EDISON

Oryzon Genomics

H123 update

H123 progress and results came in as expected

Pharma and biotech

Oryzon's H123 results highlight the continued progress of its lead clinical-stage assets, including positive aggregate safety data from the Phase IIb PORTICO trial assessing vafidemstat in borderline personality disorder. The company also indicated that enrolment is proceeding for the Phase IIb EVOLUTION trial (assessing vafidemstat in schizophrenia) and for the Phase Ib FRIDA trial (evaluating iadademstat in acute myeloid leukaemia, (AML)). Total H123 operating expenses were up by only 0.5% y-o-y (to €10.95m), despite a 6.3% increase in R&D costs (to $8.63m). With gross cash of $14.6m at the end of H123, we estimate a cash runway into Q224. We anticipate that top-line data readouts from the PORTICO trial (expected in Q124) may be the company's next significant catalyst.

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.

In Oryzon's H123 results, the company reported a net loss of $0.6m, slightly lower than the net loss of $1.3m in H122. This was mainly driven by higher other income (which usually includes capitalised R&D development expenses) recognised by Oryzon during the period ($8.3m in H123 vs $7.5m in H122). Total H123 operating expenses were up by 0.5% y-o-y (to €10.95m), with R&D expenses growing by 6.3% to $8.63m due to greater activity in its clinical development programmes. Gross cash at the end of H123 stood at $14.6m ($22.7m at the end of FY22). Based on our cash burn projections, we estimate a cash runway to Q224.

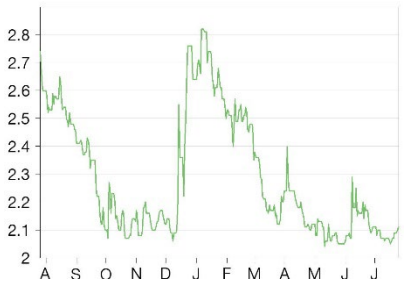
Operational highlights for the period include positive safety data for vafidemstat in the PORTICO trial. As discussed in our last note, a review of the first 167 patients treated in the trial was conducted by an independent data monitoring committee, which recommended that the trial should proceed without modifications. Oryzon also announced that patient recruitment (n=188) has been completed for this study. Additionally, the EVOLUTION trial is continuing to enrol patients and the company is finalising preparation for the Phase I/II HOPE trial (assessing vafidemstat in Kabuki Syndrome, a rare congenital disorder). Oryzon is refining the final design of HOPE and expects to submit an investigational new drug application to the FDA by the end of 2023, which is consistent with prior reported guidelines. In the oncology space, enrolment is ongoing for the FRIDA trial assessing iadademstat in combination with gilteritinib, for the treatment of relapsed/refractory (r/r) FLT3-mutant AML patients. Furthermore, the Phase II basket trial of iadademstat in combination with paclitaxel in platinum r/r small cell lung cancer and extrapulmonary high-grade neuroendocrine tumours (in collaboration with the Fox Chase Cancer Centre) also continues to enrol patients. Study updates are expected in H223.

We believe that the announcement of top-line data for the PORTICO trial, expected in Q124, may represent the company's next key catalyst in the near term.

26 July 2023

Price	**€2.11**
Market cap	**€122m**
Net debt (€m) at 30 June 2023	1.56
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.

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