

Laboratorios Farmacéuticos ROVI

DORIA update

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 placebo-controlled 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.

Pharma & biotech

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.

Analysts

Dr Susie Jana +44 (0)20 3077 5700

Dr Daniel Wilkinson +44 (0)20 3077 5734

Dr Sean Conroy +44 (0)20 3681 2534

healthcare@edisongroup.com
[Edison profile page](#)

Laboratorios Farmacéuticos ROVI is a research client of Edison Investment Research Limited

General disclaimer and copyright

This report has been commissioned by Laboratorios Farmacéuticos ROVI and prepared and issued by Edison, in consideration of a fee payable by Laboratorios Farmacéuticos ROVI. Edison Investment Research standard fees are £49,500 pa for the production and broad dissemination of a detailed note (Outlook) following by regular (typically quarterly) update notes. Fees are paid upfront in cash without recourse. Edison may seek additional fees for the provision of roadshows and related IR services for the client but does not get remunerated for any investment banking services. We never take payment in stock, options or warrants for any of our services.

Accuracy of content: All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable, however we do not guarantee the accuracy or completeness of this report and have not sought for this information to be independently verified. Opinions contained in this report represent those of the Edison analyst at the time of publication. Forward-looking information or statements in this report contain information that is based on assumptions, forecasts of future results, estimates of amounts not yet determinable, and therefore involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of their subject matter to be materially different from current expectations.

Exclusion of Liability: To the fullest extent allowed by law, Edison shall not be liable for any direct, indirect or consequential losses, loss of profits, damages, costs or expenses incurred or suffered by you arising out of or in connection with the access to, use of or reliance on any information contained on this note.

No personalised advice: The information that we provide should not be construed in any manner whatsoever as, personalised advice. Also, the information provided by us should not be construed by any subscriber or prospective subscriber as Edison's solicitation to effect, or attempt to effect, any transaction in a security. The securities described in the report may not be eligible for sale in all jurisdictions or to certain categories of investors.

Investment in securities mentioned: Edison has a restrictive policy relating to personal dealing and conflicts of interest. Edison Group does not conduct any investment business and, accordingly, does not itself hold any positions in the securities mentioned in this report. However, the respective directors, officers, employees and contractors of Edison may have a position in any or related securities mentioned in this report, subject to Edison's policies on personal dealing and conflicts of interest.

Copyright: Copyright 2019 Edison Investment Research Limited (Edison). All rights reserved FTSE International Limited ("FTSE") © FTSE 2019. "FTSE®" is a trade mark of the London Stock Exchange Group companies and is used by FTSE International Limited under license. All rights in the FTSE indices and/or FTSE ratings vest in FTSE and/or its licensors. Neither FTSE nor its licensors accept any liability for any errors or omissions in the FTSE indices and/or FTSE ratings or underlying data. No further distribution of FTSE Data is permitted without FTSE's express written consent.

Australia

Edison Investment Research Pty Ltd (Edison AU) is the Australian subsidiary of Edison. Edison AU is a Corporate Authorised Representative (1252501) of Myonlineadvisers Pty Ltd who holds an Australian Financial Services Licence (Number: 427484). This research is issued in Australia by Edison AU and any access to it, is intended only for "wholesale clients" within the meaning of the Corporations Act 2001 of Australia. Any advice given by Edison AU is general advice only and does not take into account your personal circumstances, needs or objectives. You should, before acting on this advice, consider the appropriateness of the advice, having regard to your objectives, financial situation and needs. If our advice relates to the acquisition, or possible acquisition, of a particular financial product you should read any relevant Product Disclosure Statement or like instrument.

New Zealand

The research in this document is intended for New Zealand resident professional financial advisers or brokers (for use in their roles as financial advisers or brokers) and habitual investors who are "wholesale clients" for the purpose of the Financial Advisers Act 2008 (FAA) (as described in sections 5(c) (1)(a), (b) and (c) of the FAA). This is not a solicitation or inducement to buy, sell, subscribe, or underwrite any securities mentioned or in the topic of this document. For the purpose of the FAA, the content of this report is of a general nature, is intended as a source of general information only and is not intended to constitute a recommendation or opinion in relation to acquiring or disposing (including refraining from acquiring or disposing) of securities. The distribution of this document is not a "personalised service" and, to the extent that it contains any financial advice, is intended only as a "class service" provided by Edison within the meaning of the FAA (i.e. without taking into account the particular financial situation or goals of any person). As such, it should not be relied upon in making an investment decision.

United Kingdom

Neither this document and associated email (together, the "Communication") constitutes or form part of any offer for sale or subscription of, or solicitation of any offer to buy or subscribe for, any securities, nor shall it or any part of it form the basis of, or be relied on in connection with, any contract or commitment whatsoever. Any decision to purchase shares in the Company in the proposed placing should be made solely on the basis of the information to be contained in the admission document to be published in connection therewith.

This Communication is being distributed in the United Kingdom and is directed only at (i) persons having professional experience in matters relating to investments, i.e. investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "FPO") (ii) high net-worth companies, unincorporated associations or other bodies within the meaning of Article 49 of the FPO and (iii) persons to whom it is otherwise lawful to distribute it. The investment or investment activity to which this document relates is available only to such persons. It is not intended that this document be distributed or passed on, directly or indirectly, to any other class of persons and in any event and under no circumstances should persons of any other description rely on or act upon the contents of this document (nor will such persons be able to purchase shares in the placing).

This Communication is being supplied to you solely for your information and may not be reproduced by, further distributed to or published in whole or in part by, any other person.

United States

The Investment Research is a publication distributed in the United States by Edison Investment Research, Inc. Edison Investment Research, Inc. is registered as an investment adviser with the Securities and Exchange Commission. Edison relies upon the "publishers' exclusion" from the definition of investment adviser under Section 202(a) (11) of the Investment Advisers Act of 1940 and corresponding state securities laws. This report is a bona fide publication of general and regular circulation offering impersonal investment-related advice, not tailored to a specific investment portfolio or the needs of current and/or prospective subscribers. As such, Edison does not offer or provide personal advice and the research provided is for informational purposes only. No mention of a particular security in this report constitutes a recommendation to buy, sell or hold that or any security, or that any particular security, portfolio of securities, transaction or investment strategy is suitable for any specific person.