

CREATING VALUE FOR INVESTORS  
THROUGH NEXT PHASE OF GROWTH

# CAPITAL MARKETS DAY

NOVEMBER 2021



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## AGENDA

Hour	AGENDA
10:00 am	<b>Update on ROVI's strategy</b> Juan López-Belmonte, Chairman and CEO
10:30 am	<b>Update on R&amp;D strategy</b> Ibón Gutierro, R&D Manager
10:50 am	<b>Financial results</b> Javier López-Belmonte, Vicepresident and CFO
11:00 am	<b>Q&amp;A</b>
11:30 am	<b>Closure</b> 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

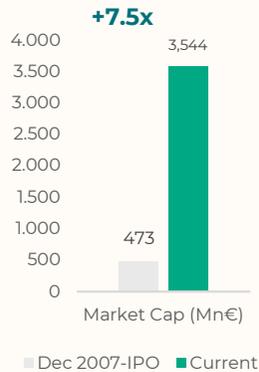
**Madrid, Spain**  
Company HQ

**1,419**  
Employees  
as of Dec 2020

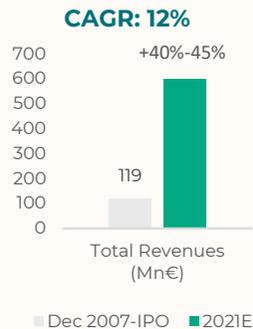
**c.250**  
Specialty  
Pharma Sales  
Force

**6**  
Fully Invested  
Manufacturing  
Facilities

## MKT CAP (€M)<sup>1</sup>



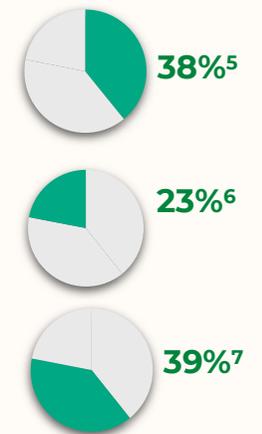
## TOTAL REVENUES (€M)<sup>2</sup>



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

<b>Leading Proprietary LMWH Franchise</b>	<p><b>Unparalleled know-how</b> of the Low Molecular Weight Heparin ("LMWH") market.</p> <p><b>2 in-house developed flagship products:</b> Bemiparin <b>Hibor®</b> ("Hibor®") and Enoxaparin biosimilar <b>Becat®</b> ("Becat®")</p>
<b>Leading Spanish Specialty Pharma Business</b>	<p>Through its <b>large and specialized sales force</b> (c. 250 employees) ROVI distributes in Spain its proprietary products and third party products through in-license agreements</p> <p>14 new in-licensed products over the last 12 years</p>
<b>CMO</b>	<p>Vertical integration and fully-invested production facilities allow ROVI to offer high-value-added injectable and oral forms CMO services</p> <p>One of the global leaders in <b>pre-filled syringes</b> manufacturing<sup>3</sup></p>
<b>ISM®<sup>4</sup> Technology Platform</b>	<p><b>Patent-protected, long-acting sustained-release injectable technology</b> provides versatile platform with wide applicability across multiple drug candidates</p> <ul style="list-style-type: none"> <li><b>Lead candidate Risperidone ISM®</b>, a long acting injectable of risperidone for schizophrenia. Application for marketing authorisation filed in Europe in Jan 2020 and in USA in Nov 2020</li> <li><b>A long-acting injectable of Letrozole</b> for hormone-dependent breast cancer is currently in Phase I</li> </ul>

## Revenue 9M 2021<sup>2</sup>



In regulatory process in Europe and United States

Currently in Clinical Development Stage

1. CapIQ as of Nov 3, 2021.

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 120 countries
Leading Spanish Specialty Pharma Business	c. 250 specialty pharma sales force	+ Specialized Psychiatric salesforce in Europe	Specialized psychiatric salesforce in Europe
CMO	6 fully invested manufacturing facilities	+ Second API LMWH plant in Granada + Risperidone and Letrozole plants + Moderna agreement	8 fully invested manufacturing facilities Manufacturing partner for Moderna outside USA
ISM® Technology Platform	2 key own products (Bemiparin and Enoxaparin biosimilar)	+ Risperidone ISM® + Letrozole ISM® + Risperidone ISM® (quarterly)	At least 5 key own products (Bemiparin + Enoxaparin biosimilar + Risperidone ISM® + Letrozole ISM® + Risperidone ISM® (quarterly))

## Proven Track Record in Creating Value for Shareholders

### Management team has created value for shareholders

Increased sales by 53% and EBITDA by 100% in 9M 2021

Successfully launched enoxaparin biosimilar Becat® in 10 new countries and signed agreements in 12 new countries in the last 12 months

Increased enoxaparin sales by 17% in 9M 2021

Risperidone ISM® in approval process in Europe and USA

Extension of the collaboration with Moderna

### ROVI share Price vs Eurostoxx50 and Ibex-35 (Base 100)



Source: Investig.com

## ROVI improves its ESG Rating in 2021

Rovi has obtained an  
**ESG Rating 2021** of

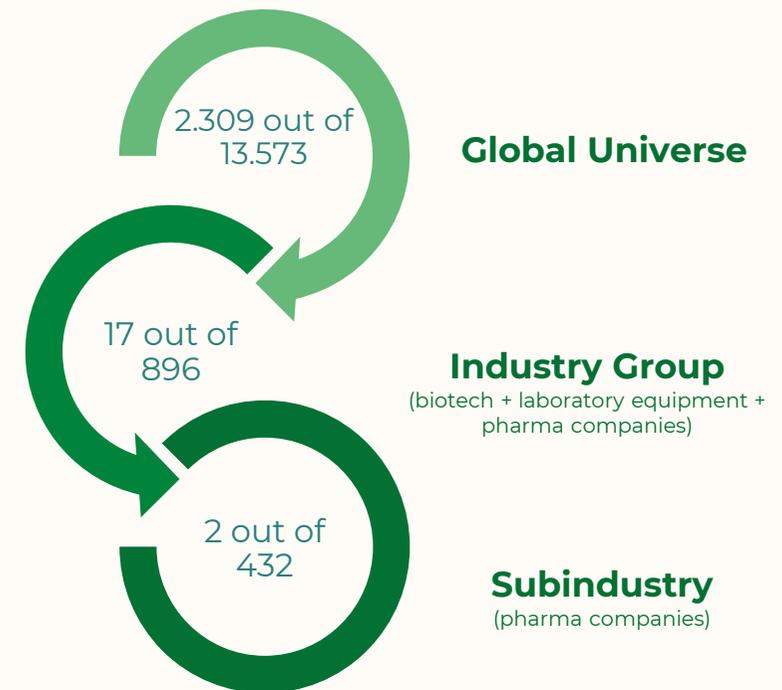
**18,4**

(low risk between 10 and 20)



**2<sup>nd</sup> position out of 432 companies**

(in the sub-industry “pharmaceuticals”)



## Key Company Highlights



Well-balanced pan-European specialty pharma business with 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

## Well-Balanced European Specialty Pharma Company with Three Diversified Growth Drivers

### Leading Proprietary LMWH Franchise

- Developed and successfully launched proprietary LMWH bemparin, the 2<sup>nd</sup> leading LMWH in Spain
- Developed enoxaparin biosimilar, one of the first to reach the market
- Vertically integrated, well positioned to benefit from significant economies of scale

### Leading Spanish Specialty Pharma Franchise

- Strong market leadership in Spain
- Partner of choice for in-licensing for leading global players
- Highly skilled c.250 person sales force

### High-Value-Added CMO Services

- One of the global leaders in pre-filled injectables manufacturing
- Fully-invested production facilities
- Help absorb fixed costs and overheads, providing for highly cost-competitive manufacturing position
- Particularly strengthens the LMWH franchise which relies on ROVI's production capabilities

### GROWTH DRIVERS

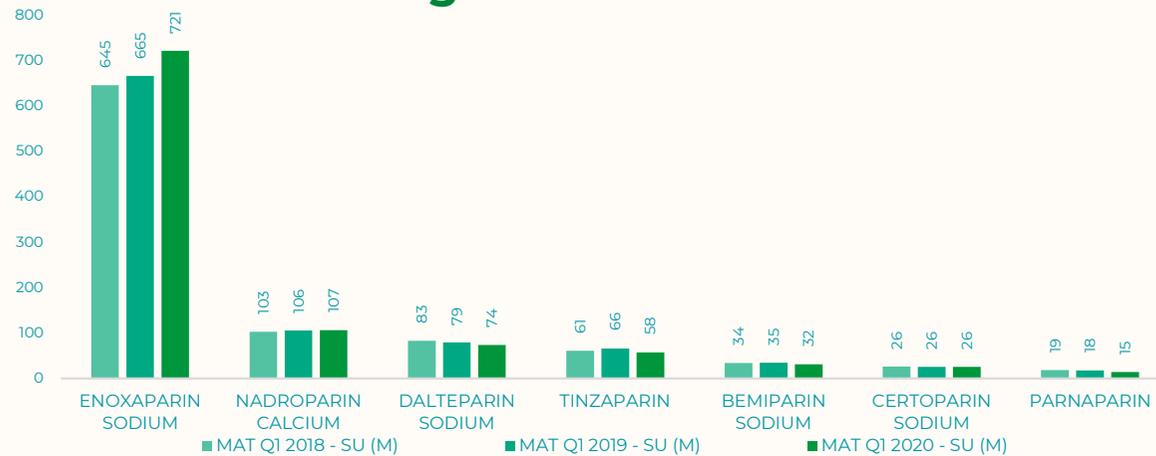
- Continue gaining branded LMWH market share through bemparin and enoxaparin biosimilar in Spain and abroad
- Launch enoxaparin biosimilar across more European countries and other international markets
- Roll-out of pan-European commercial network
- Second active principle heparin plant in Granada which will allow ROVI to double its capacity

- Leverage on leadership position in Spain
- Maintain strong sales performance and operational excellence
- New in-licensing opportunities with global players in specialty therapeutic areas

- Drive volume growth from existing customers
- Additional CMO customers given strong economies of scale
- Agreement with Moderna

## The LMWH market has increased by 3% over the last 3 years (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 means 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
<b>Total</b>	<b>2,566.5</b>	<b>349.7</b>	<b>301.2</b>	<b>335.8</b>	<b>131.6</b>	<b>370.6</b>	<b>4,055.3</b>

# 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)**
  - #2 market position in Spain** with a c.32%<sup>1</sup> market share and marketed in 59 countries in total
  - Only 2<sup>nd</sup> generation LMWH; **clinically differentiated from other competitor (such as Sanofi's Clexane / Lovenox)**
- **Vertically integrated** structure with its own **LMWH manufacturing plant**

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

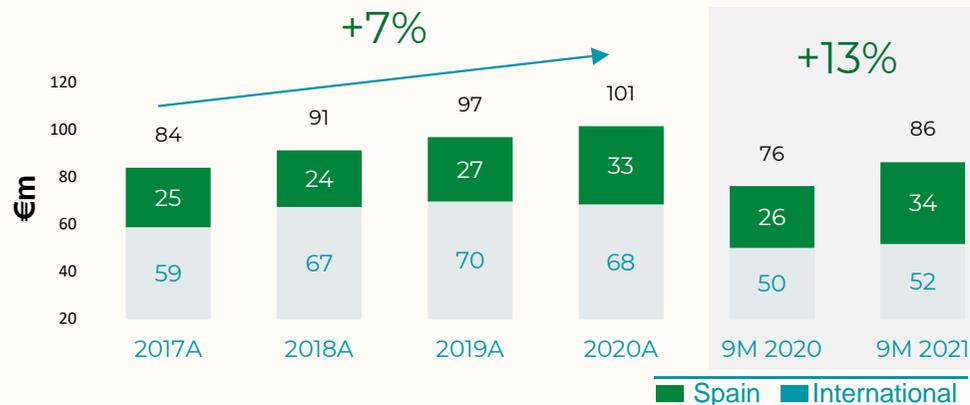
More convenient treatment: 1 daily injection needed in comparison to Sanofi's (Clexane / Lovenox) treatment (which needs 2)<sup>2</sup>

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

In-house legal team with regulatory know-how has achieved marketing authorisations worldwide

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

## Bemiparin Hibor® Global Sales



Marketed in **59** countries

Pending registration in **13** countries



1. Iqvia Midas Sep 2021  
 2. Bemiparin, thanks 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 patients' profiles, regardless of their risk level.

# Enoxaparin €2.6bn Global Market Represents an Untapped Opportunity to Be Explored with 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%)<sup>1</sup>



## European Uncrowded Competitive Landscape

Originator	<ul style="list-style-type: none"> <li>• Originator product developed by Sanofi Aventis</li> <li>• Patent expired in 2011 (high entry barriers: first biosimilar entered the market 6 years after patent expiry)</li> </ul>
Biosimilar	<p>Enoxaparin biosimilar <b>Becat®</b></p> <ul style="list-style-type: none"> <li>• ROVI markets its internally-developed enoxaparin biosimilar</li> <li>• Launched in Sep'17 with total sales of €101.4Mn in 2020 and €89.9Mn in 9M 2021</li> </ul>

In the long term, biosimilars tend to reach a 50%-70% share of the reference product market<sup>2</sup>

## 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:

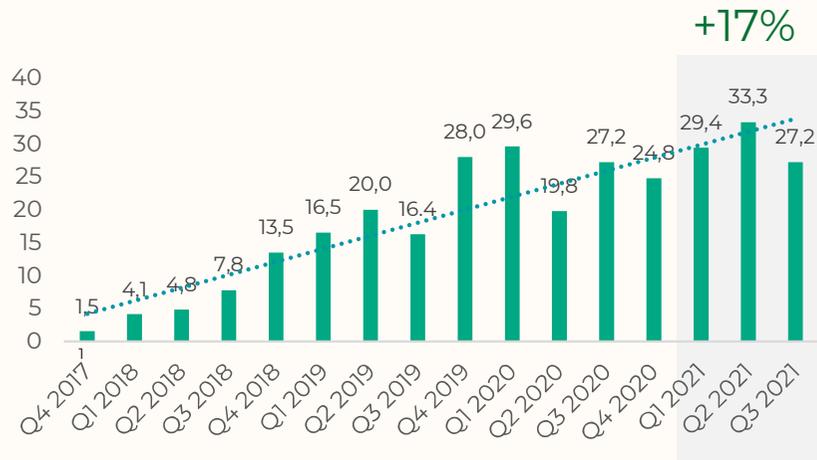


# Strong growth potential of Enoxaparin Biosimilar Becat®

## 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 **24 in the Rest of the World**
- Launched in **28 countries**

## Enoxaparin Biosimilar Becat® Sales Ramp-up



## Stage I of Commercial Strategy

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

...the largest enoxaparin market<sup>2</sup> with **€1.3bn** sales

...which account for c.75%<sup>3</sup> of the European market

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

**50-70%**<sup>4</sup> Market Share

...of the reference product market

## Launches in 9M 2021

ROVI launched enoxaparin in Canada, Malaysia, Albania, North Macedonia, Guatemala, El Salvador, Honduras, Georgia and Bahamas.



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.

# 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

Already Signed Out-Licensed Agreements: **107 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.

**€0.7bn**  
Q1 2020 MAT  
Market Sales<sup>1</sup>

## Agreements with International Partners



### 2022<sup>2</sup>

- Brazil
- Colombia
- Serbia
- Bosnia
- New Zeland
- Kosovo
- Lebanon
- Jordan
- Irak

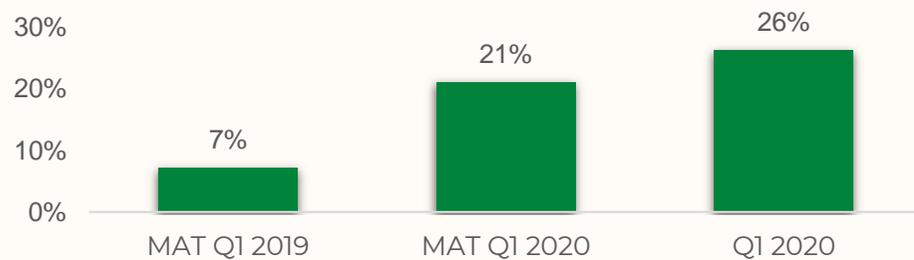
### 2023<sup>2</sup>

- Mexico
- Montenegro
- Sri Lanka
- Ecuador
- Argentina
- Vietnam

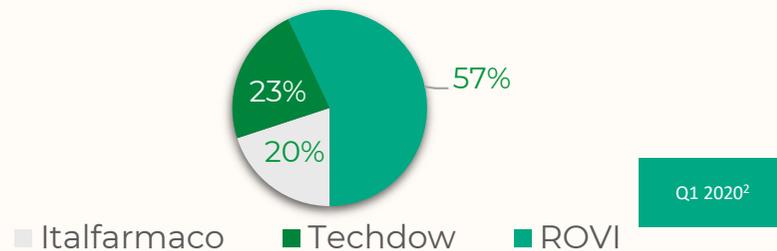
## ROVI aims to become one of the leaders in the LMWH market

### Enoxaparin biosimilar penetration in the retail market (%)

- Global market of enoxaparin (units) grew 8.3% in MAT Q1 2020<sup>1</sup>
- EMA<sup>2</sup> reached a 21.1% penetration rate (MAT Q1 2020), growing from 7.2% in MAT Q1 2019
- In Q1 2020, this EMA<sup>2</sup> penetration rate has accelerated to 26.3%

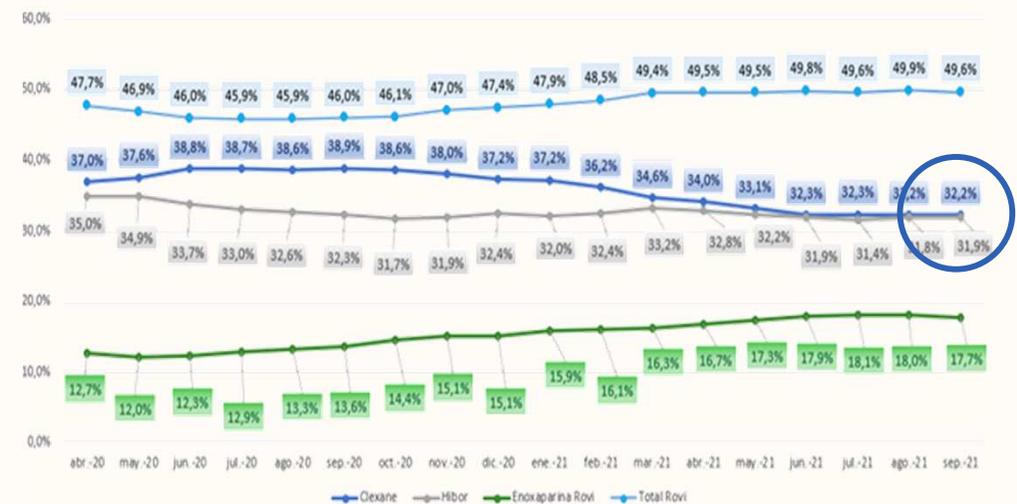


### ROVI vs competitors: European retail market in units (%)



### ROVI vs competitors: Spanish value market (%)

Hibor® close to surpass Clexane in September 2021



# Spanish Market Leadership Positions ROVI as the Partner of Choice for Global Pharma Players in Spain

Our Strong Market Leadership in Spain... ..allows us to be the Partner of Choice for Global Pharma Players in Spain

Presence in the Spanish market since 1946

Well-known proprietary portfolio driving strong leadership position

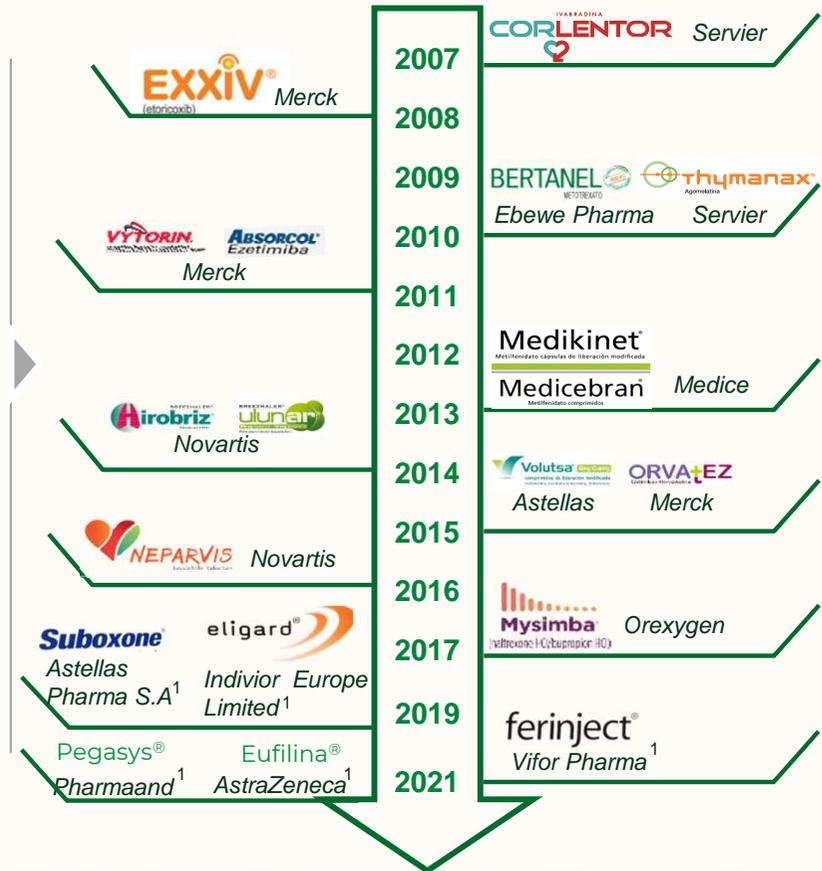
Franchise focused business: 20 proprietary and 28 in-licensed products

Multiple Strategic Alliances



One of the largest specialty pharma sales forces in Spain with c.250 employees

Strong knowledge of the Spanish regulatory framework



Broad portfolio of innovative products

Proven track record with 14 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

## High-Value-Added Global CMO Services

Customer-oriented business model

High-value-added service with pre-filled syringes toll manufacturing

Differentiated capabilities drive significant barriers to entry

Revenue visibility on the back of long-term agreements

International sales represent c.97% of CMO business

Clean regulatory track record at manufacturing plants with multiple GMP / FDA approvals

### CMO Targets

Toll manufacturing sales increased **39%** in **2020** and **187%** in **9M 2021**

**ROVI** expects the **CMO** business to increase by between **2 and 2.5** times, including production of the COVID-19 vaccine.

ROVI aims to become a long-term manufacturing partner for 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 will **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

- Expected to come into operation in Q4 2021

#### DARA 3

- Expected to come into operation between Q2 and Q3 2022

## ROVI strengthens its collaboration with Moderna (2/2)



### 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

# 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®, 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	<b>Schizophrenia</b>	Phase III	In approval process in Europe and in USA
Letrozole ISM® Long acting Letrozole	<b>Breast Cancer</b>	Phase I	Phase I started in November 2017
Risperidone, quarterly	<b>Schizophrenia</b>	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

<b>1 Predictability</b>	Pop PK <sup>2</sup> model & simulations already validated for Risperidone ISM® in Clinical Program	Expected high success rate in Phase III in new developments
<b>2 Usability</b>	Improved stability	No cold chain needed
<b>3 Flexibility</b>	Selecting the most convenient posology depending on clinical needs	From 1 to 6-month administration
<b>4 Improved Clinical Management</b>	Long-acting injection (1-6 months) plasma therapeutic levels from day 1	Rapid onset & sustained clinical effect
<b>5 Vertical Integration</b>	Technological barriers (e.g. power filling) Strong IP Manufacturing capabilities	Protected technology Fully integrated manufacturing plants



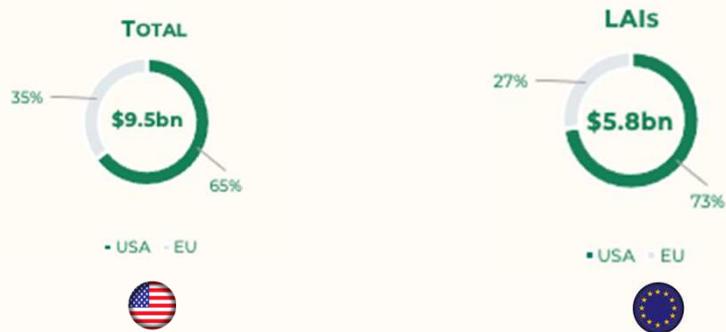
1. ISM® stands for *In Situ Microimplants*®.  
2. PK stands for pharmacokinetic.

# Risperidone ISM®: Attractive Schizophrenia Market with Strong Growth Prospects

## Attractive Schizophrenia Market

- Chronic and progressive disease
- Affects 21m people worldwide with a relatively high lifetime prevalence<sup>1</sup>
- Strict compliance needed to avoid relapses
- LAIs<sup>2</sup> are becoming the gold standard for treatment given improved adherence and effectiveness

MAT Q3-19 Schizophrenia Market Value US & EU<sup>3</sup>



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

- Second largest schizophrenia LAIs 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)<sup>4</sup>

## Solid Grounds for Success for a Risperidone LAI

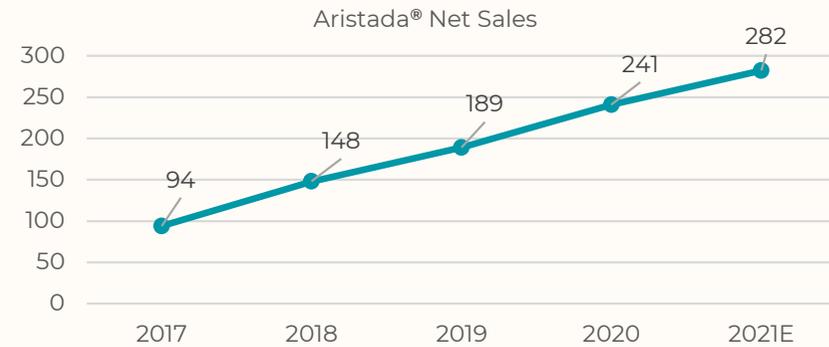
LAI schizophrenia market presents key features for a successful launch

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<sup>5</sup>



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



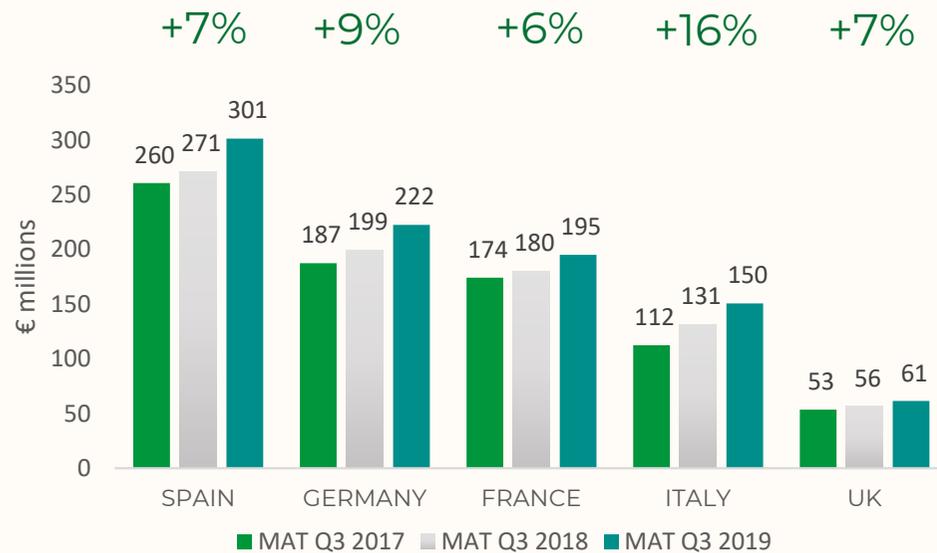
1. Epidemiology data-Kantar Health Epi Database®.  
2. LAIs stands for Long Acting Injectables.  
3. Iqvia Midas MAT Q3 2019.

4. Iqvia Midas MAT Q3 2019 and Rovi's monthly treatments estimates.  
5. Alkermes results.

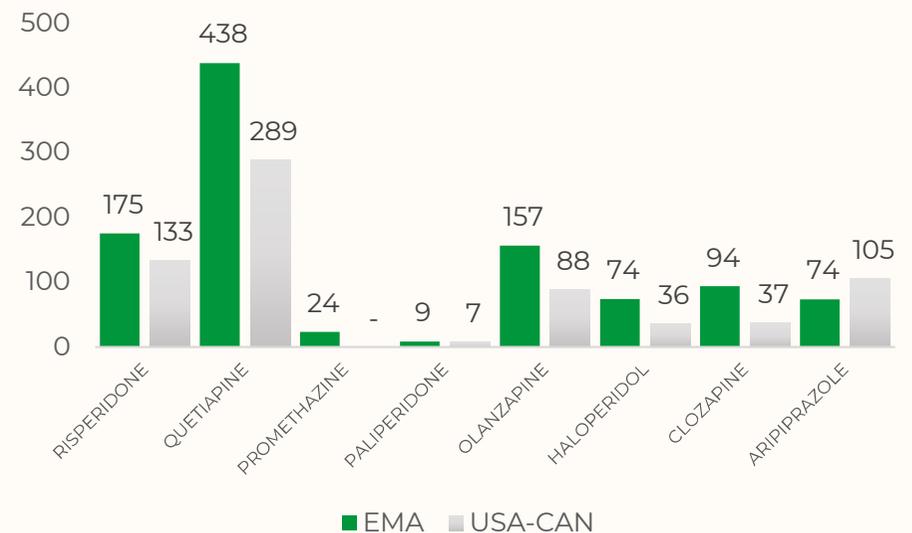
## LAI's are becoming the gold standard for treatment in EU5

- LAIs 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%<sup>1</sup> of the Spanish antipsychotic market
- Risperidone is the second preferred molecule in EMA and USA

### Antipsychotic LAIs sales – EU5 (€Mn)



### Schizophrenia market (Standard units MAT Q3 2019)



# Risperidone ISM®: Fast Onset Long-Acting Injectable of Risperidone

## Superior Value Proposition When Compared to Alternatives

Fully supervised monthly injection	<ul style="list-style-type: none"> <li>Ongoing monitoring of non-adherence through regular interactions between patient and medical staff</li> <li>Reduce the risk of accidental or deliberate overdose</li> </ul>
Clinical Convenience of Risperidone	<ul style="list-style-type: none"> <li>Proven efficacy and safety of Risperidone<sup>1</sup></li> <li>Well-known drug among psychiatrists for the treatment of schizophrenia</li> </ul>
Therapeutic plasma levels from 2 hours post dose aimed at PANSS reduction at day 8	<ul style="list-style-type: none"> <li>Fast onset of action to achieve therapeutic plasma levels from the beginning</li> <li>Achieving significant PANSS<sup>3</sup> reduction in unstable schizophrenia patients at day 8</li> <li>No need to supplement with oral medication or loading dose</li> </ul>

## Strong Product Expected to Offer Superior Characteristics

	RISPERDAL CONSTA® (Risperidone)	INVEGA SUSTENNA®/ XEPLION® (Paliperidone)	INVEGA TRINZA® / TREVICTA® (Paliperidone)	ABILIFY MAINTENA® (Aripiprazole)	ARISTADA® (Aripiprazole Lauroxil)	PERSERIS® (Risperidone Atrigel®)	Risperidone ISM® (Risperidone)
Once Monthly Administration <sup>4</sup>	✗	✓	Quarterly	✓	✓	✓	✓ <sup>12-14</sup>
No Oral Supplementation / Loading dose <sup>4</sup>	✗	✗	After ≥4 months Inv. Sustenna/ Xeplion	✗	✗	✓	✓ <sup>12-14</sup>
Therapeutic Levels <sup>2</sup> within First 2 Hours <sup>4</sup>	✗	✗	✗	✗	✗	✓	✓ <sup>12,13</sup>
Currently Marketed in Europe <sup>5,6</sup>	✓	✓	✓	✓	✗	✗	Targeted
Stability at Room Temperature <sup>4</sup>	✗	✓	✓	✓	✓	✗	✓
PANSS Reduction from Day 8 <sup>15</sup>	✗ <sup>7</sup>	✗ <sup>8</sup>	✗ <sup>4</sup>	✗ <sup>9</sup>	✗ <sup>10</sup>	✗ <sup>11</sup>	✓ <sup>14</sup>

1. Leucht et al. Am J Psychiatry 2017.

2. The therapeutic concentration range of risperidone is quite wide and can vary from 10 ng/mL to 80 ng/mL or even higher (Remington et al. Am J Psychiatry 2006).

3. PANSS: positive and negative syndrome scale. Scale used to evaluate the symptoms of patients with schizophrenia.

4. Drugs@FDA: FDA Approved Drug Product. Available at: <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm>

5. Only applies to Risperdal Consta: Heads of Medicines Agencies. MRI Product Index. Available at: <http://mri.cts-mp.eu/human/>

6. European Medicines Agency. European Public Assessment Reports. Available at: <https://www.ema.europa.eu/en/medicines>

7. Kane et al. Am J Psychiatry 2003.

8. Pandina et al. J Clin Psychopharmacol 2010.

9. Kane J et al. J Clin Psychiatry 2014.

10. Meltzer H et al. J Clin Psychiatry 2015.

11. Nasser A et al. J Clin Psychopharmacol 2016.

12. Llaudó J et al. Int Clin Psychopharmacol 2016.

13. Anta L et al. Int Clin Psychopharmacol 2018.

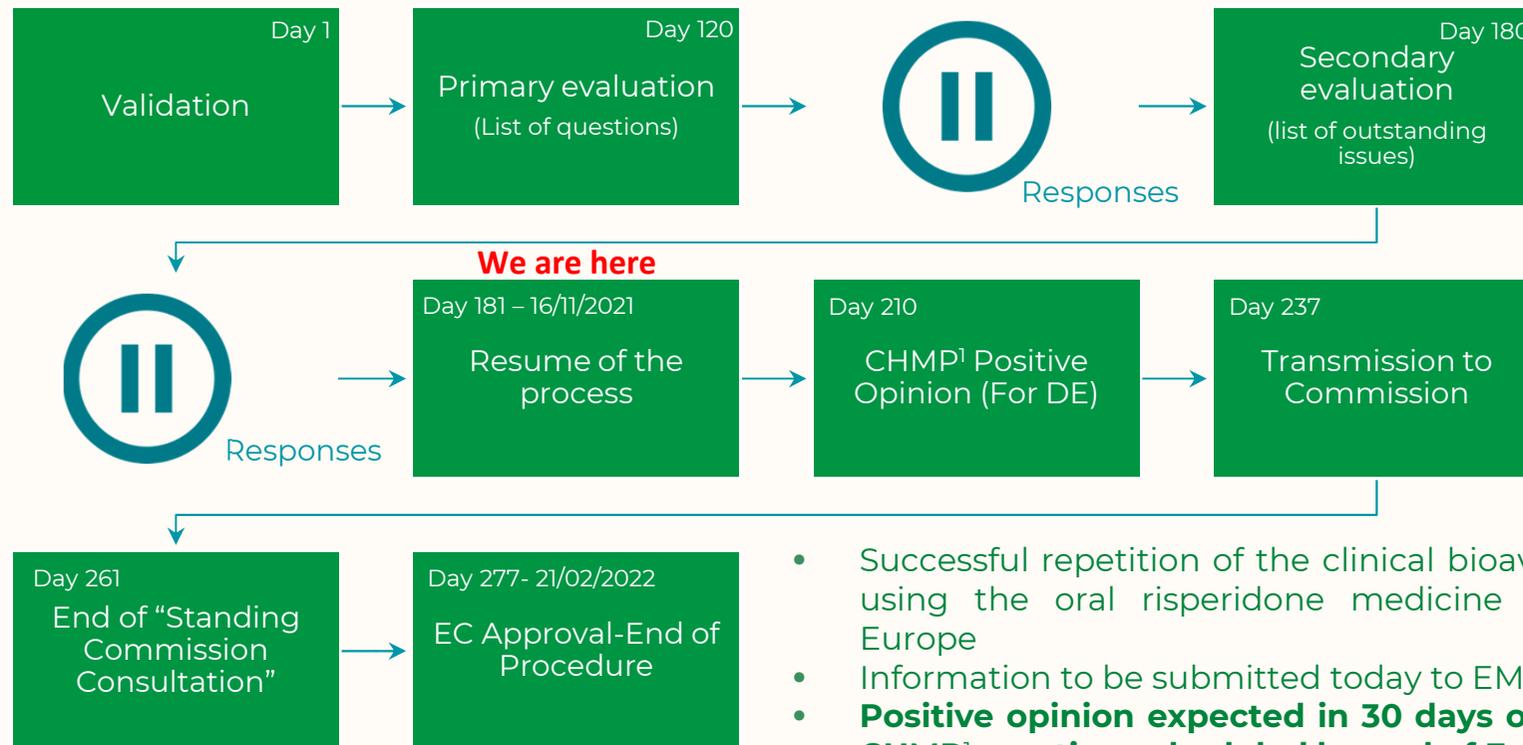
14. Correll et al. NPJ Schizophrenia 2020.

15. Statistically significant PANSS total score reduction versus placebo in acutely exacerbated schizophrenia patients after the first injection of the long-acting antipsychotic without oral antipsychotic supplementation and/or loading dose.

## European regulatory process - Where are we?



### Resume of regulatory process

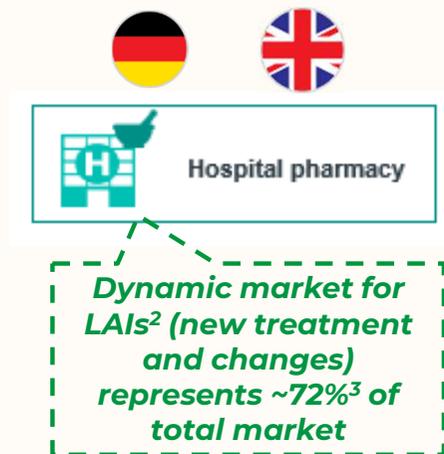


- Successful repetition of the clinical bioavailability trial using the oral risperidone medicine marketed in Europe
- Information to be submitted today to EMA
- **Positive opinion expected in 30 days or at the next CHMP<sup>1</sup> meeting scheduled by end of February 2022**

## Therapeutic Indication – Covering the Unmet Medical Need (1/2)

Requested Therapeutic Indication to EMA → **Treatment of Schizophrenia in adults**

Risperidone ISM<sup>®</sup> would be the **ONLY<sup>1</sup> Long-Acting Injectable Antipsychotic** that can be administered to **unstable patients** with severe or moderate psychotic symptoms suffering a relapse



- Dynamic market originating in hospitals
- In Germany and UK, around 72% of prescriptions in hospitals correspond to patients who start treatment with a LAI<sup>2</sup>
- Competitive advantage because of the potential unique indication of Risperidone ISM<sup>®</sup>

## Therapeutic Indication – Covering the Unmet Medical Need (2/2)

Risperidone ISM<sup>®</sup> has a **unique Pharmacokinetic profile** making the product suitable to treat stable schizophrenia patients as well as unstable schizophrenia patients requiring a fast onset of action

ACHIEVES FAST  
THERAPEUTIC PLASMA  
LEVELS<sup>2,3</sup>

NO LOADING DOSE/ORAL  
SUPPLEMENTATION  
NEEDED<sup>1-3</sup>

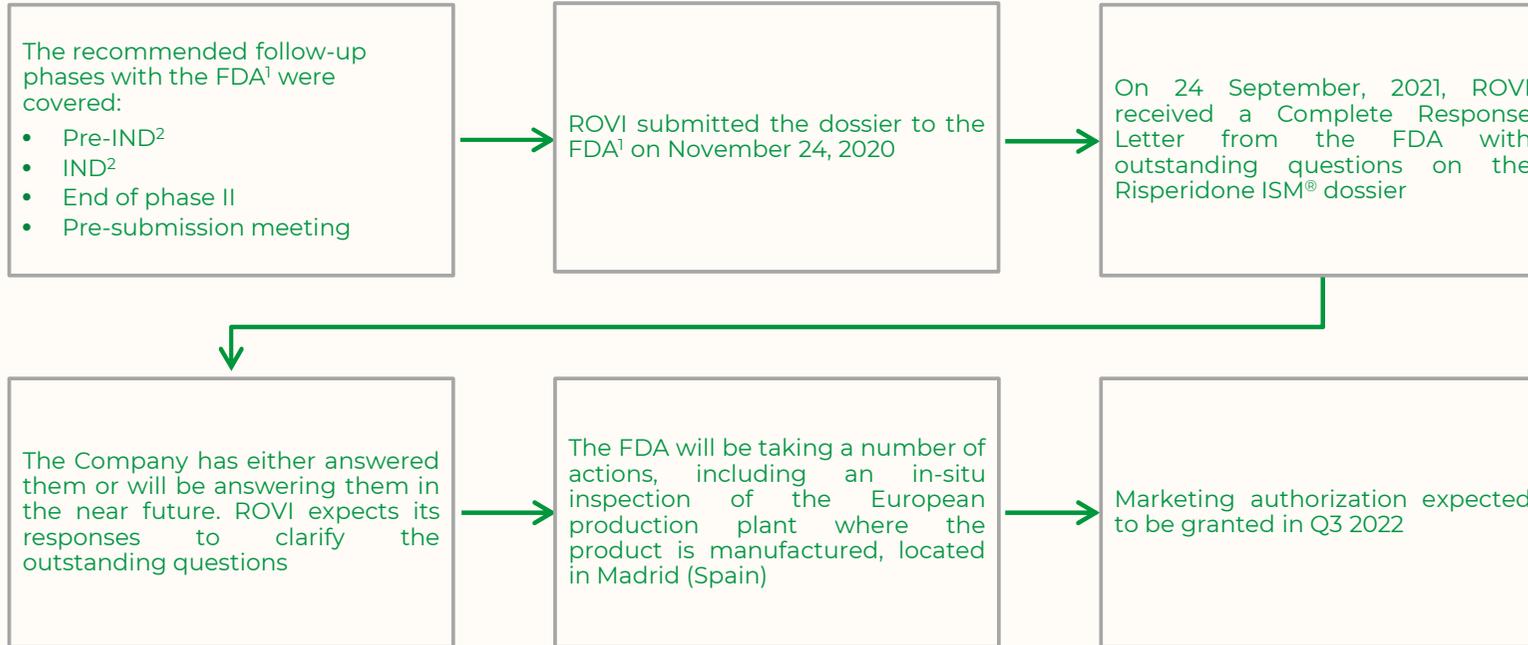
SUSTAINED THERAPEUTIC  
LEVELS ALLOWING A ONCE  
MONTHLY POSOLOGY<sup>1-3</sup>



**PRISMA-3: RISPERIDONE ISM<sup>®</sup> DEMONSTRATED  
EFFICACY IN SEVERE PATIENTS AS EARLY AS DAY 8<sup>1</sup>**

1. Correll CU, et al. Efficacy and safety of once-monthly Risperidone ISM<sup>®</sup> in schizophrenic patients with an acute exacerbation. NPJ Schizophr. 2020 Nov 25;6(1):37
2. Anta L, Llaudó J, Ayani I, Martínez J, Litman RE, Gutierrez I. A phase II study to evaluate the pharmacokinetics, safety, and tolerability of Risperidone ISM multiple intramuscular injections once every 4 weeks in patients with schizophrenia. Int Clin Psychopharmacol. 2018 Mar;33(2):79-87.
3. Llaudó J, Anta L, Ayani I, Martínez J, Schronen J, Morozova M, Ivanov M, Gutierrez I. Phase I, open-label, randomized, parallel study to evaluate the pharmacokinetics, safety, and tolerability of one intramuscular injection of risperidone ISM at different dose strengths in patients with schizophrenia or schizoaffective disorder (PRISMA-1). Int Clin Psychopharmacol. 2016 Nov;31(6):323-31.

## USA regulatory process – Where are we?



The indication pursued in the US is the same as all other LAIs<sup>3</sup> have, "Treatment of schizophrenia in adults"



1. FDA: Food and Drugs Administration  
2. IND: Investigational New Drug

3. LAI: Long-Acting Injectable

## New Risperidone ISM® brands

Risperidone ISM® trademark has changed because of a trademark conflict. New trademarks are:

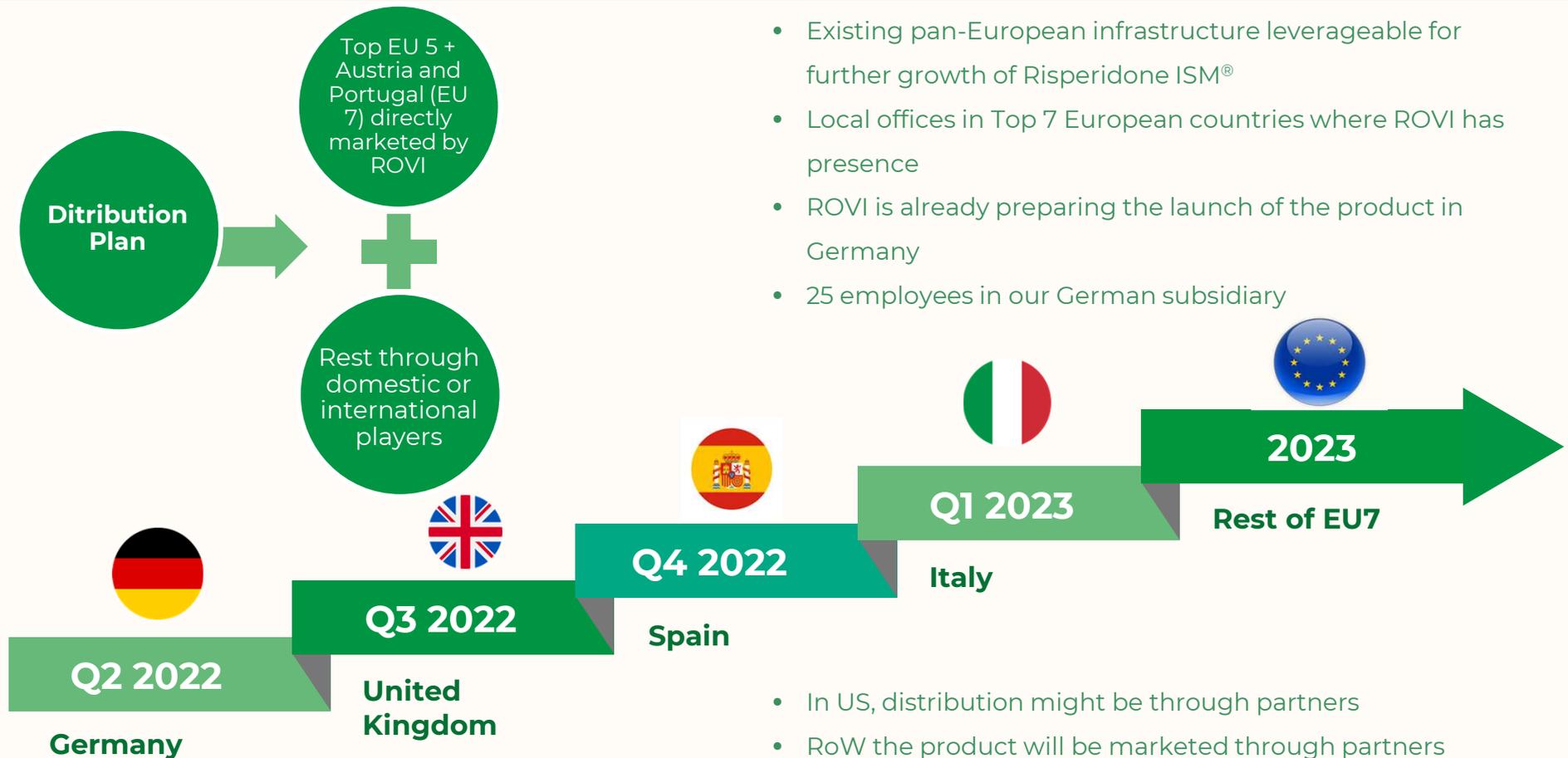


Okedi®



Risvan®

## Risperidone ISM<sup>®</sup>: International Distribution Plan



- Existing pan-European infrastructure leverageable for further growth of Risperidone ISM<sup>®</sup>
- Local offices in Top 7 European countries where ROVI has presence
- ROVI is already preparing the launch of the product in Germany
- 25 employees in our German subsidiary

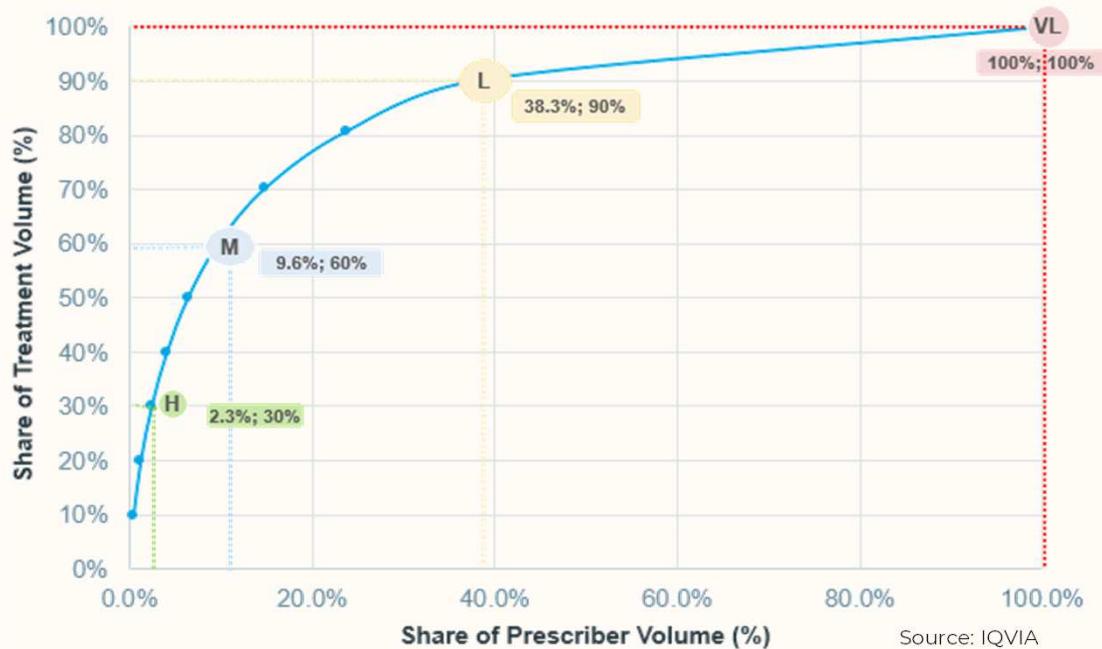
- In US, distribution might be through partners
- RoW the product will be marketed through partners

## Small Salesforce needed to address the psychiatric community



For 2nd gen LAIs, prescribers are fairly concentrated with ~10% contributing to 60% of total volume

2nd generation LAIs-Prescriber concentration



Source: IQVIA

Source: IQVIA

In United States, 7,000 prescribers account for **80%** of the 2<sup>nd</sup> generation LAI treatment volume.

**Small Salesforce to be needed to address the psychiatric community**

# Letrozole ISM®: Second ISM® Candidate in 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

### Upcoming Key Catalyst:

- The company has initiated discussions with the FDA to review Letrozole ISM® Phase I results as well as the next steps for continuing its clinical development
- 505(b)(2) path of approval for candidates leveraging ISM® technology

### Expected Value Proposition:

#### Rapid & Sustained Estrogen Suppression Targeting a LONG ACTING Injection

#### Superior Efficacy

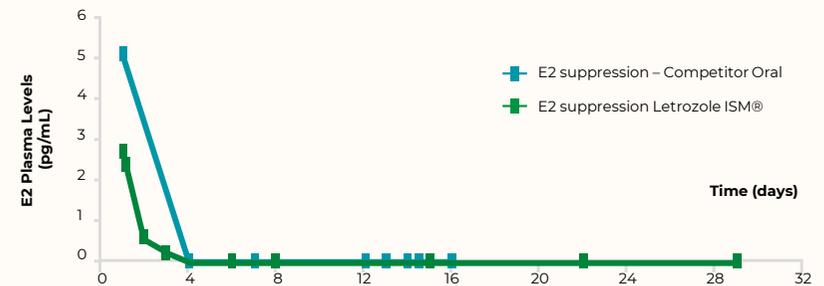
- Preliminary results suggest that sustained long-term hormone suppression therapy (HT) may obtain a superior clinical outcome in breast cancer compared to an oral daily dosage treatment
- Early discontinuation and non-adherence to HT are common and associated with increased mortality – **improved treatment compliance with Letrozole ISM® has potential to enhance treatment**

#### Improved Safety Profile

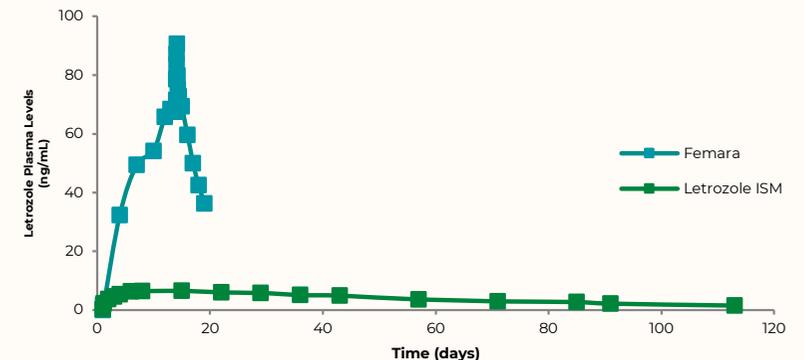
- Sustained lower effective doses (compared to oral treatment) could reduce adverse side effects (bone mass loss, bone/joint/muscle pain, dyslipidemia) due to lower exposure to drug
- Better safety profile has potential to positively impact treatment duration adherence

## Preliminary Phase I Results

### Rapid and sustained estrogen suppression with lower doses



### Rapid and sustained Letrozole plasma levels



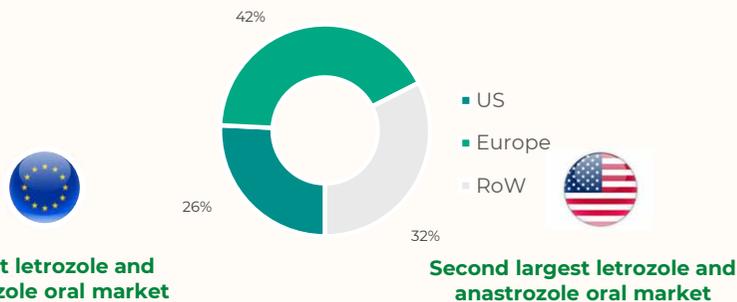
# Letrozole ISM®: Potentially unique LAI in hormone-dependent breast cancer market

## Attractive Potential Market

- Hormone receptor-positive (HR+) breast cancer market has a relatively high lifetime prevalence and is expected to grow significantly over the next ten years
- Revenues across the US, Japan, and five major EU markets expected to grow at 16.7% from 2015-2024<sup>1</sup>
- Strict compliance needed to avoid relapses during at least 3 year treatment
- LAIs<sup>2</sup> have no presence in this market but the easier posology system will become the gold standard for treatment given improved adherence and effectiveness

## Total daily units

MAT Q3-19 Letrozole and Anastrozole World Market (oral daily units)<sup>3</sup>



## Potential market for Letrozole-ISM®

No presence of LAIs for this disease: future potential target market could be a high-rate conversion from oral market

High treatment posology switching rate expected

Focused group of Letrozole and Anastrozole patients

High % of dynamic market of new treatments is expected to be targeted

All new treatments under development are on top of hormone suppression

Risk-benefit profile of hormone inhibitors is very high

ROVI is the only company researching in this hormone-dependent breast cancer market

No substitution of aromatase inhibitors is expected

# Letrozole ISM<sup>®</sup>: Approach to ROVI's Potential Market

## Potential market for Letrozole-ISM<sup>®</sup>

- 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<sup>1</sup> 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 m 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

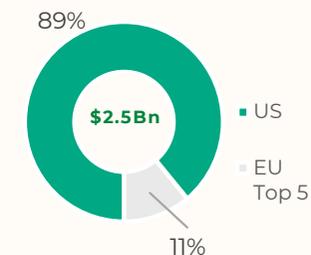


## Approach to Prostate Cancer LAIs Market

- 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<sup>1</sup> 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<sup>2</sup>  
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.

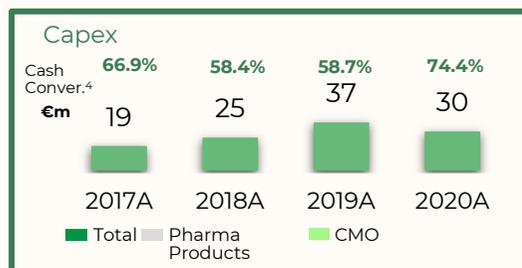
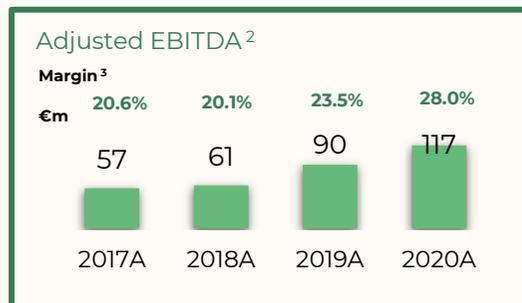
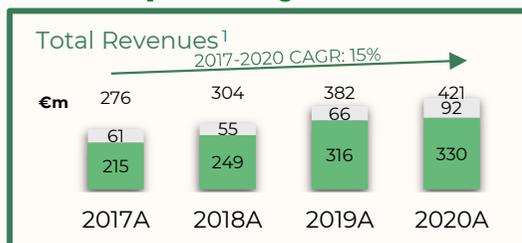
# FINANCIAL RESULTS

Javier López-Belmonte  
Vicepresident and Chief Financial Officer



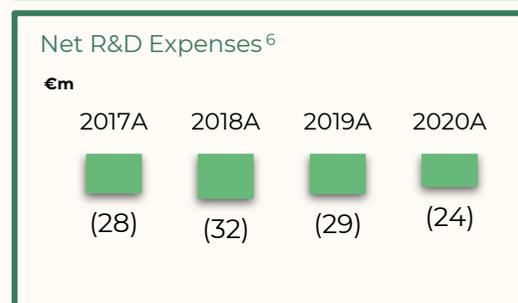
## Sound Financial Policy Supported by Strong Track Record

### Specialty Pharma



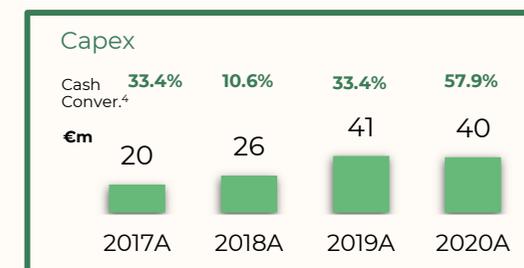
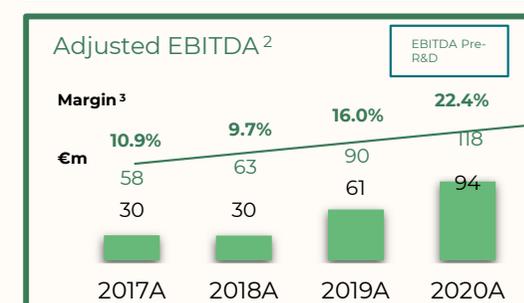
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### ISM® Platform



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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®.

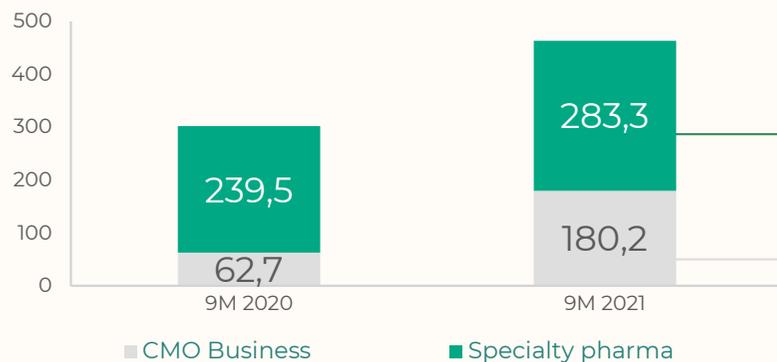
## 9M 2021 results (1/2)

REVENUE	EBITDA	EBIT
463.5 (+53%)	139.5 (+100%)	123.3 (+123%)
Net profit	Capex	Net cash
98.9 (+111%)	22.0 (30%)	74.4

**2022 operating revenue guidance:** ROVI expects a mid-single-digit growth rate for the operating revenue

For 2021, ROVI is upgrading again its 2021 operating revenue guidance from the range between 35% and 40% to the 40% and 45% range.

### Operating revenue €m



### Specialty pharma business €m



**Heparin franchise\*** €181.5 (+15%) 39% of operating revenue

**LMWH** €176.2 (+15%)

**Bemiparin sales** €86.3m (+13%)

**Enoxaparin sales** €89.9m (+17%)

**Spain** €51.8m (+3%)

**International** €34.5m (+32%)

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

✓ Launched in 28 countries.

✓ Approved in 26 countries in Europe and 24 in RoW

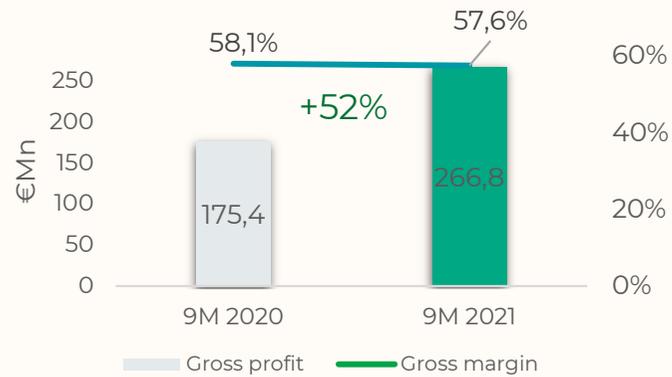
\* LMWH (Bemiparin and Enoxaparin biosimilar) + other heparins

### CMO business €m

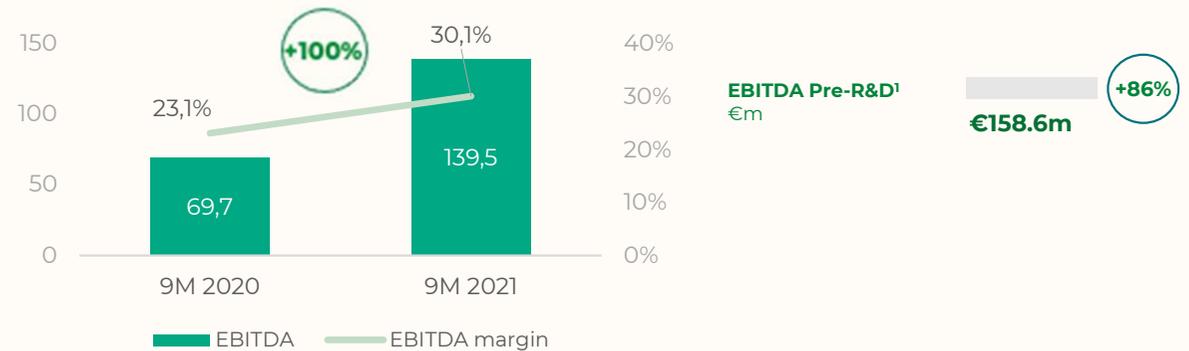
**Total** €180.2m (+187%)

## 9M 2021 results (2/2)

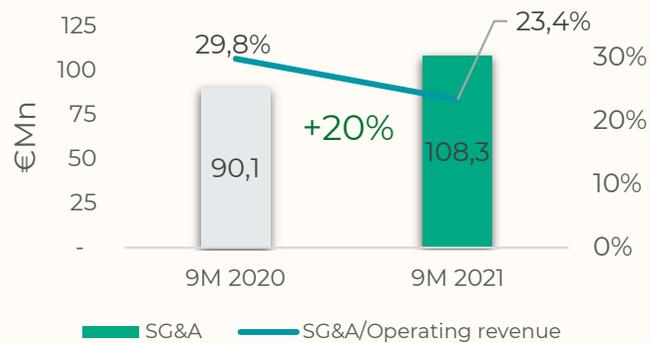
### Gross profit (€m) and gross margin (%)



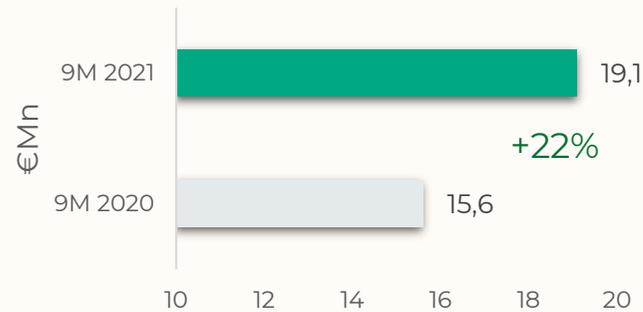
### EBITDA (€m) and EBITDA margin (%)



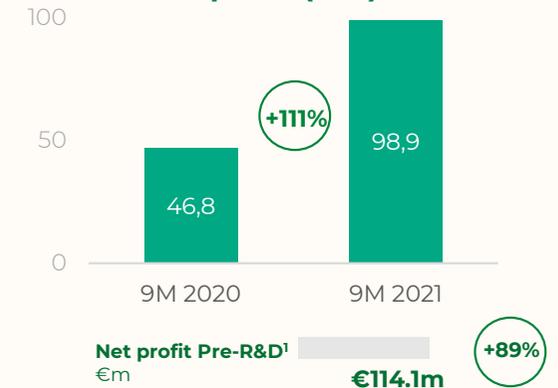
### SG&A (€m)



### R&D (€m)



### Net profit (€m)



## Capital allocation supports growth

**Cash Flow from operating activities** increased to €137.9Mn in 9M 2021 mainly due to:

- Increase of €70.1Mn in profit before income tax;
- Increase of €2.1Mn in the “inventories” line in 9M 2021 compared to a decrease of €79.4Mn in 9M 2020;
- Booking of €21.5Mn under the “Proceeds from toll manufacturing services” caption in 9M 2021 compared to the €18.1Mn euros recognized in 9M 2020; and
- Increase of €10.7Mn in the “trade and other payables” item in 9M 2021 compared to a decrease of €5.3Mn in 9M 2020.

### Debt analysis

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

**Bank borrowings represented 63% of total debt** as of 30 September 2021. They consist of a European Investment Bank loan with long maturities.

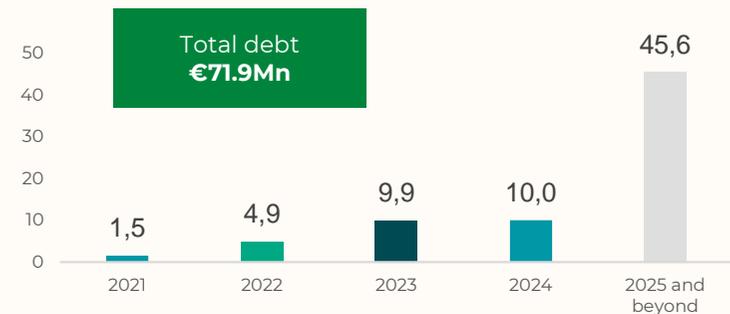
**Net cash of €74.4Mn** as of 30 September 2021 vs €56.1Mn as of 30 June 2021 and €19.8Mn net debt as of 31 December 2020.

As of 30 September 2021, ROVI had a **gross cash position of €146.3Mn**, compared to €129.0Mn as of 30 June 2021 and €54.6Mn as of 31 December 2020.

### Cash generation in 9M 2021 (€Mn)



### Debt maturities as of Sept 30, 2021 (€Mn)



**Focused on creating value**

## ROVI is increasing remuneration to shareholders

### 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, 3 November 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

## Outlook 2022



**2022 operating revenue growth rate**

**Mid-single-digit**

### The key Growth levers in 2022

Specialty Pharma	CMO
Bemiparin	Spare capacity in the manufacturing plants
Biosimilar of Enoxaparin	New customers to be acquired
Launches such as Neparvis® and Volutsa®	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.*

## 2023 long term guidance expected to be achieved in 2021

	2018	2021	LT indicative guidance 2023	
Operating revenues	€303.2Mn	€588Mn - €609Mn	X2 €606.4Mn	Expected to be achieved in 2021
EBITDA pre-R&D	€63.0Mn	€158.6Mn in 9M 2021 EBITDA pre-R&D	X2.5 €157.5Mn	Already achieved in 9M 2021

Next phase of growth achieved through several key levers (Enoxaparin biosimilar, Risperidone ISM®, Letrozole-ISM®, M&A activities, Moderna agreement)...  
 ... underpinned by solid specialty pharma and toll manufacturing businesses

## For further information, please contact:

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