

# Laboratorios Farmacéuticos ROVI

DORIA update

Pharma & biotech

DORIA Phase III trial hits primary endpoint

Laboratorios Farmacéuticos ROVI (ROVI) has announced top-line data from the pivotal Phase III PRISMA-3 trial evaluating DORIA (ISM risperidone) in schizophrenia. DORIA achieved the primary endpoint of a statistically significant reduction (p<0.0001) in PANSS score at week 12 (both 75mg and 100mg doses once-monthly intra-muscular injection). These data not only validate DORIA but also the ISM technology platform developed by ROVI. ROVI plans to file the US NDA in H219. We forecast a potential launch in 2021 in both the US and EU and peak sales opportunities of US\$411m (US and EU) in 2027. DORIA has the potential to be highly value enhancing to ROVI's long-term profit growth. This is in line with our expectations and we leave our forecasts and valuation unchanged at €1.23bn or €21.9 per share.

Year end	Revenue* (€m)	PBT** (€m)	EPS** (€)	DPS (€)	P/E (x)	Yield (%)
12/17	277.4	20.3	0.40	0.12	43.1	0.7
12/18	304.8	19.3	0.39	0.08	44.2	0.5
12/19e	335.4	26.9	0.49	0.10	35.2	0.6
12/20e	363.2	46.5	0.83	0.19	20.8	1.1

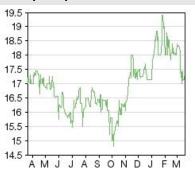
Note: \*Total revenue including government grants. \*\*PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

ROVI's R&D focus is on its proprietary ISM technology, which centres on developing novel, long-acting (once a month or once every three months) formulations of approved drugs. The PRISMA-3 Phase III study is a placebocontrolled trial designed to evaluate the efficacy and safety of monthly intramuscular injections of DORIA in patients with acute exacerbation of schizophrenia. PRISMA-3 is additionally assessing whether an improvement in PANSS from day four is achievable and statistically significant. If so, and if it is included in its label, DORIA would have a unique selling point versus its competitor long-acting injectable (LAIs). The trial is also looking at health economic-related outcomes, which could be relevant in pricing and reimbursement negotiations. We believe DORIA's profile will enable it to take a 5% share of the LAI market. We retain our probability of success of 75% for the Phase III PRISMA-3 trial and await the full data (expected by end June 2019) to assess any additional implications to our model.

# 19 March 2019

Price	€17.25
Market cap	€968m
Net cash (€m) at 31 December 2018	61.3
Shares in issue	56.1m
Free float	32%
Code	ROVI
Primary exchange	Madrid
Secondary exchange	N/A

## Share price performance



# **Business description**

Laboratorios Farmacéuticos ROVI is a fully integrated Spanish speciality pharmaceutical company involved in the development, in-licensing, manufacture and marketing of small molecule and speciality biologic drugs with a particular expertise in low molecular weight heparin.

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