EDISON

Oryzon Genomics

Operational update

Grant to bolster ALS pipeline, add funding

Pharma and biotech

Oryzon has announced the receipt of a $0.5m grant from the Amyotrophic Lateral Sclerosis (ALS) Association to support the regulatory clinical development of the company's histone deacetylase 6 (HDAC6) inhibitor, ORY-4001, as a potential treatment for ALS. We view this as a favourable advancement that enables the company to expand its preclinical pipeline. This news of this funding grant follows on the heels of Oryzon's recently announced €45m convertible financing arrangement. Oryzon plans to progress ORY-4001 through various investigational new drug (IND)-enabling studies and we anticipate updates from the company as the data become available. The most significant upcoming catalyst for Oryzon is top-line readouts for the Phase IIb PORTICO trial for lead clinical asset vafidemstat for the treatment of borderline personality disorder, expected in Q124.

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	15.9	(6.6)	(0.07)	0.0	N/A	N/A
12/24e	19.0	(10.0)	(0.13)	0.0	N/A	N/A

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

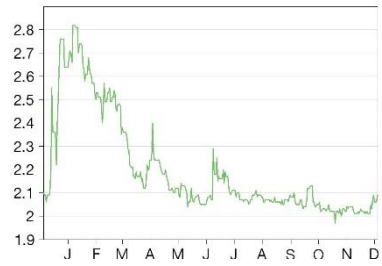
As per the announcement, the $498,690 grant has been awarded to Oryzon to support a preclinical collaboration with the ALS Association, the largest philanthropic funder of ALS research worldwide. This represents a positive development for Oryzon, in our view, and supports the company's previously disclosed plans of exploring new epigenetic therapeutic targets. ALS is a life-threatening and rare disease (affecting fewer than 50k individuals in the US) of the central nervous system and there are currently no approved curative treatment options. ALS patients typically face an extremely poor prognosis with median survival from disease onset to death ranging from 20 to 48 months, highlighting the opportunity for Oryzon to address this unmet medical need. We note that the global ALS market has been projected to reach c $1bn by 2032.

Oryzon first nominated ORY-4001 as a clinical development candidate in March 2023. The drug has been designed to target the enzyme HDAC6, the inhibition of which has been shown to protect against neurodegeneration in various mouse and human-induced pluripotent stem cell models, positioning it as a potentially effective treatment to manage the progression of ALS. ORY-4001 has previously shown efficacy in a mouse model of Charcot-Marie Tooth (CMT) type 1, the most common inherited peripheral neuropathy. As part of the collaboration with the ALS association, we expect Oryzon to continue developing ORY-4001, including validating the effects of HDAC6 inhibition in ALS mouse models, as well as advancing IND-enabling toxicology studies. If the data continue to be supportive and ORY-4001 enters clinical trials, then it will become the Oryzon's second programme in the CNS space and demonstrate the company's capabilities in progressing epigenetic candidates.

5 December 2023

Price	**€2.06**
Market cap	**€121m**
Gross cash balance (€m) at end-September 2023	8.4
Shares in issue	58.6m
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 (now the lead programme), but Oryzon is rapidly expanding its CNS R&D pipeline.

Analysts

Soo Romanoff +44 (0)20 3077 5700

Dr Arron Aatkar +44 (0)20 3077 5700

healthcare@edisongroup.com

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