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### Agenda for today

10:00 am	Section I – Update on ROVI's strategy  • Juan López-Belmonte, Chairman and CEO  Section II – CDMO  • Miguel Ángel Ortega, Corporate Industrial Director
	Section III – Specialty Pharma  • Miguel Ángel Castillo, International and Business Development Director
10:55 am	Section IV – Update on the R&D strategy  • Ibon Gutierro, Corporate R&D Director
11:15 am	Section V – Financial Results  • Javier López-Belmonte, Deputy Chairman and CFO
11:30 am	Q&A
12:00 am	Closure  • Juan López-Belmonte, Chairman and CEO

Chair: Marta Campos, Head of Finance



### Section I - Update on ROVI's Strategy

Juan López-Belmonte Chairman and CEO



#### **Brief overview of ROVI**

#### **CDMO**

Contract development and manufacturing organization



One of the largest CDMO injectable companies worldwide



One of the global leaders in prefilled syringes capacity<sup>1</sup>

#### **Specialty pharma**

Research, development and sale of heparin and other specialty pharma products



Leading proprietary heparin franchise



Risperidone ISM® (Okedi®) is our first commercialized product based on our ISM® tech



Leading Spanish Specialty Pharma business with c.200 reps

#### **ISM®** technology platform

In-situ micro implants technology



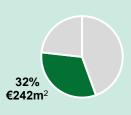
Patent-protected, long-acting sustained-release injectable proprietary technology provides versatile platform with wide applicability across multiple drug candidates

#### % of 2024 operating revenue

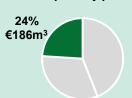
CDMO



LMWH franchise<sup>2</sup>



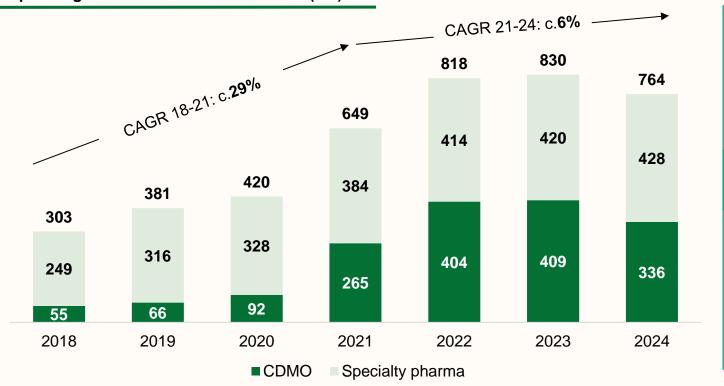
Other specialty pharma<sup>3</sup>



- ROVI's ISM® technology leverages advanced pharmacokinetic modeling to deliver highly predictable and controlled drug release, optimizing therapeutic efficacy and patient outcomes
- ISM® technology already validated and tested after the success of Okedi®

#### Our proven track-record

#### Operating revenue evolution 2018-2024 (€m)



Consistent and sustainable growth since 2018



#### **ROVI today**



#### **CDMO**

- Significant current available capacity in fill and finish (F&F) addresses structural market shortages in high growth markets
- Vertical integration with 4 fully-invested manufacturing plants that allow ROVI to offer high-value-added injectable and oral forms CDMO services
- Approved by most regulatory bodies worldwide, including FDA and GMP¹ EU Annex 1 compliant

### - 1

#### LMWH Franchise

- Unparallel know-how of the LMWH market. Presence in more than 60 countries
- 2 in-house developed flagship products: bemiparin and enoxaparin with €242m total sales in 2024
- Vertical integration to increase margins of the division through Glicopepton company

### Specialty Pharma

#### Risperidone ISM® (Okedi®)

- First commercialized product based on our ISM® technology platform
- A product with a **unique indication in Europe** and **positive feedback** from **psychiatrists**
- Sales of €29m in 2024 (vs €14m in 2023)

## Other specialty pharma

- Leading Spanish Specialty Pharma business with ~200 reps and more than 20 new in-licensed products over 15 years
- Well-established **European salesforce** with more than **120 employees** in **6 countries** (ex. Spain)

## ISM® platform

- Phase I of Letrozole SIE<sup>2</sup>
- Phase I of quarterly risperidone
- Proofs of concept with new molecules

#### **ROVI** in the future



#### **CDMO**

- New filling lines providing additional pre-fill syringes (PFS) and cartridges capacity
- Expansion assembling capacities to include autoinjectors and pens
- · Higher-priced contracts due to complex production of high added-value products
- Global leader in complex injectable manufacturing

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### LMWH Franchise

- Vertical integration through Glicopepton
- Cost efficiency
- Growth in international bemiparin sales mainly due to China, Turkey and Greece

### Specialty Pharma

## Risperidone ISM®

(Okedi®)

- Approval and launch in new countries
- Peak sales €100m €200m

## Other specialty pharma

- New in-licensing agreements to co-market products in Europe
- Excellent proven track record in launching products
- Selected M&A opportunities to complement the specialty pharma portfolio
- New diagnosis solutions powered by artificial intelligence

ISM® platform

- · Letrozole SIE (phase III)
- Quarterly risperidone (phase III)

#### **ESG** valuations

### Sustainalytics: 16.1 (low risk) 5° ranking in the global pharmaceutical industry



#### **ESG** strategy

ROVI has an ESG director plan for the period 2023-2025, which promotes sustainability through 5 pillars:



Benchmark of governance committed to sustainability



**Sustainable management of global challenges**: combating climate change, promoting circular economy and efficient water management



Key player in caring for people and integrating specialised talent



Responsible supply chain management ensuring ethical and environmental standards at every step of the supply chain



Promotion of R+D activities through the establishment of partnerships with key actors

The new ESG master plan makes a substantial contribution to the achievement of 11 sustainable development goals linked to ROVI's activity



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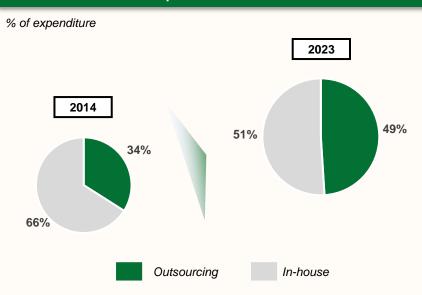
### **Section II - CDMO**

Miguel Ángel Ortega Corporate Industrial Director



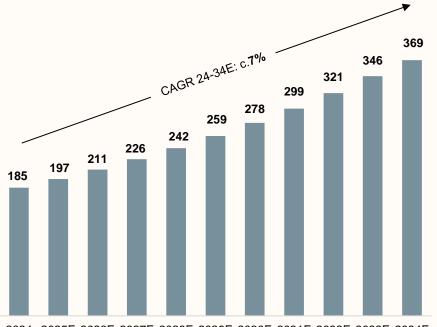
#### Outsourcing services are still increasing their penetration

#### Pharma production 2014 vs 2023



 The demand for outsourced manufacturing has been consistently rising over the past years. There is still increasing demand for outsourcing to CDMOs given lack of internal capacity and R&D focus with penetration expected to reach c.60% by 2031E

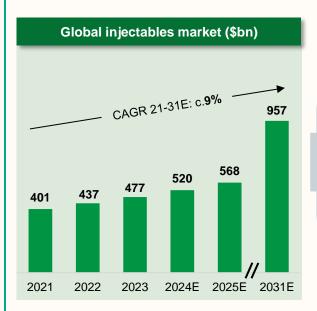
#### Global pharmaceutical CDMO market growth 2024 – 2034E (\$bn)

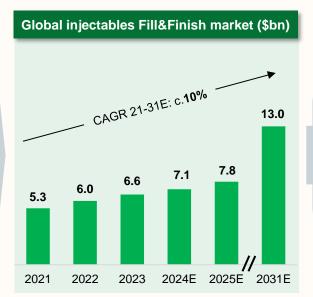


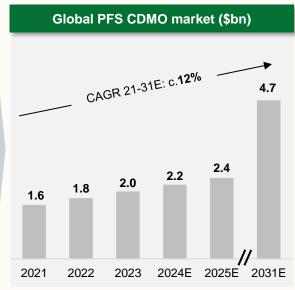
2024 2025E 2026E 2027E 2028E 2029E 2030E 2031E 2032E 2033E 2034E

# ROVI's CDMO business focuses on high value-added sterile F&F, with a high growth market in PFS...

- Injectables are the fastest-growing route of administration for the pharma market, accounting for >70% of all drugs under development
- Growth predominately driven by the biologics market, including biosimilars and blockbuster product categories such as GLP-1s
- CDMOs provide specialized technical capabilities / know-how for complex sterile fill and finish (F&F) processes
- Increasingly stringent regulatory requirements, such as EU GMP Annex 1, boost reliance on specialized and reliable external partners

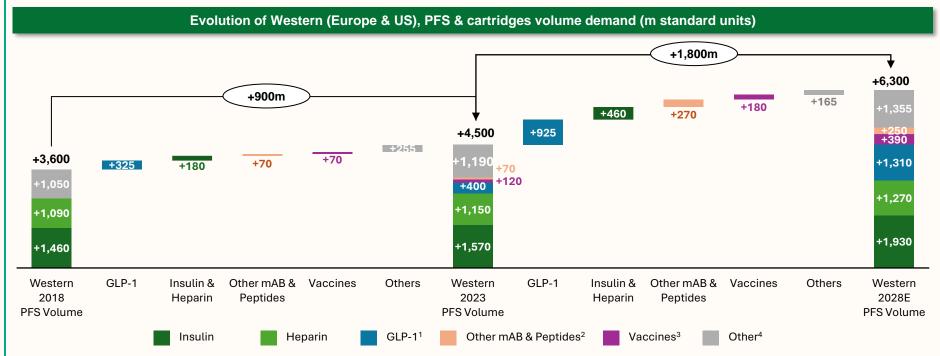






#### ...a critical part of the value chain with low available capacity and strong demand

One of the primary drivers is the increasing incidence of chronic diseases globally, which has led to a heightened demand for injectable therapies. Conditions such
as obesity, diabetes, cancer, cardiovascular diseases, and autoimmune disorders often require long-term or rapid-response treatments, and injectables are a preferred
delivery method in these cases due to their fast-acting nature. As chronic diseases rise, especially in aging populations, the demand for affordable injectable
medications continues to grow



#### **ROVI's CDMO business across the Company's history**

<2019 2020-2023 2024 2026

#### **Transition**

- · ROVI founded in 1946
- CDMO services began in the mid-90s
- In 2019, ROVI's facilities dedicated to CDMO business were integrated to create ROIS business unit (ROVI Pharma Industrial Services S.A.U)
- c.800 employees in 2019

#### **Transformation**

- Agreement with Moderna to become the first CDMO in Europe to fill and finish mRNA Covid vaccines
- Extension to 2032 and expansion of the Moderna agreement to include other mRNA products
- FDA approval of all ROIS sites, enlarging the access to the US market
- Capacity expansion program across the manufacturing network to add new aseptic filling lines and direct to carton packaging lines

#### **Execution**

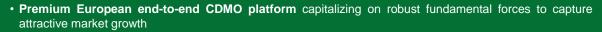
- Agreement with leading global pharma to manufacture up to 100m PFS per year for five years<sup>1</sup>
- Expanding customer base and large scale, creates global Tier I CDMO
- Legacy<sup>2</sup> business is highly diversified (>30 blue chip customers) and offers high visibility due to long-term contracts
- >1,500 employees that work as an integrated end-to-end network

#### Leadership

- Further capacity expansion and wider service offering (cartridges in addition to PFS and vias) with a total of 12 aseptic filling lines in 2026 expected to drive long term growth
- Global Tier I in injectable capacities
- New contracts expected to drive further portfolio diversification
- New assembly lines for pens and autoinjectors



#### **ROVI's CDMO business in a nutshell (1/2)**







- Extensive track record in high-quality sterile fill and finish (F&F) services with integrated capabilities across other areas
- Fully integrated offering with key points of differentiation from API services (drug substance) to commercial F&F

- Sustainable competitive advantage arising from immediate availability of large-scale, flexible capacity to address structural market shortages, coupled with a strategic end-to-end supply chain with EU footprint
- Global scale with 625-810m of PFS capacity, 140-180m of vials capacity and 85-110m of cartridges capacity. Significant flexibility to address current structural market shortages

#### **ROVI's CDMO business in a nutshell (2/2)**



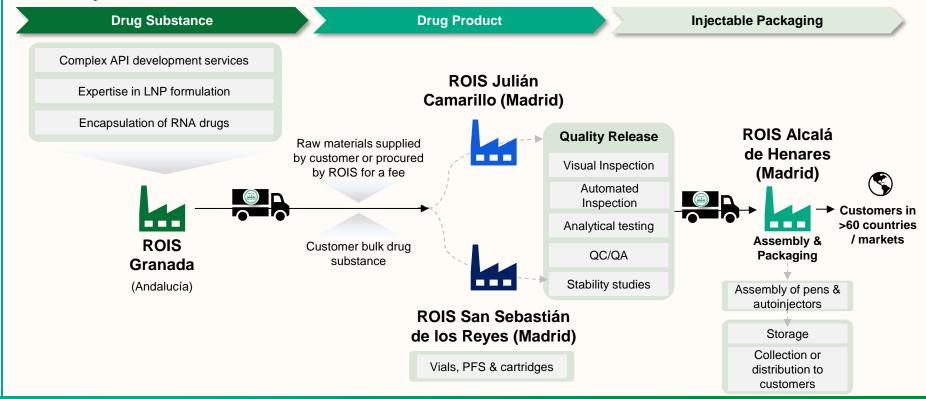


• Signing a new contract is a time-consuming process. It takes around 12-18 months from signature with a new customer to the production of commercial batches (these are expensive biological products with highly complex technology). However, this is also an advantage because once a customer has signed, it is considered a "customer for life"

• Investments on capacity expansions of €85m made by ROVI between 2020-2024 across 4 fully invested manufacturing plants in Spain (from DS¹ to DP²), approve by the FDA and compliant with GMP³ and Annex 1

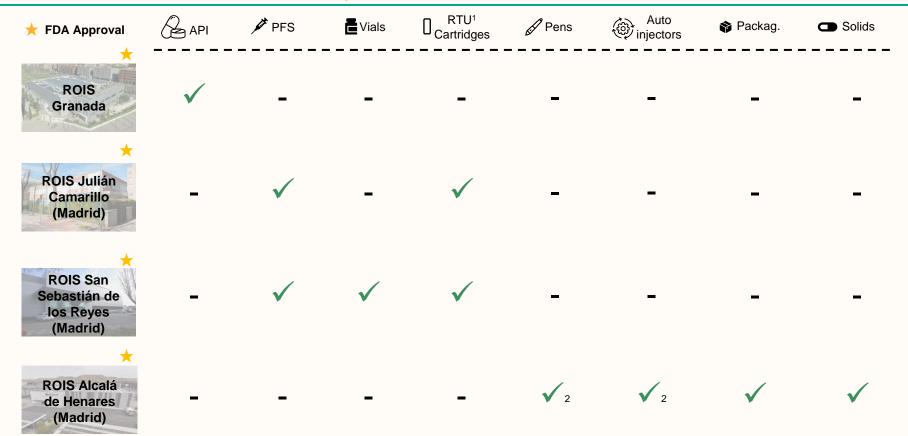
#### **ROIS** has an integrated CDMO end-to-end network

• ROVI aims to develop a one-stop shop for its CDMO business, providing customers with comprehensive, end-to-end solutions for drug development and manufacturing



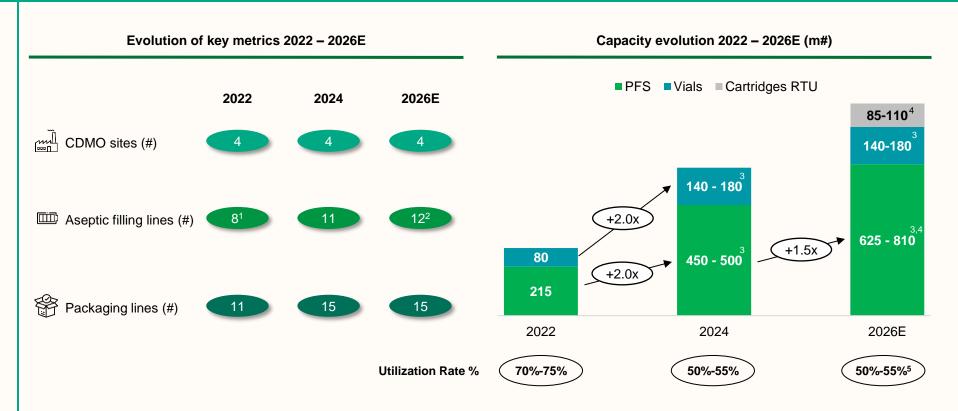


### 4 fully-invested manufacturing plants that allow ROIS to offer highvalue-added injectable and oral forms CDMO services





# Investment process across CDMO network to drive long-term growth and capture new opportunities (1/2)





## Investment process across CDMO network to drive long-term growth and capture new opportunities (2/2)

#### **CDMO** market imbalance

- There is an infra capacity vs demand, exacerbated in the short and medium term by recent market concentration
- Although additions are expected by the end of the decade, there will still be a shortfall in capacity

#### **Efficiency**

 ROIS expected to maximize capital efficiency, ensuring high returns on investment. Its strategic CAPEX allocation and deployment expected to drive sustainable growth and operational excellence

#### **Flexibility**

- ROIS can add new lines without opening new plants, which gives a great agility to address the imbalance between supply and demand in the future
- Demonstrated experience in agility for tech transfer processes

#### Competitiveness

 Cost efficiency: ability to leverage structural advantages in the Spanish labour market including the availability of skilled labour, to offer competitive global pricing

#### **Track record**

- High value-added CDMO business with more than 30 years of experience with state-of-the-art facilities to meet surging demand
- Facilities approved by the most important regulatory bodies (FDA, ANVISA, EMA, PMDA)

#### Other

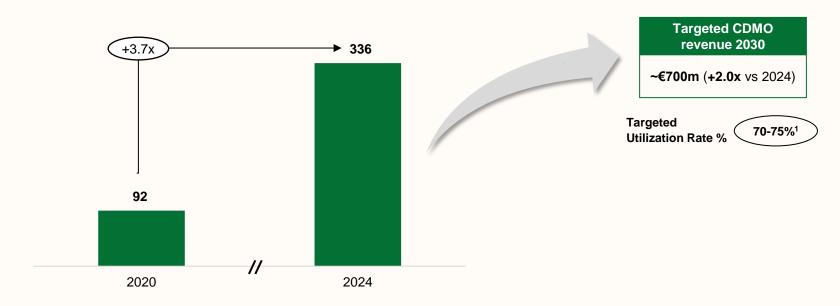
 Due to geopolitics and high strategic value of these products, we expected that large pharmas will not risk their supply chains and would rather prefer to be sourced by a large wellestablished CDMO





#### **CDMO** revenues evolution and 2030 guidance

#### CDMO revenue evolution 2020-2030E (€m)



Our focus is to become one of the top 1 CDMO worldwide in high value added injectables in PFS, cartridges and vials through current and future available capacity at our 4 state-of-the-art sites

### **Section III - Specialty Pharma**

Miguel Ángel Castillo
International and Business Development Director



#### Well-balanced European specialty pharma company with diversified growth drivers



#### **Vertically integrated LMWH franchise**

- Developed and successfully launched proprietary bemiparin, the 1<sup>st</sup> leading LMWH in Spain by market share
- Developed enoxaparin biosimilar, one of the 1<sup>st</sup> to reach the market in Europe
- Well-established pan-European commercial network

#### Risperidone ISM® (Okedi®)

- · Immediate and sustained therapeutic levels
- Simplified administration: simplified treatment regime by reducing dosing frequency thanks to its ISM® technology
- Proven efficacy and safety: significant improvement in schizophrenia patients

#### **Leading Specialty Pharma Franchise**

- · Strong market leadership in Spain
- Partner of choice for the in-licensing of products for leading pharma global players
- Specialty Pharma business with ~200 reps and more than 20 in-licensed products over 15 years
- ~120 employees in subsidiaries

#### **Growth drivers**

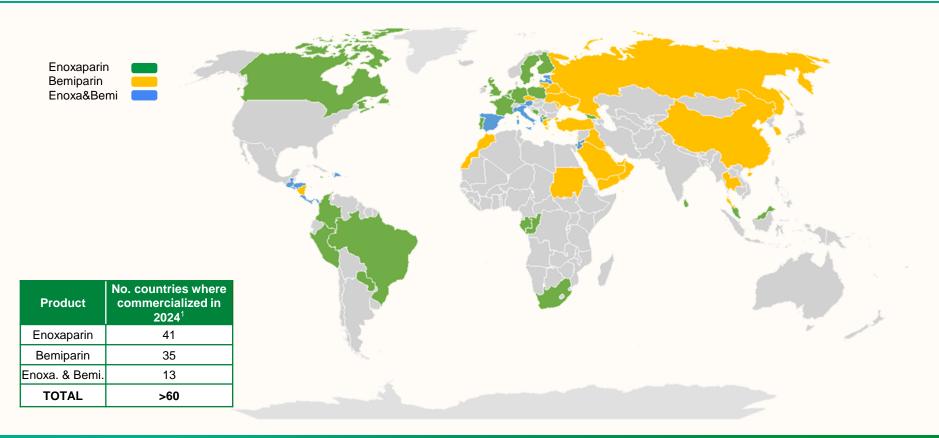
- Continued branded LMWH market share through bemiparin in Spain and abroad
- Vertically integrated, well positioned to benefit from significant economies of scale
- ROVI expects that Okedi® will reach €100m €200m revenues in future years
- Launch expected in **new international countries**
- Development of a 3-month long-acting injectable formula to increase product adherence
- Leverage leadership position in Spain and Europe
- Maintain strong sales performance and operational excellence
- New in-licensing opportunities with global players in specialty therapeutic areas



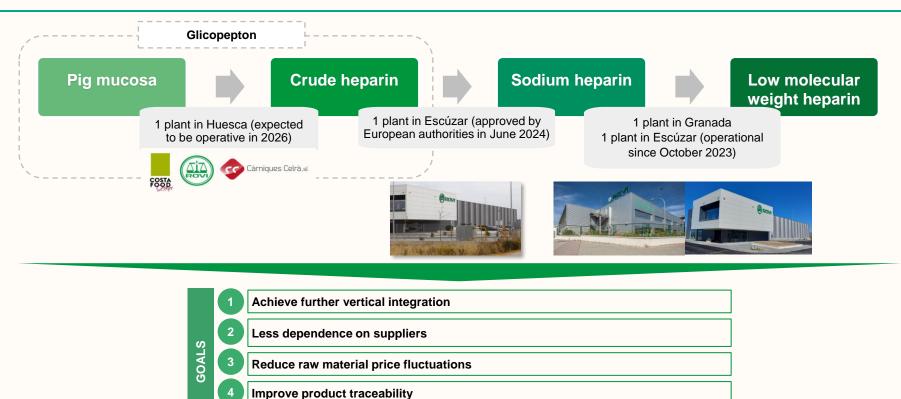
**Low Molecular Weight Heparins (LMWH)** 



### Bemiparin and Enoxaparin biosimilar international presence



#### Fully vertically integrated in the heparin value chain



Improve gross margin



#### Bemiparin 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 is a Low Molecular Weight Heparin (LMWH)
  - #1 market position in Spain with a c.31%1 share and presence in more than 60 countries
  - Only 2<sup>nd</sup> generation LMWH; clinically differentiated from other competitors
- Vertically integrated structure with its own LMWH manufacturing plant

Bemiparin is the LMWH with the **highest anti Xa/lla ratio<sup>2</sup>**, which may lead to a higher antithrombotic activity without increasing the bleeding risk



More convenient treatment: 1 daily injection needed in comparison to competitors treatment, which requires 2<sup>3</sup> shots

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

#### ROVI's Enoxaparin was one of the first enoxaparin biosimilars launched in Europe

#### International approach to maximize value of the product

Marketed directly in Germany, UK, Italy, France, Austria, Portugal and Spain Approved in c.60 countries across Europe and the rest of the world

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



...which account for c.75% of the European market<sup>1</sup>

#### **Commercial strategy through partners**

- Continue expansion in other markets with strong growth potential through **out-licensing agreements**: 81 territories already signed
- Current strategy: currently finalizing contracts with non-profitable partners to sign agreements with new, more profitable partners and target to increase revenue

Agreements with international partners



AVANSOR PHARMA OY

SANDOZ A Novartis





Norameda

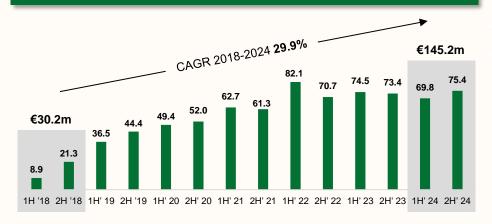








#### Enoxaparin biosimilar sales ramp-up (€m)



#### 2025<sup>2</sup>

- Romania
- Sweden
- Norway
- Denmark

#### 2026<sup>2</sup>

- Greece
  - Libya<sup>3</sup>
    - Iraq<sup>3</sup>

#### 2027<sup>2</sup>

 MENA region<sup>3</sup> (Algeria, Bahrain, Egypt, Iran, Jordan, Kuwait, Lebanon, Morocco, Oman, Qatar, Saudi Arabia, Syria, Tunisia, United Arab Emirates

and Yemen)

- QuintilesIMS, 20
- 2. Most important markets to be launched

Re-launch with new partners

### Okedi<sup>®</sup>



## Risperidone ISM® (Okedi®): fast onset long-acting injectable of risperidone with balanced efficacy and tolerability

#### **Schizophrenia Market**

- · Chronic and progressive disease
- The World Health Organization estimates it affects 24Mn people worldwide with a relatively high lifetime prevalence<sup>1</sup>
- · Strict compliance needed to avoid relapses
- LAIs (Long Acting Injectable) are becoming the gold standard for treatment, due to improved adherence and effectiveness



#### **European market**

Second largest antipsychotic LAI market



- CAGR of 7.4%<sup>4</sup>
- Relatively low competition due to few drug options

#### Superior value proposition when compared to alternatives

Fully supervised monthly injection	<ul> <li>Ongoing monitoring through regular interactions between patient and medical staff</li> <li>Reduces the risk of accidental or deliberate overdose or non-adherence to treatment</li> </ul>
Clinical convenience of risperidone	<ul> <li>Proven efficacy and safety of risperidone<sup>2</sup></li> <li>Well-known drug among psychiatrists for the treatment of schizophrenia (#2 molecule in oral form)</li> </ul>
Therapeutic plasma levels from 2 hours post dose aimed at PANSS reduction at day 8	<ul> <li>Fast onset of action to achieve therapeutic plasma levels from the beginning</li> <li>Achieving significant PANSS³ reduction in unstable schizophrenia patients at day 8</li> <li>No need to supplement with oral medication or loading dose</li> <li>Effective and well-tolerated strategy for patients with schizophrenia that have been admitted due to a relapse and need a rapid control</li> </ul>
Long-term efficacy and tolerability aiming to improve the patients' functioning and quality of life	<ul> <li>Low overall relapse (10.7%) and rehospitalization (4.2%) rates after 12 months demonstrating its extended effect in controlling symptoms in schizophrenia disease</li> <li>Low discontinuation rate of Okedi® (3.3%) due to treatment-related adverse events</li> </ul>

### Okedi® offers superior characteristics vs competitors in Europe

	RISPERDAL CONSTA® (Risperidone)	INVEGA SUSTENNA®/ XEPLION® (Paliperidone)	INVEGA TRINZA® / TREVICTA® (Paliperidone)	INVEGA HAFYERA®/ BYANNLI® (Paliperidone)	ABILIFY MAINTENA® (Aripiprazole)	ABILIFY MAINTENA® 720/960 mg (Aripiprazole)	OKEDI® (Risperidone)
Once Monthly Administration <sup>2</sup>	×	<b>√</b>	Every 3 months	Every 6 months	<b>√</b>	Every 2 months	<b>√</b> 8-10
No Oral Supplementation / Loading dose <sup>2</sup>	×	×	After ≥4 months Inv. Sustenna/ Xeplion	After ≥4 months Inv. Sustenna/ Xeplion or ≥3 months Trevicta	×	×	<b>√</b> 8-10
Therapeutic Levels <sup>1</sup> within First 2 Hours <sup>2</sup>	×	×	NA: maintenance treatment	NA: maintenance treatment	×	×	<b>√</b> 8,9
Currently Marketed in Europe <sup>3, 4</sup>	<b>√</b>	<b>√</b>	<b>✓</b>	<b>√</b>	<b>√</b>	<b>✓</b>	✓
Stability at Room Temperature <sup>2</sup>	×	✓	✓	<b>√</b>	<b>√</b>	<b>√</b>	✓
PANSS Reduction from Day 8 <sup>11</sup>	<b>X</b> <sup>5</sup>	<b>X</b> 6	NA: maintenance treatment	NA: maintenance treatment	<b>x</b> <sup>7</sup>	No data on acute patients	<b>√</b> 10



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



 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

Sustained therapeutic levels from DAY 1

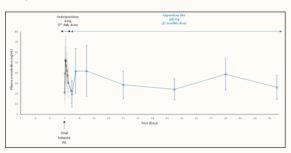
Without the need of oral supplementation or loading doses

High efficacy of Okedi® balanced with outstanding tolerability in the short and long-term treatment of Schizophrenia

#### – Pivotal clinical studies

#### **Boris Study**

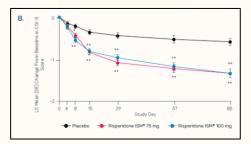
 Improved PK/PD profile, with optional D2 receptor occupancy from Day 1, correlated with high efficacy and minimal adverse events



#### Prisma-3 short-term

OKEDI® achieves significant symptom reduction as early as:

### DAY 8



#### Prisma-3 long-term

#### OKEDI® has a low overall relapse rate of

10.7% (%) (95% Ct. 6.9% to 15.6%) in 12 months<sup>4</sup>

which demonstrates its extended effect in controlling psychotic symptoms in Schizophrenia disease<sup>4</sup>

OKEDI® presents a low rate of discontinuation caused by treatmentrelated TEAEs after 12 months:

**3.3**%

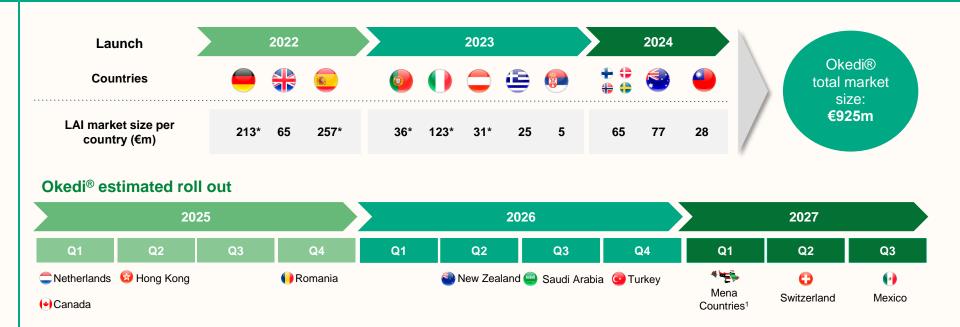
(7 out of 215 patients)

Only 9 out of 215 patients required re-hospitalization





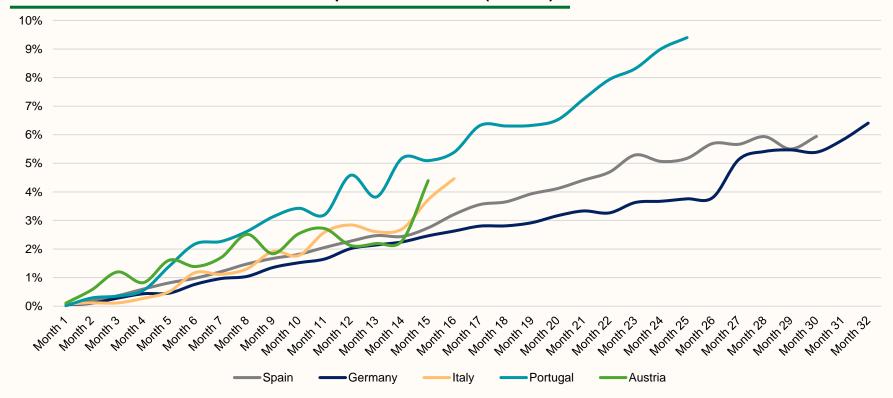
#### Okedi® launch plan in Europe and the rest of the world



ROVI expects Okedi® to reach potential global sales of between €100m and €200m in upcoming years

#### Schizophrenia LAI market & Okedi® market share evolution

#### Okedi® % market share evolution in schizophrenia LAI market (in value)





# ROVI's market leadership in Spain positions the Company as the partner of choice for global pharma players

Presence in the market since 1946 Well-known proprietary portfolio driving strong leadership position Franchise focused business: 16 proprietary and 20 in-licensed products Multiple Strategic Alliances **b** NOVARTIS \*\*astellas - ORGANON BRACCO **MSD** One of the largest specialty pharma sales forces with c. 200 reps Strong knowledge of the regulatory framework





## In 7 years ROVI has successfully internationalised with subsidiaries in 6 countries and more than 120 employees

#### Germany

#### Headcount: 54

- Enoxaparin
- Risperidone ISM®
- Falithrom

#### Italy

#### Headcount: 44

- Enoxaparin
- Risperidone ISM®
- Normoparin
- Bemiparin

### Uni

#### **United Kingdom**

#### **Headcount: 3**

- Enoxaparin
- Risperidone ISM®
- Heparin



In 2024, ROVI sold €97m through its international subsidiaries

#### Portugal

#### **Headcount: 15**

- Risperidone ISM®
- Iomeron
- Enoxaparin
- Other

### -

#### **France**

#### Headcount: 4

- Enoxaparin
- Polaramine
- Enoxaparin

#### **Austria**

#### Headcount: 4

- Enoxaparin
- Risperidone ISM®
- Bemiparin



## **Section IV - Update on the R&D Strategy**

**Ibon Gutierro**Corporate R&D Director



# Quarterly Letrozole with Superior Estrogen Suppression (Letrozole SIE)



#### Letrozole SIE: a quarterly formulation of Letrozole with Superior Inhibition of Estrogens

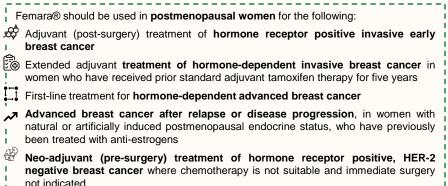
A quarterly injectable aromatase inhibitor for the **treatment of hormone receptor positive breast cancer** that provides superior estrogen suppression compared to Femara®

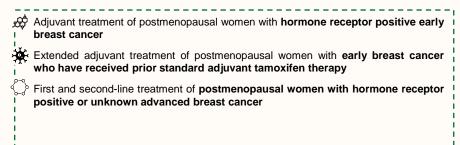


intends to achieve the same indications as Femara® in the label:











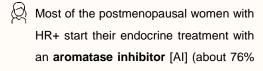
#### Most of breast cancers are HR+ and aromatase inhibitors remain as primary treatment

Subtypes			
Intrinsic subtype	Hormone receptor status	HER2	Distribution (%)
Luminal A	Positive	Negative	70
Luminal B	Positive	Positive	9
HER2- enriched	Negative	Positive	4
Triple negative	Negative	Negative	10
Unknown	Unknown	Unknown	7

# 66 Localized Regional Distant Unkown extension extension

Stage at diagnosis (%)

#### Use of endocrine therapy



start an AI)1

In early breast cancer, patients starting treatment with an AI are expected to remain in the treatment for 3-5 years or longer

Letrozole was the most commonly aromatase inhibitor used in both metastatic (76.5%) and non-metastatic (52.2%) settings in 5 large European Countries in a real-world study <sup>2</sup>

#### Phase I results confirm Letrozole SIE provides superior estrogen suppression



Quarterly 225 mg injections of Letrozole SIE provide superior inhibition of estrogens compared to daily 2.5 mg Femara® in healthy female postmenopausal volunteers



Current readout of tolerability results on a single 225 mg injection of Letrozole SIE show a very good profile, in particular in arthralgias



Letrozole SIE also **shows fast onset of action and provides sustained plasma levels**, which are linear with the dose, and therefore allows to make predictions on pK and efficacy in pivotal clinical trials

Positive results on phase I allows ROVI to go to efficacy clinical trial

#### Letrozole SIE efficacy clinical trial

ROVI will conduct an efficacy clinical trial of Letrozole SIE vs Femara® in female postmenopausal women with two objectives:

- Verify that superior estrogen suppression achieved with Letrozole SIE provides a significant impact in clinical endpoints like Progression-Free Survival
- Evidence improved tolerability profile expected from steady letrozole plasma levels and sustained estrogen suppression



#### Phase III Clinical Trial program to start in Q4 2025 for Quarterly Letrozole SIE

Regulatory strategy for a LAI of Letrozole SIE is identical to Okedi® and involves two clinical trials:



#### A Phase III Efficacy Clinical Trial

- Study population: HR+ HER2 female patients with advanced breast cancer
- Treatment with CDK 4/6 inhibitors is indicated in coadministration with aromatase inhibitors in this population with a significant cost



#### A PK/Bioavailability Study

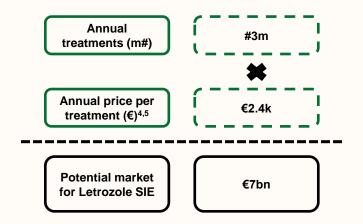
 To compare exposure of quarterly 225 mg injections of Letrozole SIE vs daily 2.5 mg Femara® oral administrations in steady state



#### Letrozole SIE: approach to ROVI's potential market

#### Potential market for Letrozole SIE<sup>1</sup>

- There are 1.126 m daily units of the two molecules (letrozole and anastrazole) that, converted to yearly treatment, bring c.3m potential yearly treatments for LAIs² market
- ROVI aims to reach a significant portion of the market



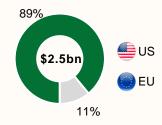
Price includes a total of 4 shots.

#### Approach to prostate cancer LAIs market

- Breast cancer can be **compared to prostate cancer**, as it has a similar behavior 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>2</sup> have a **strong presence in this market** and have become the **gold** standard for treatments

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>3</sup> Prostate Cancer Market



LAIs and Orals in value



MAT Q1 2020

<sup>4.</sup> The annual price is based on the average price of LAIs for schizophrenia in Europe. This is therefore a conservative scenario

IOVIA-Midae MAT O3 2019

**Quarterly Risperidone (Risperidone QUAR)** 



#### **Quarterly Risperidone (Risperidone QUAR)**

A quarterly injectable Risperidone for the treatment of Schizophrenia that provides plasma levels in the therapeutic range from day 1 without the need of oral doses, previous injections of monthly Risperidone formulation or additional loading doses



intends to achieve the same indication as Okedi® in the label:





Treatment of schizophrenia in adults for whom tolerability and effectiveness have been established with oral risperidone



## Positive readout from Phase I with Quarterly Risperidone (QUAR) allows progression to Phase III clinical trial

Expected clinical trial package is similar to Okedi® and will require two additional clinical trials:



#### A Phase III Efficacy Clinical Trial

- Design pending to be discussed with regulatory authorities
- ROVI plans to conduct a clinical trial vs oral Risperdal® in patients with moderate to severe symptoms



#### A PK/Bioavailability Study

- To compare exposure of quarterly 300 mg injections of Risperidone QUAR vs daily 4 mg Risperdal® oral administrations in steady state
- Clinical trials are expected to start in Q4 2025



# Creation of Terafront Pharmatech for R&D of Advanced Therapies



#### **Creation of Terafront Pharmatech for the R&D of advanced therapies**



- On March 2024, an agreement was reached between ROVI, Insud Pharma and Innvierte (investment company of CDTI Centro para el Desarrollo Tecnológico Industrial EPE) to create **Terafront Pharmatech**, a **platform engaged in the research and development of advanced therapies**
- This agreement falls within the framework of the Vanguard Health Strategic Project for Economic Recovery and Transformation (PERTE), promoted by the Spanish Government
- The goal is to favour the deployment of the technical and industrial capacities necessary to generate a high-performance healthcare system intended to protect health by providing an immediate and flexible response to healthcare challenges and favoring sustainability



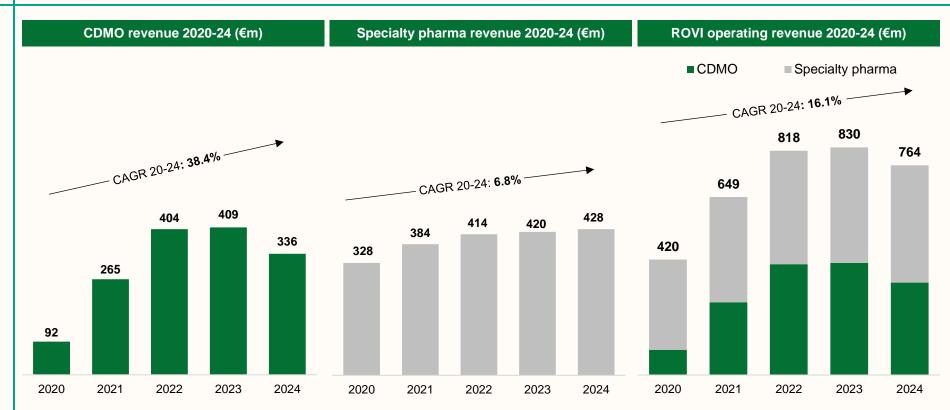


### **Section V – Financial Results**

Javier López-Belmonte
Deputy Chairman and CFO



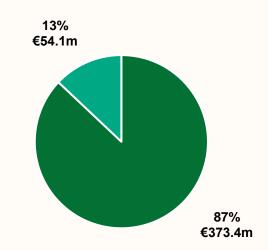
#### Sound financial policy supported by strong track record





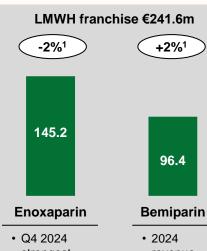
#### **Specialty pharma revenues overview**

#### Specialty pharma revenues breakdown (%)



- Prescription products
- Contract agents, hospital products and other

#### Main prescription products 2024 performance (€m)



- strongest quarter of the year
- Approved in c.60 countries
- revenue
  increased by
  higher sales
  in China,
  Greece and
  Turkey





### Neparvis®

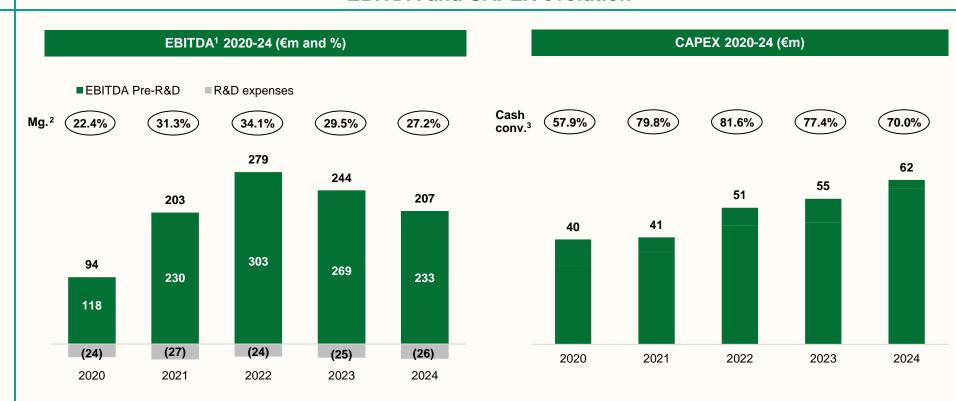
51.4

- Specialty product from Novartis, launched in Spain in Dec-16
- Indicated for the treatment of chronic heart failure

#### 28.8 Okedi®

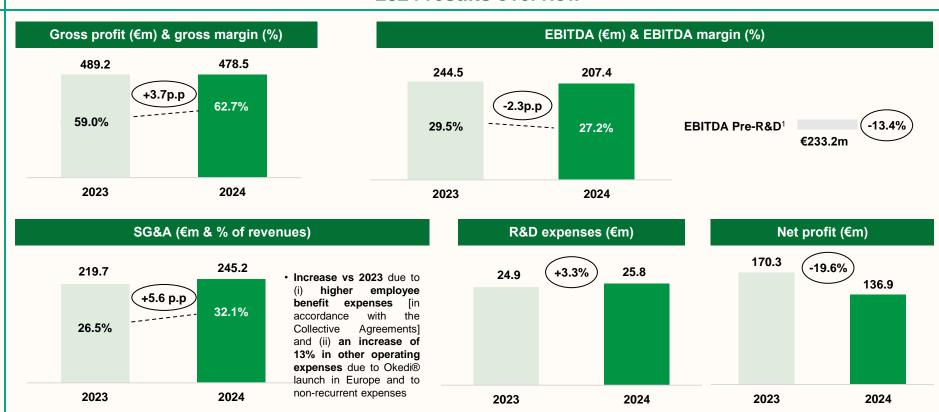
- Risperidone ISM®, LAI of risperidone for schizophrenia
- Marketed in Europe, and approved in Australia, Taiwan & Canada

#### **EBITDA and CAPEX evolution**





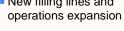
#### 2024 results overview





#### CAPEX, cash flow and debt structure





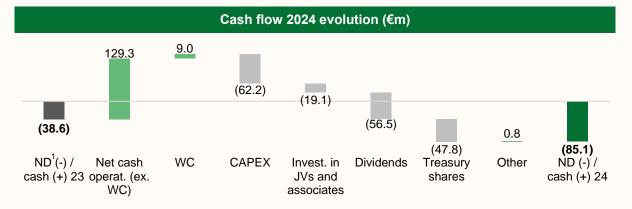
Glicopepton

#### Debt 2024 breakdown by source

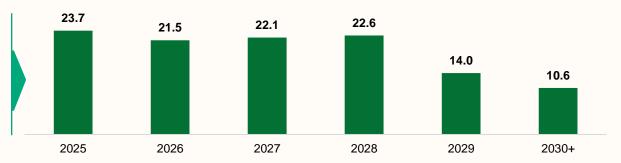
57%

- Financial liabilities for leases
- Debt with public administration
- Bank borrowings





#### Future debt repayments (€m)



## Our capital allocation mixes shareholder returns, business expansion and innovation



#### Shareholder remuneration

- Attractive and recurring dividend policy (35% of the consolidated net profit of 2024)
- Completion of several share buyback programs:
  - €125m Nov-21 to Feb-22
  - €46m Feb-22 to Mar-22

>€300m

- €130m Jul-23 to Jul-24
- Committed to consider and propose future dividend payout



#### Investments in production capacity

- ROVI has invested >€180m CAPEX in its 8 facilities across the 2020-2024 period
- €60m estimated investment in **filling line in** San Sebastian de los Reyes in 2026
- Enhancing capacity to meet growing demand





#### **Balance sheet strength**

- Strong balance sheet position due to low debt position
- Net debt of €85.1m as of 2024 (0.4x ND / EBITDA)
- Conservative balance sheet management



#### **R&D** investments

- Long-acting sustained-release injectable proprietary technology
- Development of two Phase I formulas (Letrozole SIE and quarterly risperidone)
- Enables long-term value creation



#### Outlook 2025



#### 2025 operating revenue growth rate

Decrease by a mid-single-digit percentage vs 2024

#### The key growth expected levers in 2025:

СДМО	Specialty Pharma	
New business to be acquired	Launch and marketing of Risperidone ISM® in new countries	
Agreement with Moderna	LMWH franchise	
Capacity increase	<ul> <li>Existing portfolio of specialty pharmaceuticals</li> <li>New product distribution licenses</li> </ul>	
New formats (cartridges)		
	New diagnosis solutions powered by artificial intelligence	



#### Long-term targeted guidance for 2030

**Operating revenue 2024** Targeted operating revenue 2030 €763.7m 1.5x - 1.8x vs 2024CDMO revenue 2024 **Targeted CDMO revenue 2030** €336.2m ~€700m (+2x vs 2024) Specialty pharma revenue 2024 Targeted specialty pharma revenue 2030 €427.5m Low single digit growth vs 2024 EBITDA "pre-R&D" 2024 Targeted EBITDA "pre-R&D" 2030 €233.2m 2.5x - 2.8x vs 2024 R&D expense 2024 Annual average R&D expenses 2025-2030 €25.8m ~€40-60m

Creating value for investors through our next phase of growth



## Q&A



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