EDISON

# Oryzon Genomics

KOL event

## KOL event puts near-term catalysts in the spotlight

Pharma and biotech

**At Oryzon's recent key opinion leader (KOL) event, management elaborated on the near-term clinical catalysts for its lead assets iadademstat, in oncology, and vafidemstat, in central nervous system (CNS) indications. Following the positive results of the ALICE trial, the company is fast approaching the initiation of the Phase Ib FRIDA study for iadademstat in FLT3+ relapsed/refractory (r/r) acute myeloid leukaemia (AML) patients. Management believes the r/r AML setting may represent a faster route to market for iadademstat, targeting a patient population with currently limited and sub-optimal treatment options. Management originally guided for FRIDA to be initiated by end-2022; however, this delay has been attributed to slower-than-expected trial site activation. Management has communicated that trial site activation is now progressing and that FRIDA could begin imminently. Additionally, interim data analysis from the PORTICO study in borderline personality disorder (BPD) in Q123 represents a significant catalyst for vafidemstat in the company's leading CNS programme.**

| 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 | 15.7 | (6.6) | (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.

At its KOL event, management focused squarely on the FRIDA and PORTICO studies, which represent Oryzon's near-term share price catalysts and most-immediate strategic priorities. With the Phase IIa ALICE study focusing on first-line AML patients, FRIDA will look to address second-line r/r AML patients, investigating iadademstat in combination with Astella's FDA-approved FLT3 inhibitor gilteritinib (Xospata). Oryzon has commented that first-line AML is still of interest and that it may look to investigator-sponsored trials to pursue future studies in this setting but that r/r represents a potentially quicker route to market, avoiding competition with existing first-line AML standard of care venetoclax/azacitidine.

In our view, the most significant upcoming clinical milestone for Oryzon is the interim analysis (n=90) from its Phase IIb randomised, double-blind, placebo-controlled PORTICO study (vafidemstat for treating BPD) in Q123. The study is assessing multiple primary efficacy endpoints, which include overall clinical BPD improvement and reduction in aggression. The use of multiple clinical trial endpoints, such as those utilised in Oryzon's studies, may help mitigate some of the challenges associated with subjective measurements in CNS trials.

While we caution against interpretation of clinical results prior to the unblinding of data, we note that two of PORTICO's principal investigators who took part in the KOL event both commented that enrolled patients appeared to be tolerating treatment well. Vafidemstat's potential tolerability is further supported by the positive interim PORTICO safety data, which reported no serious adverse events and only mild adverse events with no patient discontinuation.

**28 February 2023**

| | |
|---|---|
| **Price** | **€2.47** |
| **Market cap** | **€139m** |
| | US$1.07/€ |
| Gross cash (€m) at 31 December 2022 | 21.4 |
| Shares in issue | 56.3m |
| Free float | 81% |
| 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 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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