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Oryzon Genomics

Patent update

Strengthening vafidemstat's IP profile

Pharma and biotech

Oryzon Genomics continues to fortify its IP profile for vafidemstat, which is being developed for borderline personality disorder (BPD) and for the potential application to attention deficit hyperactivity disorder (ADHD). Oryzon has received positive acceptance decisions for two incremental patent applications from the Japanese Patent Office (JPO), which should provide protection until 2040 (excluding potential extensions). Oryzon was also notified of similar patent grants from the European and Korean patent offices, which may extend the drug's exclusivity in those jurisdictions. Oryzon is advancing its lead CNS asset towards an end-of-Phase II (EoP2) meeting with the FDA to discuss a potentially registrational Phase III trial in BPD. Vafidemstat already holds composition of matter patents in the US and EU providing protection up to 2037 and 2036, respectively.

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	(4.1)	(0.03)	0.0	N/A	N/A
12/25e	33.7	15.4	0.29	0.0	6.2	N/A

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

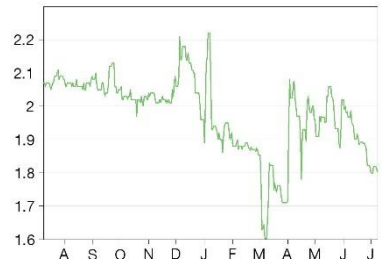
The JPO has issued 'Decision to grant' communications for two patent applications for vafidemstat: 'Methods of treating borderline personality disorder' and 'Methods of treating attention-deficit hyperactivity disorder using KDM1A inhibitors such as the compound vafidemstat.' The drug is an inhibitor of the epigenetic target LSD1 (KDM1A), a histone-modifying enzyme that forms part of complexes responsible for the regulation of genes implicated in both cancer and CNS disorders. The JPO's 'decision to grant' communications indicate that the final regulatory hurdles for patent issuance have been met. Management expects these will provide protection in the Japanese market until at least 2040. Oryzon had also received a patent in Russia and 'Decision to grant' communications from the European and Korean patent offices, providing additional 'use' protection for vafidemstat (until 2038) in treating aggression and social withdrawal, which relate to its BPD and schizophrenia programmes. Oryzon also holds composition-of-matter patents for vafidemstat, expected to expire in the US and EU in 2037 and 2036, respectively, including patent term extension/supplementary protection certificates.

While Oryzon does not have any active programmes in ADHD, its lead CNS programme is focused on BPD, for which the Phase IIb PORTICO trial reached a conclusion in January 2024. While the primary endpoints (BPD Checklist and Clinical Global Impression – Severity Agitation/Aggression) were not met with statistical significance, the drug candidate was favoured over placebo in all efficacy measures. We believe encouragement should be taken from the fact that nominal statistical significance was achieved in two key secondary endpoints (Borderline Evaluation of Severity and State-Trait Anger Expression Inventory 2 Trait Anger). We highlight that, with the limited treatment options available in BPD, a sizable opportunity remains for Oryzon in this space, contingent on clinical progression. An outcome from FDA EoP2 meeting with the FDA is anticipated within H224, representing a major potential inflection point.

9 July 2024

Price	**€1.81**
Market cap	**€115m**
Net debt (€m) at 31 March 2024	3.7
Shares in issue	63.5m
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 leukaemia, small-cell lung cancer and neuroendocrine tumours. Vafidemstat, its central nervous system asset, has completed several Phase IIa trials and a Phase IIb trial for borderline personality disorder (now the lead programme), and is in a Phase IIb trial for schizophrenia.

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