EDISON

Oryzon Genomics

External recognition

Third time is a charm; INNOVATIVE SME Seal

Pharma and biotech

For the third consecutive time, Oryzon Genomics has received the INNOVATIVE SME Seal from the Spanish Ministry of Science and Innovation. This external recognition highlights Oryzon's key R&D activities, including its lead central nervous system (CNS) asset, vafidemstat, and lead oncology asset, iadademstat, and overall contributions to the field of epigenetics. Along with the acknowledgement, the INNOVATIVE SME Seal may allow Oryzon to benefit from certain tax deductions and incentives, as well as potential access to certain financing facilities.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/22	15.7	(6.3)	(0.07)	0.0	N/A	N/A
12/23	14.2	(6.0)	(0.06)	0.0	N/A	N/A
12/24e	12.9	(4.2)	(0.03)	0.0	N/A	N/A
12/25e	33.7	15.5	0.29	0.0	7.0	N/A

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

As per the announcement, Oryzon has received the INNOVATIVE SME Seal from the Spanish Ministry of Science and Innovation, and will accordingly be registered in the Public Registry of Innovative SMEs. We view this as an encouraging announcement for the company, marking formal acknowledgement of its efforts to advance novel therapies with epigenetic targets. Oryzon's two clinical-stage assets both target LSD1, a histone-modifying enzyme that forms part of complexes responsible for the regulation of genes implicated in both cancer and CNS indications.

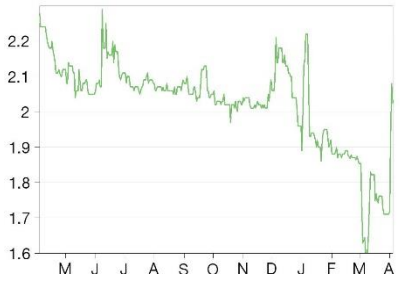
In CNS, vafidemstat has been tested in over 400 subjects, and has shown desirable safety and tolerability. The lead programme is targeting borderline personality disorder (BPD), for which the Phase IIb PORTICO trial concluded in January 2024. While the study did not meet its primary endpoints, vafidemstat was favoured over placebo in all measures, and Oryzon plans to request an End of Phase II (EoP2) meeting with the FDA in Q224 to discuss a potential registrational Phase III programme. Beyond BPD, vafidemstat is also in a Phase IIb trial (EVOLUTION) for schizophrenia, a timeline update for which is expected in 2024. It is also being explored as a potential treatment for Kabuki syndrome, a rare congenital disorder caused by variants in the KMT2D gene. Management believes LSD1 inhibition represents a promising treatment approach and plans to submit an IND application in 2024.

In oncology, the lead programme (FRIDA) is evaluating iadademstat in combination with gilteritinib in patients with relapsed/refractory AML harbouring the FLT3 mutation. Oryzon is targeting the second-line AML treatment setting, which could expedite the route to market compared to other drugs in development targeting the first-line setting, in our view. The first cohort for FRIDA (six patients) has completed treatment, showing that the combination is safe with anti-leukemic activity; further interim results from FRIDA are expected in Q224. Iadademstat is also being developed as a potential treatment for small-cell lung cancer and high-grade extrapulmonary neuroendocrine tumours. For a more detailed overview of Oryzon's active clinical pipeline, we direct readers to our previous update note.

5 April 2024

Price	**€2.03**
Market cap	**€126m**
Net debt* (€m) at end-December 2023 *Excluding post-period debt-to-equity conversion	6.3
Shares in issue	62.0m
Free float	82%
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 asset, has completed several Phase IIa trials and a Phase IIb trial in borderline personality disorder (now the lead programme), and is in a Phase IIb trial in schizophrenia.

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