EDISON

Oryzon Genomics

Q122 update

FRIDA funding and orphan drug designation

Pharma and biotech

Oryzon Genomics has been awarded a $2m public grant to support its ongoing Phase Ib FRIDA clinical study. This follows recent FDA approval of its investigational new drug (IND) application of this initiation Phase Ib study of iadademstat. FRIDA aims to investigate the safety, tolerability and recommended dose for Phase II of one of Oryzon's lead assets, the LSD1 inhibitor iadademstat, in combination with FDA-approved FLT3 inhibitor gilteritinib for treating patients with FLT3-mutated acute myeloid leukaemia (AML) in a second-line setting. We anticipate a positive readout from the FRIDA trial would likely provide a positive catalyst for the company's shares. Iadademstat is also being investigated for its use as a first-line treatment in patients with metastatic small-cell lung cancer (SCLC) for which the FDA has now granted orphan drug designation (ODD). This ODD in SCLC will help expedite development in a further area of high unmet clinical need. Based on the current annual burn rate of around €13–15m (c €15m cash spent in FY21) and the company's gross cash position of $28m (€26.2m) at end-March 2022, we estimate Oryzon has a cash runway through early FY24. We will revisit our estimates and valuation based on this news.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/20	9.5	(4.8)	(0.07)	0.0	N/A	N/A
12/21	10.6	(7.2)	(0.09)	0.0	N/A	N/A

Note: *Normalised, excluding amortisation of acquired intangibles and exceptional items.

Oryzon Genomics specialises in epigenetic therapeutics. Its primary oncology clinical asset, iadademstat, is being investigated for the inhibition of epigenetic target LSD1 in the treatment of AML and SCLC. The latest commitment of €1.87m of additional capital comes as a result of Oryzon Genomics being awarded the Seal of Excellence, a quality label awarded by the European commission, which will be used exclusively within the FRIDA study.

Iadademstat has already shown some initially positive efficacy results in a clinical setting. Oryzon's separate ongoing Phase IIa ALICE trial is evaluating the overall response rate (ORR) of newly diagnosed elderly AML patients treated with a combination of iadademstat and standard-of-care chemotherapy drug azacitidine. ORR has been reported at around 80%, which is significantly higher than classic chemotherapy (c 30%). These results, combined with previously demonstrated safety profiles, provide an encouraging baseline for the FRIDA study. Following the FDA approval, FRIDA will aim to recruit approximately 45 patients. The ODD for iadademstat in SCLC follows the design of the Phase Ib/II STELLAR, which will investigate the combination of iadademstat with a checkpoint inhibitor in patients with advanced SCLC. The designation includes benefits such as market exclusivity on regulatory approval, if received, exemption of FDA application fees and tax credits for qualified clinical trials.

9 June 2022

Price	**€2.77**
Market cap	**€146m**
	US$1.07/€
Net cash (€m) at end FY21	11.1
Shares in issue	52.8m
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 and SCLC. 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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