EDISON

Oryzon Genomics

Operational update

Favourable safety reported in PORTICO Phase II

Pharma and biotech

Oryzon presented a positive update on vafidemstat's ongoing Phase IIb PORTICO trial in borderline personality disorder (BPD) at the ECNP Congress. The aggregated blinded safety data, as of 23 August, demonstrated a well-tolerated safety profile for a cohort with baseline characteristics reflecting real-world demographics of a typical BPD population. This is a critical consideration for therapies to progress and be successful once commercialised. We also note a low rate of discontinuations (2%) due to treatment-emergent adverse events (TEAEs) and zero discontinuations attributed to serious TEAEs. Screen failure and dropout rates, at 37% and 21%, respectively, were also favourable compared to other agents in development for BPD, such as brexpiprazole, which had higher rates (62% and 27%). As a reminder, the primary objective of the PORTICO trial is efficacy of vafidemstat, and we anticipate top-line data in Q124. Although the shared data was blinded, the overall results suggest a favourable safety profile for vafidemstat and we await next year's efficacy readout as (if positive) it will be a key catalyst and potentially increase the probability of success for vafidemstat in BPD.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/21	10.6	(7.2)	(0.09)	0.0	N/A	N/A
12/22	15.7	(6.4)	(0.07)	0.0	N/A	N/A
12/23e	17.3	(4.2)	(0.03)	0.0	N/A	N/A
12/24e	19.0	(10.0)	(0.14)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

At the ECNP Congress, Oryzon presented aggregated baseline characteristics, demographics and safety data from the ongoing Phase IIb PORTICO trial in BPD. Analyses of aggregated blinded data, as of 23 August 2023, indicate a 2% discontinuation rate due to TEAEs and no discontinuations due to serious TEAEs. Additionally, screen failure (37%) and dropout rates (21%) appear favourable when compared to other agents in development for BPD, such as brexpiprazole, which reported screen failure and dropout rates of 62% and 27%, respectively.

The baseline data demonstrated that the trial enrolled a representative real-world BPD population as it allowed patients with common comorbidities and concomitant medications typically excluded in other BPD trials. This is a critical consideration as the therapy progresses through the clinical and regulatory phases and potential launch, as it seeks to address the needs of a broader patient population. Currently there are no drugs specifically approved for BPD patients and there is a significant unmet need.

As a reminder, PORTICO is a global, double-blind, randomised, placebo-controlled, adaptive 14-week Phase IIb trial evaluating the efficacy and safety of vafidemstat. The primary objectives are to investigate vafidemstat's efficacy in treating agitation and aggression, as well as overall disease severity. The trial is fully recruited and top-line results are anticipated in Q124.

11 October 2023

Price	**€2.03**
Market cap	**€118m**
Net debt at 30 June 2023	€1.56m
Shares in issue	57.9m
Free float	80%
Code	ORY
Primary exchange	Madrid Stock Exchange
Secondary exchange	N/A

Share price performance

Business description

Oryzon Genomics is a Spanish biotech focused on epigenetics. Iadademstat is being explored for acute leukaemias, small-cell lung cancer and neuroendocrine tumours. Vafidemstat, its central nervous system (CNS) asset, has completed several Phase IIa trials and a Phase IIb trial in borderline personality disorder is now the lead study, but Oryzon is rapidly expanding its CNS R&D pipeline.

Analysts

Soo Romanoff +44 (0)20 3077 5700

Zoe Karamanoli +44 (0)20 3077 5700

healthcare@edisongroup.com

Edison profile page

Oryzon Genomics is a research client of Edison Investment Research Limited

General disclaimer and copyright

This report has been commissioned by Oryzon Genomics and prepared and issued by Edison, in consideration of a fee payable by Oryzon Genomics. Edison Investment Research standard fees are £60,000 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 research department of Edison 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 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.

Australia

Edison Investment Research Pty Ltd (Edison AU) is the Australian subsidiary of Edison. Edison AU is a Corporate Authorised Representative (1252501) of Crown Wealth Group Pty Ltd who holds an Australian Financial Services Licence (Number: 494274). 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

This document is prepared and provided by Edison for information purposes only and should not be construed as an offer or solicitation for investment in any securities mentioned or in the topic of this document. A marketing communication under FCA Rules, this document has not been prepared in accordance with the legal requirements designed to promote the independence of investment research and is not subject to any prohibition on dealing ahead of the dissemination of investment research.

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.

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

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.

London | New York | Frankfurt
20 Red Lion Street
London, WC1R 4PS
United Kingdom