EDISON

Oryzon Genomics

FY22 update

Progress in oncology and CNS in FY22

Pharma and biotech

Oryzon Genomics has presented headline FY22 financial results, which reflect continued progress on its clinical activities for key assets iadademstat (oncology) and vafidemstat (central nervous system; CNS) across different programmes. Total operating expenses for the year were US$22.9m, up by 13.5% from US$20.2m in FY21 and slightly higher than our estimate of US$20.1m. As expected, the bulk of these costs (c 80%) related to R&D expenses (US$18.1m) as the company continues to focus on advancing its clinical pipeline. The period-end gross cash balance was US$22.7m, which at historical burn rates (€6.92m/US$7.3m in H122) should fund the company into H225, past key clinical readouts. Looking ahead, we see the start of patient enrolment in the FRIDA study for relapsed/refractory (r/r) FLT3+ acute myeloid leukaemia (AML) patients and top-line data from the PORTICO study for borderline personality (BPD) disorder in Q123 as key upcoming catalysts.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/21	10.6	(7.2)	(0.09)	0.00	N/A	N/A
12/22**	16.1	(5.5)	(0.08)	0.00	N/A	N/A
12/23e	15.9	(5.8)	(0.06)	0.00	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, other income and exceptional items. **FY22 figures based on available preliminary headline data.

Despite higher operating expenses, Oryzon's net operating loss for FY22 contracted to US$5.9m from US$7.9m in FY21, driven by higher levels of R&D grants received during the year (US$17.0m vs US$12.2m in FY21). Q422 total operating expenses amounted to US$6.3m (US$5.9 in Q421), including R&D expenses of US$5.0m (US$3.9m in Q421). Oryzon ended the year with cash and cash equivalents of US$22.7m, which we estimate is sufficient to fund operations to H225, based on historical burn rates.

With the conclusion of the ALICE study, Oryzon intends to keep up the clinical pace of iadademstat in AML with the initiation of the Phase Ib FRIDA study in r/r FLT3+ AML patients, for which patient recruitment is expected imminently. Management has said that FRIDA will be the Oryzon's core strategic priority and potentially its fastest route to the market. While the AML space is highly competitive, second-line treatment options in r/r FLT3+ AML remain limited and suboptimal, so we view management's pursuit of this setting as a sensible clinical strategy to maximise the opportunity for iadademstat. Also, FLT3+ patients in the ALICE study (n=3) all showed a response to the treatment, providing encouraging signs for this AML sub-population in FRIDA.

The most significant upcoming clinical milestone for Oryzon's ongoing CNS programmes is the interim analysis (n=90) from its Phase IIb randomised, double-blind PORTICO study (vafidemstat for treating BPD), which we anticipate in Q123. The primary endpoints for the study are overall clinical BPD improvement and reduction in aggression. We expect the results of the interim analysis to dictate patient enrolment (with plans to recruit up to 156), with final readouts expected in Q423.

21 February 2023

Price	**€2.54**
Market cap	**€143m**
	US$1.07/€
Gross cash (€m) at 31 December 2022	21.4
Shares in issue	56.3m
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, SCLC and NECs. 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.

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