



TO THE NATIONAL SECURITIES MARKET COMMISSION (CNMV)

Madrid, 24 June 2024

INSIDE INFORMATION

In compliance with the reporting requirements provided for in article 226 of Law 6/2023, of 17 March, on Securities Markets and Investment Services, Laboratorios Farmacéuticos Rovi, S.A. ("ROVI") hereby submits and publishes the attached press release in relation to information and guidance on its strategic plan for expansion and growth that it is planned to announce in the course of the Ordinary General Shareholders' Meeting to be held today. The press release will be distributed today and may be consulted through the company's website.

I remain

Yours faithfully,

Juan López-Belmonte Encina
Chairman and Chief Executive Officer
Laboratorios Farmacéuticos ROVI, S.A.

Disclaimer: Forward-looking statements

This press release contains forward-looking statements. Such forward looking statements involve known and unknown risks, uncertainties and other factors which might cause the actual

ROVI – Business information and guidance (General Shareholders' Meeting 2024)

results, financial performance or achievements of ROVI, or its industrial results, to be materially different from any future results, performance, or achievements expressed or implied by such forward looking statements. The information contained in this press release represents ROVI's expectations and beliefs as of the date hereof. ROVI clarifies that subsequent events and developments may cause these expectations and beliefs to change. However, while ROVI may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing ROVI's expectations or beliefs as of any date subsequent to the date of this press release.



ROVI forecasts potential Risperidone ISM[®] sales of between 200 and 300 million euros globally in upcoming years

- ✓ The company will be submitting for the approval of the Ordinary General Shareholders' Meeting the annual accounts for the financial year 2023, which show operating revenue that rose 1% to 829.5 million euros in 2023, mainly due to the CDMO business, which grew by 1%, rising to 409.3 million euros, and the specialty pharmaceutical business, whose sales were 1% up on the preceding year, totalling 420.2 million euros.
- ✓ In September 2023, the U.S. Food and Drug Administration (FDA) approved ROVI's injectables manufacturing plants in Madrid, San Sebastián de los Reyes and Alcalá de Henares for the fill-and-finish of syringes with the Moderna mRNA COVID-19 vaccine. ROVI also expects to produce other Moderna vaccines to be marketed in the United States from now onwards. Furthermore, in January 2024, the FDA approved ROVI's active substance manufacturing plant in Granada. This approval authorises Moderna to market the vaccine manufactured by ROVI in the United States.
- ✓ Positive evolution of Okedi[®] (Risperidone ISM[®]), sales of which rose 42% in the fourth quarter of 2023 in comparison with the third quarter of the year.
- ✓ In the first quarter of 2024, the FDA approved the marketing of Risvan[®] (Risperidone ISM[®]) in the United States to treat schizophrenia in adults. In addition, the company obtained marketing approval for Okedi[®] in Canada and Australia.
- ✓ In July 2023, ROVI obtained the best rating in the Sustainalytics ESG risk ranking for the second consecutive year.

Madrid, 24 June 2024. Today, Laboratorios Farmacéuticos Rovi, S.A. will be holding its Ordinary General Shareholders' Meeting, at which it will present an evaluation of the financial year 2023 and its plan for the launch of Risperidone ISM® for Europe and the rest of the world, with which it hopes to achieve potential sales of between 200 and 300 million euros globally in upcoming years.

The Meeting, with quorum on the first call, is expected to pass all the motions on the Agenda that are submitted for its approval, including, among others, the motion to approve the individual and consolidated annual accounts of the company and the respective management reports for the year ended 31 December 2023, as well as the corporate management during the last financial year.

The company will present its shareholders with consolidated operating revenue of 829.6 million euros in 2023, representing 1% growth on 2022, demonstrating the resilience of its business in the first year of a new endemic scenario.

CDMO sales rose 1% in 2023 compared with the preceding year 2022, totalling 409.3 million euros in 2023, mainly due to: (i) the booking of the revenue related to production of the COVID-19 vaccine; (ii) the booking of the revenue related to the activities carried out to prepare the plant to produce the vaccine under the agreement with Moderna; and (iii) the reorientation of the CDMO strategy towards products with a higher value-added.

The specialty pharmaceutical business sales increased 1% in 2023 compared to 2022, totalling 420.2 million euros, mainly driven by Okedi®, Neparvis® and Orvatez®.

Sales of Okedi®, ROVI'S first product based on its vanguard drug delivery technology, ISM®, indicated for the treatment schizophrenia in adults for whom tolerability and effectiveness have been established with oral risperidone, were 14.4 million euros in 2023. These sales increased 42% in the fourth quarter of 2023 in comparison with the third quarter of the year. In 2022, the product was launched in Germany, the United Kingdom and Spain and, in 2023, in Portugal, Italy, Austria, Greece and Serbia. It is important to highlight the fact that, in the first quarter of 2024, the product was approved in the United States (under the trademark Risvan®), Canada and

Australia.

Sales of Neparvis® grew 16% to 45.5 million euros, compared to 39.1 million euros in 2022. This is a prescription product from Novartis indicated for the treatment of adult patients with symptomatic chronic heart failure and reduced ejection fraction, which ROVI has been distributing in Spain since December 2016.

Sales of Orvatez®, a prescription product from the company Organon & Co. (“Organon”) indicated as adjunctive therapy to diet in patients with hypercholesterolemia, increased 8% to 26.5 million euros in 2023, compared with the 24.5 million euros of 2022.

Regarding the heparin franchise, ROVI aspires to become a global leader in the low-molecular-weight heparin (“LMWH”) field. The commitment to this franchise can be seen with the inauguration, in the fourth quarter of 2023, of a new production plant for the active substance of heparins, and the addition, in the second quarter of 2024, of a new sodium heparin facility, both of which are in Escúzar (Granada). Likewise, the company continues with its commitment to the vertical integration of the heparin supply chain by investing in the creation of the first national structure for the self-supply of low-molecular-weight heparins. ROVI expects this investment to contribute to an increase in the future margins of the heparin franchise and believes that the plant is likely to come into operation in 2026. Additionally, LMWH raw material prices dropped 35% in 2023 compared with 2022. This decrease is expected to accelerate during 2024 and to have a positive impact on the group’s gross margin from 2025 onwards.

In 2023, LMWH sales decreased 6% on 2022, dropping to 242.1 million euros in 2023, mainly as a result of the difference between the increase in partners’ orders related to COVID-19 treatment in 2022 and the lower volume of orders from partners in 2023, since they had held higher stocks of the products since 2022.

EBITDA decreased 12% on 2022 to 244.5 million euros in 2023, reflecting a drop of 4.6 percentage points in the EBITDA margin, which was 29.5% in 2023, compared to 34.1% in 2022. Net profit totalled 170.3 million euros in 2023, showing a 15% decrease on the 2022 figure, which had been 199.7 million euros.

Research and development (R&D) expenses increased 4% to 24.9 million euros in 2023. These R&D expenses relate mainly to (i) developing the phase 1 of Letrozole LEBE and (ii) developing the phase I of the new formulation of Risperidone ISM® for a three-monthly injection.

Sales, overhead and administration expenses rose 2% to 219.7 million euros in 2023, mainly resulting from the increase in expenses related to the launch of Okedi® in Europe. Notwithstanding, other operating expenses (excluding R&D and employee benefit expenses) decreased 11% to 106.4 million euros in 2023, due to an efficient cost containment policy.

Consolidation and international expansion plan for Risperidone ISM® in Europe and the rest of the world

The European Commission authorised the marketing of Okedi® (Risperidone ISM®) in February 2022. Since then, the product has been marketed in a number of European countries. In 2022, Okedi® was launched in Germany, the United Kingdom and Spain and, in 2023, in Portugal, Italy, Austria, Greece and Serbia. These launches have consolidated ROVI's internationalisation strategy as one of its pillars for future growth.

Furthermore, in March 2024, the FDA approved the marketing of Risvan® (Risperidone ISM®) for the treatment of schizophrenia in adults. Additionally, the FDA has required, as a postmarketing requirement following normal market practice, that a pharmacokinetic study be conducted to evaluate exposure to Risvan® similar to the daily administration of 6mg of oral risperidone. The protocol for the clinical study will be previously reviewed and agreed with the FDA and the final report on the study will be submitted before July 2026. This additional study does not affect either the approval or the marketing of Risvan®. Likewise, ROVI remains committed to the company's international expansion outside Europe as a result of the approval of this product in Canada and Australia, also in 2024.

ROVI expects that, given its differential characteristics, Risperidone ISM® will reach potential sales of between 200 and 300 million euros globally in upcoming years and will become a significant player worldwide in the field of long-acting injectables to treat schizophrenia.

Expansion of ROVI's industrial presence

In June 2024, ROVI has obtained the European authorities' approval for the commencement of commercial activity at its new sodium heparin plant in Escúzar (Granada). Thus, ROVI is positioned as one of the largest pharmaceutical industrial groups in Spain, with eight fully-integrated plants and a ninth under construction.

The Group has five plants to manufacture its own products and three for contract manufacturing. In Andalusia, it has three plants for its own manufacturing: two engaged in producing the active substance of low-molecular-weight heparins, in Granada and Escúzar, and the new plant that will be producing sodium heparin. ROVI is, therefore, prepared for production of a medicine like sodium heparin, which is classified as essential by the World Health Organisation and is, moreover, among the medicines included in the European Union's Critical Medicine Alliance, in which ROVI participates.

Additionally, ROVI has two plants in Madrid engaged in the production of medicines based on its ISM[®] technology, in which 35.6 million euros has been invested in the last five years: at the first plant, the company produces Risperidone ISM[®], while the second is used to manufacture products under development that use highly potent active ingredients.

Furthermore, ROVI has three plants engaged in contract manufacturing: in particular, two injectables manufacturing plants, located in San Sebastián de los Reyes and Madrid, and a third in Alcalá de Henares, which is engaged in producing solid oral forms and is a packaging centre of excellence.

Likewise, ROVI remains committed to the vertical integration of its value chain in order to achieve strategic autonomy in its medicine manufacturing process. In this respect, ROVI is making significant investments in the construction of a new plant in Huesca, which will transform pig mucosa into crude heparin and is considered likely to come into operation in 2026.

Clinical development of a new three-monthly formulation of Letrozole LEBE

In April 2023, ROVI commenced the clinical development of a new three-monthly formulation

of letrozole, Letrozole LEBE, instead of the initially-planned annual formulation. With this new formulation, bioequivalence with the daily doses of Femara® 2.5 mg could be achieved, allowing shorter research times and a reduction in the amount of the investment required in comparison with the previous annual formulation. At present, ROVI is conducting the phase I clinical trial in Europe (LEILA-1 study) to evaluate the pharmacokinetics, safety and tolerability of Letrozole LEBE in healthy post-menopausal women. The trial began in July 2023.

Commitment to research and development through a public-private vehicle

In March 2024, ROVI informed of the creation, together with Insud Pharma, S.L. and Invierte Economía Sostenible SICC, SME, S.A. (investment company of Centro para el Desarrollo Tecnológico Industrial EPE – CDTI), of Terafront Farmatech, a limited company engaged in the research and development of advanced therapies. This partnership strengthens ROVI's commitment to innovation by expanding its future range of R&D product beyond its ISM® technology.

Forecast growth

Regarding guidance for 2024, ROVI expects its operating revenue to decrease by a mid-single-digit percentage, although this guidance considers certain factors that, although they could be relevant and affect these estimates, are difficult to specify at the present time, such as, for example, the COVID-19 vaccination campaign, since there was a saturation of the National Health Systems partly derived from the low vaccination rates in the 2023 campaign, which could favour a vaccination campaign with higher rates in 2024. However, at present, it is impossible to anticipate how the demand and production will evolve in 2024 for the vaccination campaign.

Mr Juan López-Belmonte Encina has stated: *“2023 was a year of transition, the first year of a new endemic scenario. In this context, we were able to continue growing sustainably, obtaining truly satisfactory results. We are in a growth phase focused on reinforcing the company's internationalisation through Risperidone ISM®, a drug with extraordinary potential thanks to the innovative ISM® technology, which we forecast will reach potential sales of between 200 and 300 million euros globally in upcoming years. Our commitment to innovation, sustainable growth*

and the continuous improvement of our technological and industrial capacities positions us as a global player in the pharmaceutical industry. We are prepared to tackle the challenges and take advantage of any opportunities that arise, always with the goal of contributing to a better future for society overall.”

About ROVI

ROVI is a pan-European biopharmaceutical company specialising and engaging in the research, development, contract manufacturing and licensing of small molecules and biological specialties. The company, in a continuous expansion process, has subsidiaries in Portugal, Germany, the United Kingdom, Italy, France and Poland and has a diversified marketing portfolio of over 40 products, among which its flagship product, bemiparin, now present in more than 60 countries all over the world, should be highlighted. Likewise, ROVI markets its enoxaparin biosimilar, developed in-house, in Europe and this product is already present in 40 countries. ROVI is continuing to develop the ISM[®] technology platform, a leading-edge line of research in the field of prolonged drug release with proven advantages. For more information, please visit www.rovi.es.

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