

# Oryzon Genomics

Q224 results

## Multiple milestones anticipated in H224

Oryzon's Q224 results summarised an active quarter for its clinical pipeline, with multiple milestones expected in H224. Central to the H224 momentum will be the upcoming FDA end-of-Phase II (EoP2) meeting for vafidemstat in BPD, for which a positive outcome would provide impetus to subsequent plans. Interim data from FRIDA (iadademstat in AML) was encouraging, and with several additional combination trials planned, the second half of the year will continue to be highly active. Operating results threw no surprises, with R&D expenses remaining soft (€2.2m in Q224) following the PORTICO trial completion in late 2023. The period-end gross cash balance of €10.1m was supported by another €4m drawdown from the November 2023 convertible debt facility and should support operations into FY25. As we make minor revisions to our estimates, our valuation adjusts to €774.7m versus €748.8m previously. Our per share valuation remains unchanged (€12.1) on a higher post-conversion share count.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/22	15.7	(6.6)	(0.07)	0.0	N/A	N/A
12/23	14.2	(6.1)	(0.06)	0.0	N/A	N/A
12/24e	8.6	(4.9)	(0.05)	0.0	N/A	N/A
12/25e	31.6	15.5	0.28	0.0	N/A	N/A

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

## Q224 results summarise an active period

Oryzon's [Q224 results](#) reflect an active period, and borderline personality disorder (BPD) for vafidemstat and acute myeloid leukaemia (AML) for iadademstat remain top priorities. Notably in AML, Oryzon reported [a positive update](#) in June 2024 for the FRIDA trial, with the next update expected in December 2024. Beyond its clinical activities, Oryzon recently received the [INNOVATIVE SME](#) seal from the Spanish Ministry of Science and Innovation, and was selected as an associated partner of [Med4Cure](#). In our view, such external recognition serves as an endorsement of Oryzon's R&D capabilities and robust position in the field of epigenetics.

## Next key catalyst: End-of-Phase II meeting for BPD

Management confirmed that it has been granted an FDA EoP2 meeting to discuss a registrational Phase III BPD programme for vafidemstat. While a precise date has not yet been disclosed, [FDA guidelines](#) aim to schedule EoP2 meetings within 70 days from the receipt of the request, with formal written minutes from the regulators within 30 days after the meeting. As such, we expect an update within Q424, with the outcome potentially representing Oryzon's next significant upcoming catalyst.

## Valuation: €774.7m or €12.1 per basic share

We have made only minor adjustments to our estimates based on the Q224 results. Our overall valuation benefits (€774.7m vs €748.8m previously) from the model roll-forward and a slightly lower net debt position. However, the per share valuation remains unchanged at €12.1 given the higher share count following €3.6m of debt-to-equity conversion in the quarter. Current gross cash balance (€10.1m) should support operations into FY25, although we expect further debt drawdowns in H224.

Pharma and biotech

1 August 2024

Price **€1.86**

Market cap **€119m**

Net debt (€m) at 30 June 2024 3.2

Shares in issue 64.0m

Free float 82%

Code ORY

Primary exchange Madrid Stock Exchange

Secondary exchange N/A

### Share price performance



% 1m 3m 12m

Abs 2.4 (5.0) (10.3)

Rel (local) 1.3 (6.8) (21.8)

52-week high/low €2.22 €1.60

### 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 asset, has completed several Phase IIa trials and a Phase IIb trial in borderline personality disorder (now the lead programme), and is in a Phase IIb trial in schizophrenia.

### Next events

FDA EoP2 meeting (BPD) outcome Q424

EVOLUTION trial timeline update H224

FRIDA trial update Dec 2024

HOPE trial initiation 2024

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## CNS and oncology pipelines continue to advance

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### Vafidemstat – central nervous system indications

Oryzon's lead central nervous system (CNS) programme is developing vafidemstat as a potential treatment for BPD. As part of its Q224 results, the company confirmed that it has been granted an EoP2 meeting with the FDA for a potential registrational Phase III programme, and the current strategic priority for management is focused on preparing for this meeting. While a precise date has not yet been disclosed, we anticipate a meeting in Q324, with an outcome to be reached before year-end (we project an outcome in Q424). As a reminder, the Phase IIb PORTICO trial [concluded](#) in January 2024, and while the study fell short of meeting its primary endpoint, nominal statistical significance was achieved in two key secondary endpoints, and vafidemstat was favoured over placebo in all efficacy measures. Oryzon has now completed the full data analysis and final data will be presented at the 37th European College of Neuropsychopharmacology annual conference in September 2024. We highlight that the FDA has in the past provided provisional support for Phase III study proposals in instances where there have been Phase II setbacks if the data is otherwise compelling on other parameters. This was recently [exemplified](#) with IRLAB Therapeutics (a Sweden-based company focused on CNS indications), which [received the FDA green light](#) for a Phase III programme to evaluate its lead asset for Parkinson's disease levodopa-induced dyskinesias, despite it only meeting the secondary endpoint in its prior Phase IIb study. Given the [unmet need](#) in BPD, we remain optimistic on a meaningful discussion with the FDA at the EoP2 meeting. We also note that Oryzon recently received an 'intention to grant' communication from the Japanese Patent Office for vafidemstat as a potential method to treat BPD, providing protection in the Japanese market until at least 2040, contingent on successful clinical progression.

Vafidemstat is also being developed as a potential treatment for schizophrenia, and in its Q224 results, Oryzon stated that it has continued to enrol patients for the Phase IIb [EVOLUTION](#) study, which is partially funded by the Spanish Ministry of Science and Innovation. Specifically, this clinical trial has been designed to assess the effectiveness of vafidemstat in addressing negative symptoms (affective flattening, hedonia, avolition) and cognitive impairments (deficits in memory, attention, learning, executive function) associated with schizophrenia. We look forward to management sharing a timeline update within H224.

Beyond these clinical-stage programmes, management has also re-affirmed its plans to submit an investigational new drug (IND) application to the FDA for the planned Phase Ib/II HOPE study by end-2024. This will evaluate vafidemstat as a potential treatment for [Kabuki syndrome](#), a rare congenital disorder characterised by a specific variant in the KMT2D gene, which Oryzon believes it can address through vafidemstat's mechanism of LSD1 inhibition.

### Iadademstat – oncology

Oryzon has also continued to make headway in exploring iadademstat in haematological cancers during the quarter:

- The key highlight in Q224 was the interim results of the [FRIDA](#) study, Oryzon's top priority in oncology. FRIDA (expected n=45) is a Phase Ib trial investigating iadademstat in combination with gilteritinib as a potential treatment for relapsed or refractory (r/r) AML in patients harbouring the FLT3 mutation. The [latest update](#) related to the first two cohorts (13 patients), which demonstrated desirable safety and efficacy. Encouragingly, 69% of patients reported bone marrow blast cell clearance in the first treatment cycle and 39% of patients achieved complete remission with full or partial hematologic or blood count recovery. As part of its Q224 results, management communicated that enrolment for the third cohort is now complete and

the next data update will be presented at the American Society of Hematology annual meeting in December 2024.

- Under the cooperative research and development agreement (CRADA) signed with the National Cancer Institute (NCI), a new US-based Phase I trial will focus on iadademstat in combination with venetoclax and azacitidine as a potential first-line treatment regime for AML. Dr Natalie Galanina from the University of Pittsburgh Cancer Institute will be the principal investigator for the trial, which will aim to enrol 45 treatment naïve AML patients. It is due to commence recruitment within Q324.
- Iadademstat in combination with venetoclax and azacitidine for the first-line treatment of AML will also be assessed in another investigator-initiated study (IIS) led by the Oregon Health & Science University. This will be a Phase Ib dose-finding study, for which recruitment is also expected to commence in Q324. We note that Oryzon has already obtained [encouraging results](#) in the ALICE trial assessing iadademstat in combination with azacitidine for AML, and now intends to evaluate any potential incremental benefits from a broader combination approach. Management believes that, collectively, the array of trials should open a range of options for its clinical development strategy in this space.
- Oryzon has also announced a new IIS, sponsored by the Medical College of Wisconsin, which will assess iadademstat in combination with azacitidine as a potential treatment for myelodysplastic syndrome, a group of disorders triggered by abnormal functioning of blood-forming bone marrow cells. We await further details and planned timings for this trial.

Beyond these programmes focused on blood cancers, Oryzon has several other ongoing and planned trials seeking to maximise the value proposition for iadademstat in oncology:

- A Phase II basket trial assessing iadademstat in combination with paclitaxel in platinum r/r small cell lung cancer (SCLC) and extrapulmonary high-grade neuroendocrine tumours in collaboration with the Fox Chase Cancer Center is ongoing. Updates are expected in H224.
- In early Q224, Oryzon announced FDA clearance for the IND application to conduct a Phase I/II trial evaluating iadademstat in combination with checkpoint inhibitors for first-line, extensive-stage SCLC. This trial will be conducted under the CRADA agreement signed with the NCI in the US. The study is due to start enrolling patients in Q324 (expected n=45–50), with the Memorial Sloan Kettering Cancer Center as the main trial site.
  - We consider the outcome from this trial to be material as the data from the study will be used to refine the design of the planned STELLAR study, a larger randomised Phase II trial (to be funded by Oryzon) evaluating the same drug in the same indication. Management believes that STELLAR could support an accelerated approval application.

## Earlier-stage programmes

Throughout Q224 Oryzon has continued to advance its preclinical portfolio. ORY-4001 (an inhibitor of histone deacetylase 6, HDAC6) is being developed for the treatment of neurological conditions such as Charcot-Marie-Tooth disease and amyotrophic lateral sclerosis; it is progressing through IND-enabling studies in preparation for the clinical stages of development.

An overview of Oryzon's active pipeline is shown in Exhibit 1.

## Exhibit 1: Oryzon's clinical pipeline

Program	Study	Preclinical Phase	Phase I		Phase II		Status	Expected Milestone(s)
			Phase Ia	Phase Ib	Phase IIa	Phase IIb		
<b>CNS: Vafidemstat (ORY-2001) – CNS optimized LSD1 inhibitor</b>								
Borderline personality disorder Agitation / Aggression & Overall Improvement	PORTICO						Completed Study has results	Top line data in January 2024 Final Data ECNP-2024 EoP2 FDA meeting in 2024 ★
Schizophrenia Negative Symptoms & Cognition	EVOLUTION						Recruiting	Timeline updates in 2024
Kabuki Syndrome	HOPE			Phase Ib/II			IND in preparation	IND in 2024
<b>Oncology: Iadademstat (ORY-1001) – Selective LSD1 inhibitor</b>								
AML 1L Unfit Patients Combination with azacitidine	ALICE						Completed Study has results	Final positive results published May 2024 (Lancet Haematology)
AML 1L Unfit Patients Combination with azacitidine and venetoclax	IIS-X002			Phase Ib			IND Approved Sponsor: OHSU	FPI 3Q 2024
AML R/R-Fit3mut+ Combination with gilteritinib	FRIDA			Phase Ib			Recruiting	EHA-2024, ASH-2024 ★
Neuroendocrine High Grade R/R Combination with pacitaxel	C-X001 NET Basket						Recruiting Collab Study with FCCC	Study Updates 2H 2024
ED-SDLC 1L Combination with ICI	CRADA-SCLC				Phase I/II		IND Approved Sponsor: NCI, Led by MSKCC	FPI 3Q 2024
ED-SCLC 1L Combination with ICI	STELLAR				Phase II pivotal		IND in preparation Company sponsored	IND 2025
<b>Other Programs</b>								
ORY-3001 (LSD1) Sickle Cell Disease							IND enabling tox completed	
ORY-4001 (HDAC8) CMT, ALS							IND enabling tox ongoing	

ALS: amyotrophic lateral sclerosis; AML: acute myeloid leukemia; CMT: Charcot-Marie-Tooth disease; NETs: neuroendocrine tumors; SCLC: small cell lung cancer; ICI: immune checkpoint inhibitor; FCCC: Fox Chase Cancer Center; MSKCC Memorial Sloan Kettering Cancer Center; OHSU Oregon Health & Science University; IIS: investigator-initiated study

Source: Oryzon Genomics website. Note: some finalised trials are not yet shown.

## Financials

Oryzon's Q224 results broadly mirrored the performance in the previous quarter. R&D expenses continued to trend down following the completion of PORTICO in late-FY23 and came in at €2.2m, down c 44% from the Q223 figure of €3.9m. The expense run-rate was similar to Q124 (€2.4m). We note that €4.1m of the €4.6m R&D expenses in H124 have been capitalised, which management accounts for as other income in the profit and loss statement. With the FDA EoP2 meeting anticipated in H224, we expect any further development work on BPD to commence only from 2025, and therefore estimate the H224 spending to remain at similar levels to H124. Personnel expenses stayed largely unchanged year-on-year at €1.7m. Given that the company has capitalised the bulk of its R&D expenses in H124, operating loss for the period saw little fluctuation at €1.4m (vs €1.2m in Q223). Net loss was reported at €1.1m, a c 30% improvement over the Q123 figure of €1.6m. The free cash outflow for H124 was €8.1m, an improvement over the €10.0m recorded in H123. Based on the H124 R&D trend and expectation of a similar pace in H224, we have adjusted our R&D expense estimate for FY24 downwards to €9.0m (vs €12.3m previously). Accordingly, we have also reduced our estimate for other income to €8.6m, from €12.9m previously. Our other estimates remain largely unchanged. We now expect the FY24 operating loss to be €4.2m (vs €3.2m previously). The FY25 operating loss estimate stays put at €16.6m (€16.7m previously).

The company ended Q224 with net debt of €3.2m, including a €10.1m cash balance and €10.2m in short-term debt (bonds: €4.8m; credit institutions: €5.4) and €3.1m in long-term bank debt. The cash reserves were supported by another €4m in drawdowns (two tranches of €2m each) from the €45m convertible debt facility, announced in November 2023. As per our calculations, Oryzon has utilised €14m of the facility thus far, of which €11m (equivalent to 1,100 bonds) has been converted to equity to date (including €5.4m in H124) against the issue of 5.0m shares of common stock. Request for the conversion of a further 27 bonds (for 151.2k shares) was raised on 12 July and is pending execution.

Based on our projected burn rates (free cash outflow of €13.6m in FY24) we estimate the available cash balance (excluding upcoming debt repayments) to be sufficient to fund operations into FY25. Readers should note that our estimated burn rates for H224 (€5.5m) are lower than the €8.1m figure in H124 because we expect inflows from R&D tax credits (c €2m) in the second half of the year. This does not consider further drawdowns from the convertible debt facility, which we expect the company to continue to utilise in H224. We model Oryzon drawing down another €6m from the facility in H224, with the remaining €25m in FY25. We continue to reflect these capital infusions as illustrative debt in our model.

## Valuation

We have made minor adjustments to our near-term forecasts to reflect the H124 performance and run-rate, but have kept our long-term assumptions unchanged for now. We also incorporate the latest net debt figure and roll our model forward by a quarter. Our overall risk-adjusted net present value (rNPV) valuation goes up to €774.7m from €748.8m previously. However, the per share valuation remains unchanged at €12.1 given the higher number of shares outstanding following recent debt-to-equity conversions (shares outstanding have gone up to 64m vs 62m at end-Q124).

A breakdown of our rNPV is shown in Exhibit 2.

Exhibit 2: Valuation of Oryzon (rNPV)							
Product	Indication	Launch	Peak sales (US\$m)	Value (€m)	Probability	rNPV (€m)	NPV/share (€/share)
ladademstat	2L AML	2029	555	541.9	30%	154.5	2.4
	1L SCLC	2030	720	635.1	20%	120.0	1.9
Vafidemstat	BPD	2028	1,625	830.1	20%	245.0	3.8
	Schizophrenia, negative symptoms	2029	702	582.1	15%	120.8	1.9
	Aggression related to AD	2029	911	686.4	15%	137.8	2.2
Net debt at end-June 2024				(3.2)	100%	(3.2)	(0.1)
<b>Valuation</b>				<b>3,272.3</b>		<b>774.7</b>	<b>12.1</b>

Source: Edison Investment Research

As indicated in our previous notes, our model reflects licensing deals in FY25 and FY26, associated with cash inflows that should support break-even in FY26. If Oryzon does not finalise a partnership deal, and self-commercialises all programmes, we continue to see the need to raise €45m in capital across FY26 and FY27 (modelled as illustrative debt) before becoming self-sustainable in FY28. Assuming all funding requirements across FY24–27 (c €76m) are realised through equity raises, Oryzon would have to issue 40.8m shares (assuming the current trading price of €1.86/share). Our per share valuation would be diluted to €8.1/share, from €12.1/share currently (shares outstanding would increase from 64m to 104.8m).

**Exhibit 3: Financial summary**

Accounts: Spanish GAAP. Year end 31 December (€000s)	2021	2022	2023	2024e	2025e
<b>INCOME STATEMENT</b>					
Total revenues	10,615	15,698	14,192	8,550	31,550
Cost of sales	(746)	(464)	(244)	(317)	(333)
Gross profit	9,869	15,234	13,948	8,233	31,217
Gross margin %	93%	97%	98%	96%	99%
SG&A (expenses)	(3,782)	(3,163)	(3,390)	(3,424)	(3,458)
R&D costs	(9,746)	(13,681)	(12,177)	(9,000)	(11,000)
Other income/(expense)	(3,203)	(3,714)	(2,777)	74	0
Exceptionals and adjustments	(4)	0	0	55	0
Reported EBITDA	(6,866)	(5,323)	(4,396)	(4,062)	16,759
Depreciation and amortisation	(144)	(167)	(153)	(129)	(110)
Reported EBIT	(7,011)	(5,490)	(4,549)	(4,191)	16,649
Finance income/(expense)	(169)	(1,067)	(1,555)	(755)	(1,172)
Other income/(expense)	0	0	0	0	0
Reported PBT	(7,180)	(6,557)	(6,104)	(4,946)	15,477
Income tax expense (includes exceptionals)	2,493	2,325	2,751	1,878	2,315
Reported net income	(4,687)	(4,231)	(3,353)	(3,067)	17,791
Basic average number of shares, m	53.1	53.3	57.6	62.6	64.0
Basic EPS (€)	(0.09)	(0.08)	(0.06)	(0.05)	0.28
Adjusted EBITDA	(6,862)	(5,323)	(4,396)	(4,117)	16,759
Adjusted EBIT	(7,007)	(5,490)	(4,549)	(4,246)	16,649
Adjusted PBT	(6,896)	(6,320)	(6,004)	(5,001)	15,477
Adjusted EPS (€)	(0.08)	(0.07)	(0.06)	(0.05)	0.28
Adjusted diluted EPS (€)	(0.08)	(0.07)	(0.06)	(0.05)	0.28
<b>BALANCE SHEET</b>					
Property, plant and equipment	682	611	481	379	298
Intangible assets	60,254	75,843	89,895	98,418	109,939
Investments	29	31	26	26	26
Deferred tax assets	1,812	2,050	2,222	2,222	2,222
Total non-current assets	62,778	78,535	92,624	101,045	112,484
Cash and equivalents	28,725	21,317	12,257	4,903	34,154
Trade and other receivables	3,645	3,709	1,909	2,809	2,359
Inventories	104	10	6	6	6
Other current assets	132	129	104	104	104
Total current assets	32,606	25,165	14,276	7,822	36,623
Deferred tax liabilities	1,812	2,050	2,222	2,222	2,222
Long term debt	13,354	10,346	6,335	3,172	3,148
Other non-current liabilities	285	0	155	155	155
Total non-current liabilities	15,451	12,396	8,711	5,549	5,525
Trade and other payables	3,518	5,742	4,210	2,986	3,598
Short term debt	4,306	12,920	12,194	16,194	38,056
Other current liabilities	847	70	11	11	11
Total current liabilities	8,672	18,732	16,414	19,190	41,664
Equity attributable to company	71,262	72,572	81,775	84,127	101,919
	0	0	0	0	0
<b>CASH FLOW STATEMENT</b>					
Profit before tax	(7,180)	(6,557)	(6,104)	(4,946)	15,477
Cash from operations (CFO)	(3,626)	(1,848)	(575)	(5,062)	18,964
Capex	(175)	(76)	0	0	0
Acquisition of intangible assets	(11,586)	(14,195)	(14,503)	(8,550)	(11,550)
Other investing activities	37	(1)	(1)	0	0
Cash used in investing activities (CFIA)	(11,724)	(14,271)	(14,504)	(8,550)	(11,550)
Net proceeds from issue of shares	0	(932)	(1,880)	5,420	0
Movements in debt	4,123	9,642	7,901	838	21,838
Other financing activities	0	0	0	0	0
Cash from financing activities (CFF)	4,123	8,710	6,021	6,258	21,838
Increase/(decrease) in cash and equivalents	(10,880)	(7,408)	(9,060)	(7,354)	29,251
Currency translation differences and other	348	1	(3)	0	0
Cash and equivalents at start of period	39,605	28,725	21,317	12,257	4,903
Cash and equivalents at end of period	28,725	21,317	12,257	4,903	34,154
Net (debt) cash	11,065	(1,948)	(6,272)	(14,464)	(7,050)
Free cash flow (CFO + Net capex + Intangible assets)	(15,388)	(16,118)	(15,078)	(13,612)	7,414

Source: Company reports, Edison Investment Research

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