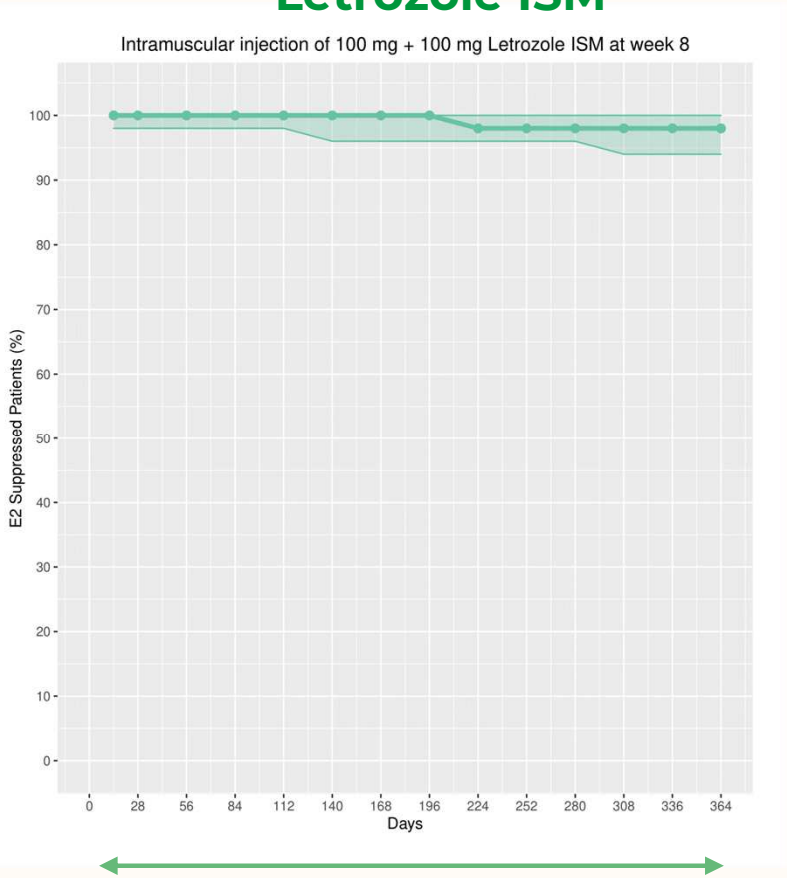
LISA-1 results: Advanced PK-PD modelling predicts a high estrogen suppression throughout the whole year for 100 mg + 100 mg Letrozole ISM® at week 8

Femara®



1 day

Letrozole ISM®

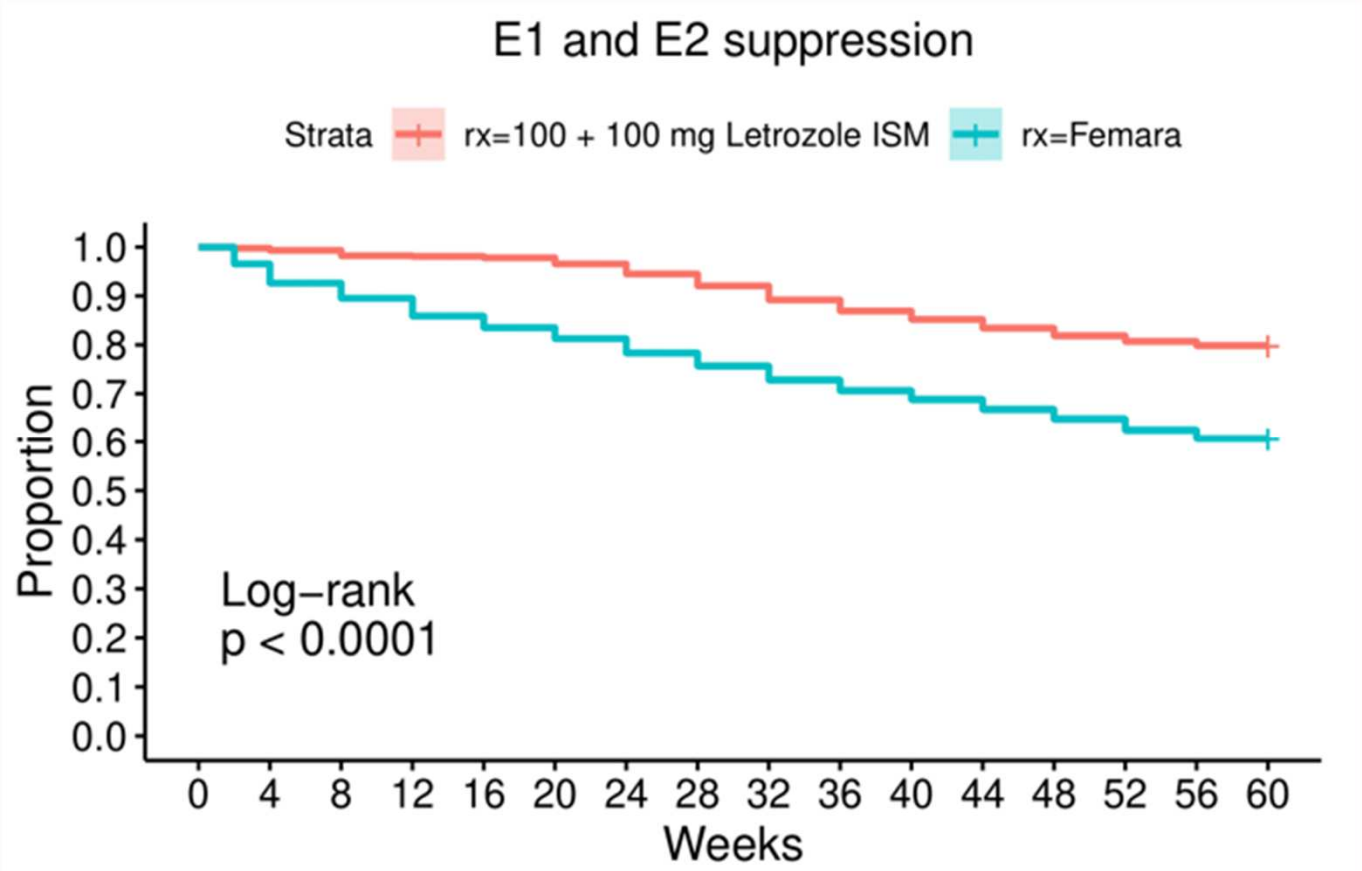


1 year

- Superior oestrogen suppression vs Femara®.
- 4-fold reduction in %unsuppressed patients vs oral medication at 100% Compliance.
- It is expected that most patients whose breast cancer progresses will be concentrated among those unsuppressed.
- Literature evidence shows 51% unsuppressed patients on Estradiol (E2) after 6 months vs 2% predicted after 1 year with Letrozole ISM®.

1. ROVI data on file

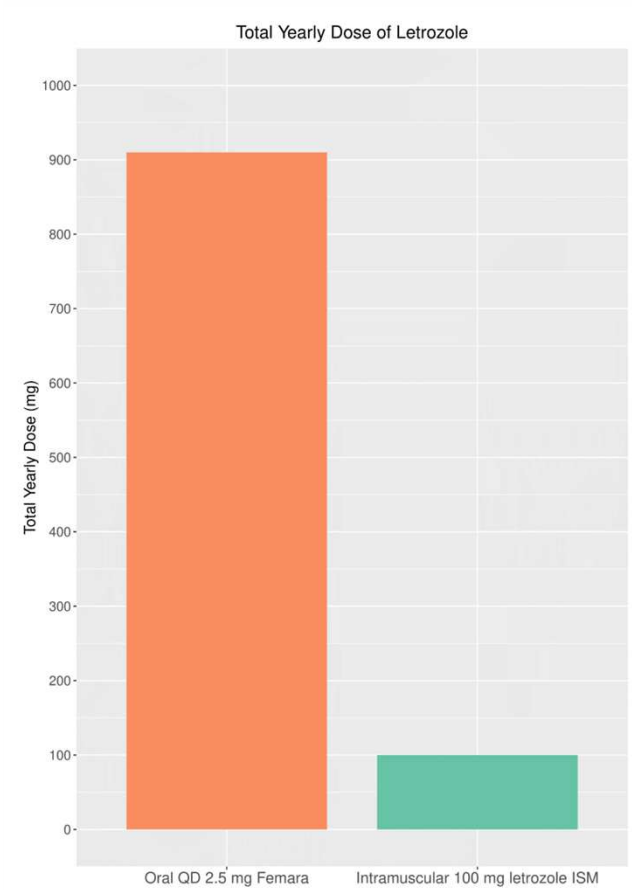
LISA-1 results: Advanced PK-PD modelling predicts superiority vs 2,5 mg daily oral dose of Femara® in the proportion of patients that achieved and maintain full oestrogen suppression



- At 100% Compliance of Femara®, the proportion of patients expected to be inhibited and maintain inhibition at any time is superior for Letrozol ISM® over Femara®.
- The difference increases over time, even considering 100% Compliance on oral Femara®.
- The difference is expected to further increase in real clinical setting.

1. ROVI data on file

LISA-1 results: The total amount of drug required for a similar efficacy is about 9 times lower as compared to Femara®



Advantages 100 mg Letrozole ISM® *versus* oral QD 2.5 mg Femara®

- Superior estrogen suppression.
- Reduction in % patients at high risk of tumor progression or EBC event[1].
- Convenient yearly intramuscular injection versus daily oral intake.
- **Much less amount of yearly drug for a similar efficacy.**
- No issues of non-adherence due to daily oral intake.

1. EBC event means early (within five years of starting aromatase inhibitors therapy) breast cancer event .

Clinical Efficacy Program for Letrozole ISM®

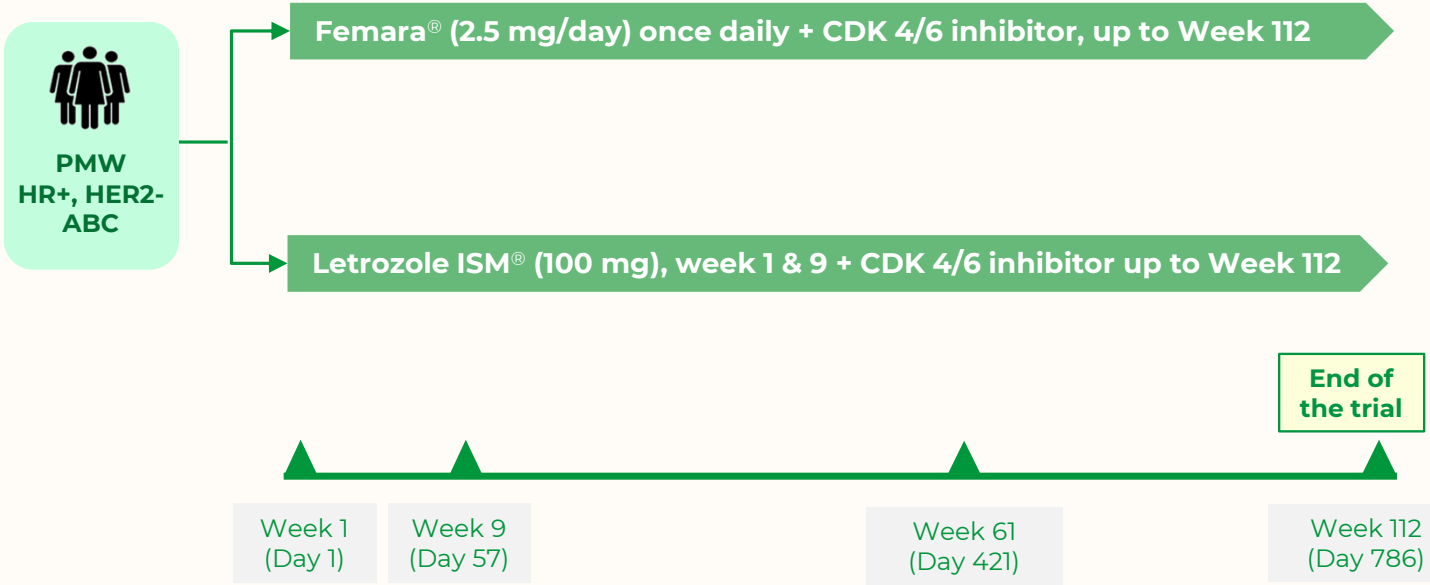
Next steps

- ROVI to continue rewieving with the FDA the whole clinical efficacy program, and in particular details for the requested phase 2 efficacy trial with Femara®.
- Design: 2 parallel cohorts (Letrozole ISM®+CDK4/6 inhibitor vs Femara®+CDK4/6 inhibitor), postmenaopausal women with advanced breast cancer, open label, clinical efficacy endpoint.
- Phase 2 trial will be supportive to prepare efficacy phase 3 trial with letrozole as adjuvant therapy in Early Breast Cancer, which is the main indication.
- Due to dimension of the clinical program, ROVI will evaluate whether to get an agreement with a partner.
- Clinical trial expected to start 2H 2023.

Letrozole ISM® Phase 2: LISA-2

Letrozole ISM® Phase 2: LISA-2
Current proposal: Exploratory eff. / 2 arms / 112 weeks

A Multicenter, Randomized, Open-label, Phase 2 Study Exploring the Efficacy and Safety of Letrozole ISM® Compared to Femara® (combined with a CDK4/6 inhibitor) in Postmenopausal Women With HR-Positive, HER2-Negative, Locally Advanced or Metastatic Breast Cancer



1. Primary Endpoint: Progression Free Survival (PFS)
2. Secondary Endpoints:
   - % Pats with estrogen suppression
   - Objective response rate (ORR)
   - Time to response (TTR)
   - Duration of Response (DOR)
   - PK profile
   - % Pats. with TEAEs

Letrozole ISM®: Approach to ROVI's potential market

Potential market for Letrozole-ISM®

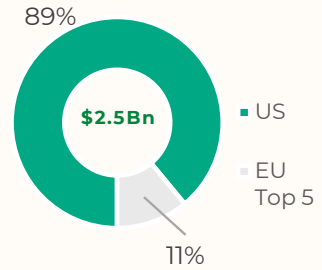
- There are 1.074 m daily units of these two molecules that, converted to yearly treatment, bring 2.9 m potential yearly treatments for LAIs[1] market
- Exemestane is a third molecule to treat this disease with oral posology, so it is another candidate to switch to LAI
- There are 123 million daily units of exemestane that, converted to yearly treatment, bring 338,239 treatments for LAI market
- ROVI aims to reach a significant portion of the market

Approach to prostate cancer LAIs market

- Breast cancer can be compared to prostate cancer, as it has a similar behaviour in prevalence
- Around 3 years of strict compliance are needed to avoid relapses
- Goserelin, Histrelin, Degarelix, Leuprorelin and Triptorelin are the molecules to treat prostate cancer
- LAIs[1] have a strong presence in this market and have become the gold standard for treatments (89% market share in value)

LAIs represent 89% of total prostate cancer market in value in EU and US

MAT Q3-19 Market Share of LAIs in US & EU[2] Prostate Cancer Market



LAIs and Orals in value

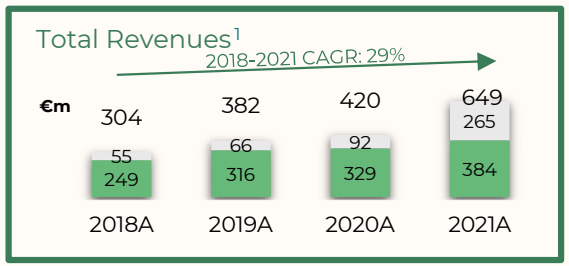
1. LAIs stands for Long Acting Injectables.
2. IQVIA-Midas MAT Q3 2019: EU is Total Europe.

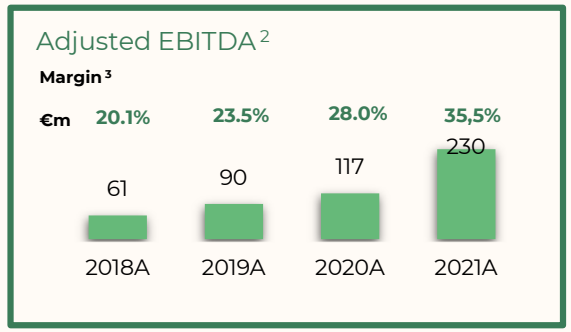
FINANCIAL RESULTS

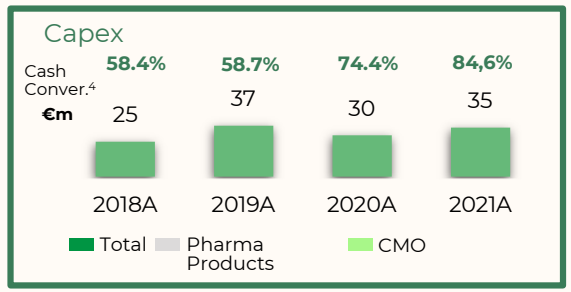
Javier López-Belmonte
Deputy Chairman and Chief Financial Officer

Sound financial policy supported by strong track record

Specialty Pharma







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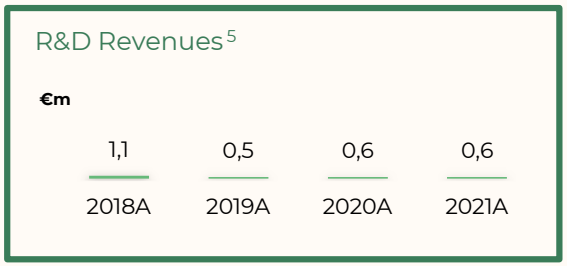
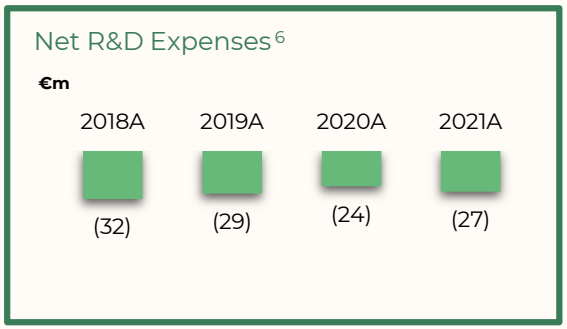
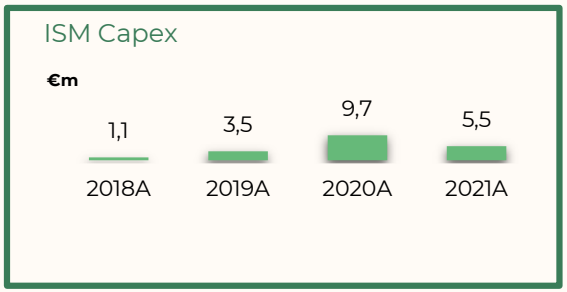
ISM® Platform







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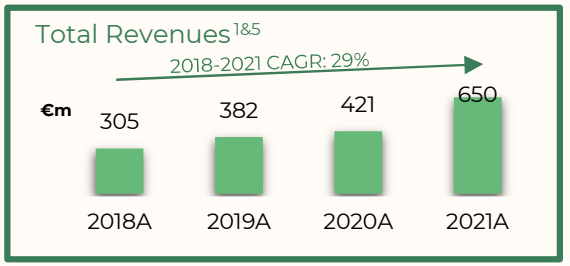
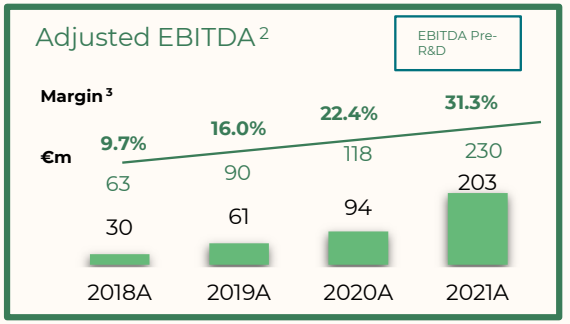
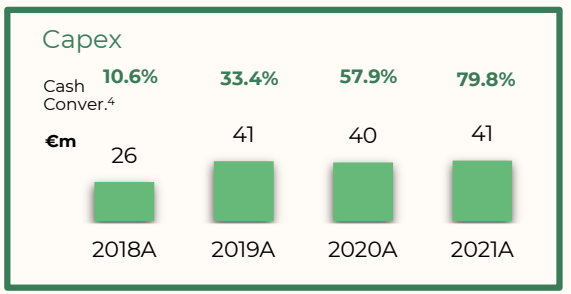
ROVI Group







Proven track record of Specialty Pharma business

1. Toll Manufacturing total revenues are ROVI's Sales of services. Pharma products total revenues include Sales of goods, Revenues from licenses and government grants.
2. Adjusted EBITDA defined as profit for the year, before income tax, finance costs-net and depreciation and amortization.
3. Adjusted EBITDA margin calculated as Adjusted EBITDA divided by Operating revenues (defined as Total revenues minus grants).
4. Cash Conversion calculated as (Adjusted EBITDA – Capex)/Adjusted EBITDA.
5. ISM® Platform total revenues are fully comprised of government grants.
6. Calculated as R&D revenues minus R&D expenses, which include Specialty Pharma R&D expenses of enoxaparin biosimilar Becat®.

9M 2022 results (1/2)

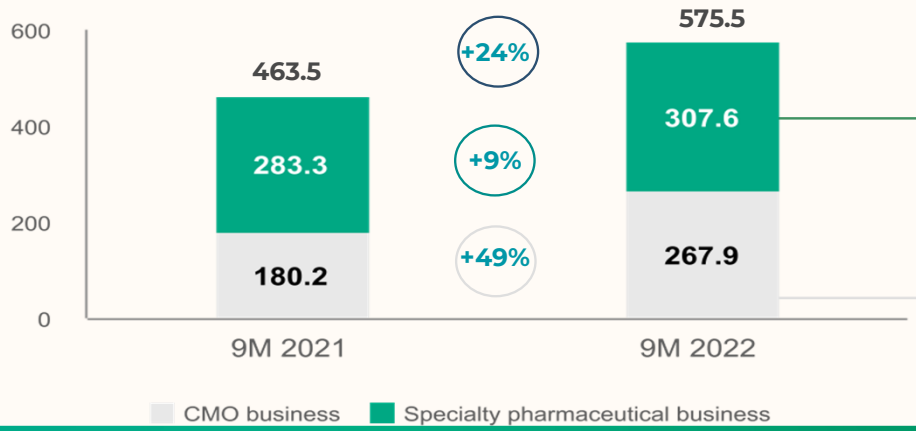
Main figures €Mn

REVENUE	EBITDA	EBIT
575.5 (+24%)	173.9 (+25%)	156.8 (+27%)
Net profit	**Capex**	**Net cash**
121.5 (+23%)	18.5 (-16%)	25.9

2023 operating revenue guidance:
Low-double-digit negative growth vs 2022
Positive growth of between 5% and 10% vs 2021

ROVI presents Glycopepton Biotech, S.L., a joint venture with Càrniques Celrà, S.L. and Grupo Empresarial Costa, S.L., that involves the construction of a facility which will poduce heparins, in order to be present in all the manufacturing phases of LMWH

Operating revenue €m



Specialty pharma business €m

Total
€307.6m
+9%

€277.2	**+8%**	Prescription products
€29.3	**+14%**	Contrast agents
€1.1	**+15%**	OTC & Other

Heparin franchise* **€200.6** **+11%** 35% of operating revenue

LMWH **€195.1** **+11%**

Bemiparin sales
€75.8m **-12%**

Enoxaparin sales
€119.2m **+33%**

Spain
€50.4m **-3%**

International
€25.4m **-26%**

✓ Directly marketed in Germany, UK, Italy, Portugal, Spain and Poland

✓ Launched in 38 countries.

✓ Approved in 26 countries in Europe and 31 in RoW

* LMWH (Bemiparin and Enoxaparin biosimilar) + other heparins

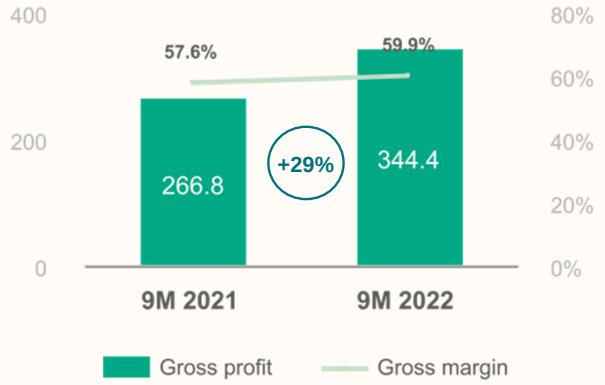
CMO business €m

Total
€267.9m

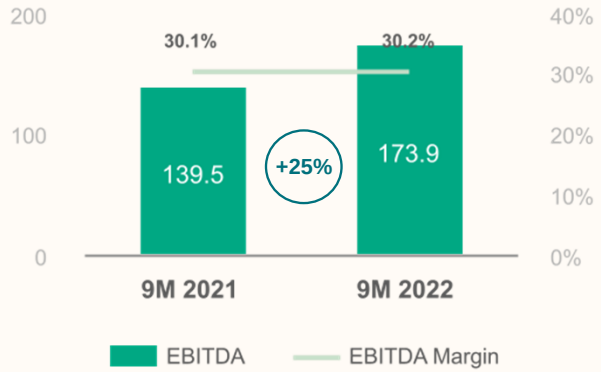
+49%

9M 2022 results (2/2)

Gross profit (€m) and gross margin (%)



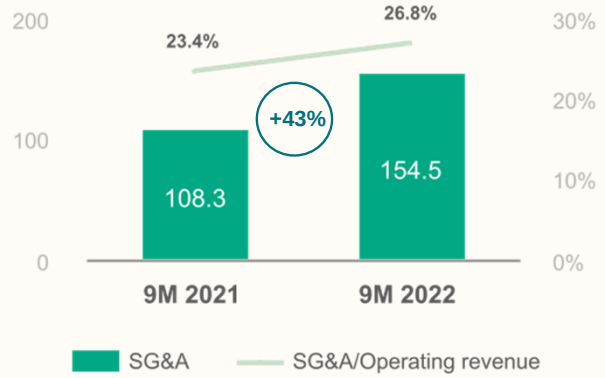
EBITDA (€m) and EBITDA margin (%)



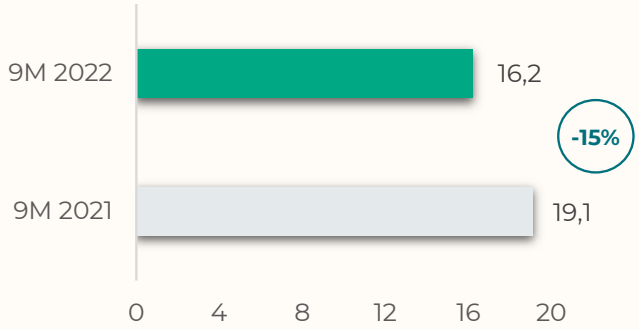
EBITDA Pre-R&D[1]
€m

€190.1m +20%

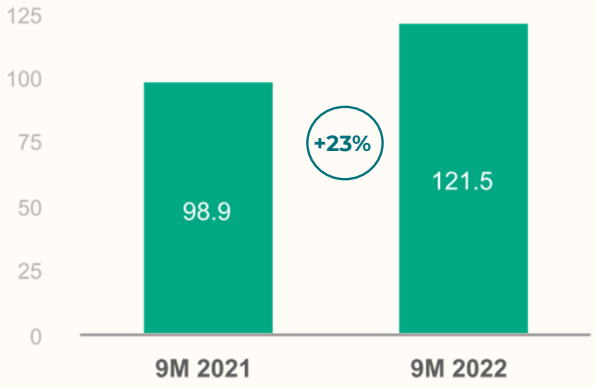
SG&A expenses (€m)



R&D (€m)



Net profit (€m)



Net profit Pre-R&D[1]
€m

€134.0m +17%

[1] Calculated excluding R&D expenses in 9M 2022 and 9M 2021

Capital allocation supports growth

Cash Flow from operating activities increased to €170.0Mn in 9M 2022 mainly due to:

- the increase of 33.6 million euros in profit before income tax;
- the booking of 55.3 million euros under the "Proceeds from CMO services" caption in the first nine months of 2022 relating to payments received but not yet allocated to the income statement, compared to the 21.5 million euros recognized in the first nine months of 2021; and
- the increase of 2.6 million euros in the "trade and other receivables" caption in the first nine months of 2022 compared to a decrease of 33.6 million euros in the same period of 2021.

Debt analysis

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

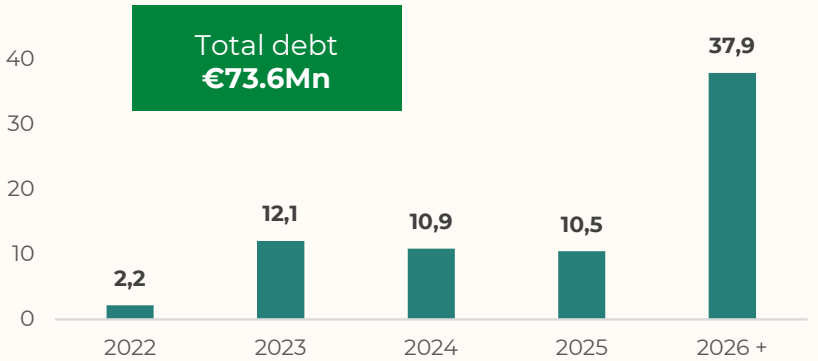
Bank borrowings represented 60% of total debt as of 30 September 2022. They consist of a European Investment Bank loan with long maturities.

Net cash of €25.9Mn as of 30 September 2022 vs €27.4Mn as of 31 December 2021.

As of 30 September 2022, ROVI had a **gross cash position of €99.5Mn**, compared to €100.5Mn as of 31 December 2021.

Cash generation in 9M 2022 (€Mn)

Debt maturities as of Sept 30, 2022 (€Mn)



Focused on creating value

Focus on increasing the remuneration of ROVI's shareholders

Share buyback programs
€135.0Mn

First 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 November 3rd, 2021, for a **twelve-month** period.

Maximum monetary amount

Up to **125,000,000 euros**.

Maximum number of shares to be acquired

1,682,000 shares of the Company, representing approximately 3% of the Company's share capital

Second 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 February 23rd, 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

✓ **2,052,808 shares repurchased under both programs (already amortized)**

Dividend
€51.0Mn

ROVI General Shareholders Meeting, on 14 June 2022, approved the payment of a gross dividend of 0.9556 euros per share on 2021 earnings; this means an increase of 151% compared to the dividend on 2020 earnings (€0.3812/share) and represents a 35% pay out. This dividend was paid on 7 July 2022.

Total
€186.0Mn

Outlook 2023

2023 operating revenue growth rate
Low-double-digit negative growth vs 2022 **Positive growth of between 5% and 10% vs 2021**

The key Growth levers in 2023

Specialty Pharma	CMO
• Launch and marketing of Okedi® in Europe • LMWH franchise • License agreements (Neparvis® and Volutsa®) • Existing portfolio of specialty pharmaceuticals • New product distribution licenses	• New customers to be acquired • Agreement with Moderna • Capacity increase

Notwithstanding, in 2023 ROVI will face a new COVID-19 post-pandemic scenario in which the uncertainty related to the evolution of the disease is very high. It is not, therefore, possible to make a precise assessment of the impact that this new scenario could have on its CMO business.

News-flow 2022-2023

Specialty pharma	Sales of biosimilar of Enoxaparin
	Additional new products to be launched in 2022-2023
	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 and marketing of Okedi® in Europe Marketing authorization for Risperidone ISM® in USA
	Starting an efficacy clinical trial of Letrozole ISM®

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