Oryzon Genomics

Q125 results update

Preparations in place for an active 2025

Healthcare

19 May 2025

Q125 saw Oryzon make significant headway towards Phase III for vafidemstat in BPD and clinical advancement for iadademstat across multiple early-stage studies. Operating performance was unsurprising, with opex rising slightly (+5.6% y-o-y to €3.4m) as the company continues to prepare for submitting the vafidemstat Phase III study protocol to the FDA (expected in Q225). The liquidity position has improved materially so far in Q2, supported by a €30m equity raise and another €13.3m in grant income. We estimate that pro forma gross funds (c €47m, including end-Q125 cash of €3.8m) will provide runway through 2027, excluding the BPD trials, which we model will be funded by a licensing partner. We adjust our launch timelines for the iadademstat programmes based on current visibility, with our valuation shifting modestly to €862.4m (€885.1m previously). We adjust our per-share valuation to €11.0 from €13.5, reflecting the increased number of shares outstanding following the equity raise.

Year end	Revenue (€m)	PBT (€m)	EPS (€)	DPS (€)	P/E (x)	Yield (%)
12/23	14.2	(6.1)	(0.06)	0.00	N/A	N/A
12/24	7.4	(5.6)	(0.06)	0.00	N/A	N/A
12/25e	38.9	39.3	0.55	0.00	4.8	N/A
12/26e	43.3	32.0	0.43	0.00	6.1	N/A

Note: PBT and EPS are normalised, excluding intangibles, exceptional items and share-based payments.

Progress made across the pipeline in Q125

With the Phase III study endpoints finalised in March, Oryzon is working on preparing the additional data requested by the FDA. Study protocol submission is expected in Q225, with approval likely by Q2/Q325. We expect Phase III trials to commence in 2026 (launch in 2030), potentially under a partnering agreement. The oncology asset, iadademstat, is being tested as a combination treatment in five ongoing trials. The highlight in Q1 was commencement of patient enrolment in the NCI-sponsored Phase I/II trial in SCLC. We expect this to inform Oryzon's decision on whether to carry out its in-house STELLAR trial, a key pipeline priority. We look forward to the next data readout from the Phase Ib FRIDA study in AML, to be announced at the ASH conference in December 2025.

New funds raised provide operational flexibility

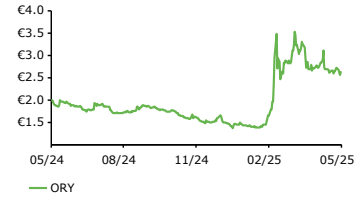
Oryzon ended Q125 with a gross cash balance of €3.8m, which was bolstered post-period with proceeds from the €30m equity raise and the announced €13.3m in grant income under the Med4Cure project. We expect the combined funds (c €47m) to provide operational headroom through 2027, assuming the Phase III BPD trials are undertaken under an out-licensing partnership.

Valuation: Adjusts to €862.4m or €11.0/share

Our long-term assumptions for the vafidemstat CNS programmes are unchanged, but we tweak our estimated launch timelines for iadademstat in AML (2031 vs 2029 previously) and SCLC (2032 vs 2030) based on current progress. Along with adjustments for the latest pro forma net cash position, this results in our valuation shifting to €862.4m (€885.1m previously). Our revised per-share valuation of €11.0 (from €13.5) reflects the increased share count post the equity raise.

Price	**€2.63**
Market cap	**€207m**
Pro forma net cash/(debt) at 31 March 2025 (including proceeds from the April 2025 equity raise and grant income)	€31.2m
Shares in issue	78.5m
Free float	82.0%
Code	ORY
Primary exchange	MADRID
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(5.4)	55.6	34.7
52-week high/low		€3.7	€1.4

Business description

Spanish biotech Oryzon Genomics is focused on epigenetics. Iadademstat is being explored for acute leukaemias, small-cell lung cancer and neuroendocrine tumours. Central nervous system (CNS) asset vafidemstat has completed several Phase IIa trials and a Phase IIb trial in borderline personality disorder (preparations for Phase III are underway). It is also currently involved in a Phase IIb trial for schizophrenia.

Next events

Clinical protocol submission for Phase III in BPD	Q225
FDA clearance for Phase III	Q2/Q325

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Encouraging pipeline progress in Q125

Oryzon's business model is a mix of self-funded, investigator-sponsored and collaborative studies, which aim to minimise the risks related to drug development while offering opportunities to explore therapeutic and commercial potential across a wide range of indications. Q125 saw the company make progress across several of its pipeline programmes, spanning both the central nervous system (CNS, vafidemstat) and oncology (iadademstat) indications.

Vafidemstat (CNS)

Borderline personality disorder (BPD): this is Oryzon's most clinically advanced in-house programme and the company's primary value driver. Following the positive end of Phase II (EoP2) meeting with the FDA in Q424, the company has been working on finalising the study protocol for the Phase III programme (PORTICO-2) in BPD in collaboration with its newly founded Clinical Advisory Board (CAB). In March 2025, Oryzon announced that it had defined the primary and key secondary endpoints for its planned Phase III clinical trial, in alignment with FDA expectations. As expected, STAXI-2 Trait Anger was established as the primary endpoint, in which vafidemstat had previously shown a statistically significant benefit in the Phase IIb PORTICO study (as a secondary endpoint). The secondary endpoints will involve patient-rated and clinician-rated scales. Management has indicated that Oryzon is on track to submit the clinical trial protocol as well as the additional complementary data requested by the FDA, in Q225.

Given that BPD has no approved treatments or well-defined study endpoints, we continue to believe there is a high probability that Oryzon will receive regulatory clearance for the Phase III programme, which we expect by Q2/Q325. We estimate that the pivotal study will commence in early 2026, contingent on capital adequacy and funding. For our analysis, we assume that the Phase III programme will be undertaken under an out-licensing partnership, to be signed in H225. Note that, based on feedback from regulators, the Phase III programme may require either one or two clinical trials, to be run in parallel or sequentially. The trials will be similar in design, each enrolling c 350 patients, randomised 1:1 to receive either vafidemstat or placebo for an 18-week treatment duration. Our model assumes two separate Phase III studies for a total cost of c €80m.

Schizophrenia: the Phase IIb EVOLUTION trial, which commenced in November 2021, is evaluating vafidemstat as a potential treatment to address the negative symptoms of schizophrenia as a primary focus, with secondary endpoints focused on positive symptoms and cognitive impairment. It is being carried out across multiple hospitals in Spain, with the programme partially funded by the Spanish Ministry of Science and Innovation. In late 2024, Oryzon announced that the enrolment target for the study has been increased to 220 from 100 patients previously, following a re-evaluation of effect sizes observed in its BPD programme and to ensure that the study is sufficiently powered. According to the latest available information, the trial is continuing to recruit patients, although the total number of patients recruited and treated to date has not been disclosed. We note that patient enrolment has been more protracted than we had anticipated, although we believe the pace is likely to pick as the BPD Phase III programme gets underway and resources are freed up.

Iadademstat (oncology)

Extensive-stage small cell lung cancer (SCLC): a key development post-period was the initiation of patient dosing in the Phase I/II clinical trial evaluating iadademstat in combination with immune checkpoint inhibitors in first-line, extensive-stage SCLC. This trial will be conducted under the Cooperative Research and Development Agreement (CRADA) signed with the National Cancer Institute (NCI) in the US in 2022. The study will be sponsored by the NCI and aims to recruit 40–50 patients. We note that results from this trial hold considerable importance for Oryzon, as the study data are planned to be used to refine the design for the self-sponsored, randomised Phase Ib/II STELLAR trial, which will evaluate iadademstat in the same indication. Management expects that data from the study could allow Oryzon to move the STELLAR trial to Phase II, foregoing the need for the Phase Ib dose-finding and tolerability study.

Relapsed/refractory (r/r) acute myeloid leukaemia (AML): another key value driver for Oryzon in the oncology space is the Phase Ib/II FRIDA study (self-sponsored) assessing iadademstat in combination with gilteritinib as a potential treatment for r/r AML in patients harbouring the FLT3 mutation. The study aims to recruit c 45 patients across the US and, according to the latest available information, a total of 13 patients (across two cohorts) have completed the study (showing desirable safety and antileukemic activity to date) and a third cohort has been completely enrolled. We look forward to the next interim update, which will be presented at the American Society of Hematology (ASH) meeting in December 2025. Based on the results, Oryzon plans to discuss the next steps for the programme with the FDA.

First-line AML: iadademstat is also being studied as a first-line treatment in AML in two separate Phase I trials, in combination with the standards of care, venetoclax and oral azacitidine. According to the Q125 release, both studies – one sponsored by NCI under the CRADA agreement and the other sponsored by the Knight Cancer Institute at Oregon Health & Science University (OHSU) – are currently recruiting patients. Note that, in January 2025, the NCI-sponsored study enrolled its first patient (n=45). For the OHSU-sponsored study (n=25), in September 2024 the first patient was dosed and, as of Oryzon's update in February 2025, the first two cohorts had been enrolled.

Myelodysplastic syndrome (MDS): in late 2024, Oryzon announced another investigator-sponsored study, a Phase I dose-finding trial of iadademstat in combination with azacitidine in MDS, a rare form of blood cancer. According to the Q125 report, the study continues to enrol patients (first cohort enrolled) and the first patient was dosed in January 2025.

Financials

No surprises in Q125 operating performance

Oryzon's Q125 results were unsurprising and broadly in line with our expectations. As a clinical-stage company, Oryzon does not recognise any revenue from product sales, although we highlight that it capitalises part of its R&D investments, reflecting this as other income. This partially offsets the R&D expenses booked in the income statement. In Q125, Oryzon recorded €2.0m as other income (€2.2m in Q124). R&D expenses (70.5% of total operating expenses vs 75.0% in Q124) for the period came in at €2.4m (the same as the Q124 figure), of which €2.1m related to clinical development and the other €0.3m to other R&D activities. Note that R&D expenses during the quarter were 30–40% higher than in the previous two quarters (Q3/Q424) and we believe this may be connected to preparatory activities around the forthcoming trial protocol submission (in Q225) for the Phase III studies in BPD. We therefore see the possibility of these expenses coming down slightly in H225. Personnel expenses rose by 17.5% y-o-y to €1.0m (Q124: €0.87m) with the increase primarily related to higher wage and salary expenses. Net loss was reported at €1.7m, c 48% higher than the Q124 figure of €1.1m.

Increased operational flexibility with post-period funding

Oryzon ended Q125 with net debt of €12.1m. This includes €3.8m in cash and cash equivalents, €8.8m in short-term debt (bonds: €3.3m, credit institutions: €4.8m, others: €0.8m) and €7.1m in long-term debt (credit institutions: €3.4m, others: €3.7m). Post period, in April 2025, the company raised €30m through an oversubscribed equity issue, against an issue of 12.8m new shares, at €2.35 per share. We note that the issue was straight equity (without attached warrants) and upsized from the initially planned €25m due to significant market interest. Management communicated that the offering was significantly oversubscribed with strong investor demand, noting that €15m of the round was anchored by a US-based institutional investor, with the remaining demand filled by investors across the US, Europe and Spain. We understand that the anchor investor was Heights Capital Management, which becomes the largest shareholder in the company with a c 8% stake. Note that Oryzon also has a €45m convertible debt facility at hand (4,500 bonds worth €10,000 each; November 2027 maturity), of which €15m has been utilised to date. We believe the increased financial flexibility provided by the recent equity raise could reduce the company's reliance on drawdowns from the convertible debt facility.

In May 2025, the company announced that it had been awarded a €13.26m (US$15m) non-dilutive grant under the Med4Cure initiative, part of the Important Project of Common European Interest framework, launched in May 2024. As an associate partner, Oryzon will undertake the development of project VANDAM (validation of epigenetic agents for neuro-related rare diseases applying a personalized medicine approach), focused on personalised medicine approaches in rare and orphan diseases. The grant represents c 64% of the €20.68m accepted budget for the project, which will run until August 2026. Disbursement is expected in the coming weeks, pending final administrative approvals, and will be paid out in a single tranche. As part of this initiative, Oryzon will initially pursue indications of aggression in specific subtypes of autism spectrum disorder, such as Phelan-McDermid and Fragile X syndromes, leveraging its CNS asset, vafidemstat. The decision on a possible investigational new drug submission will be made in 2025. We believe this represents a natural expansion of Oryzon's existing programme in BPD, for which Phase III protocol submission to the FDA is anticipated in Q225, with clearance in Q2/Q325. Additionally, Oryzon plans to explore the therapeutic potential of its second lead candidate, iadademstat, in several challenging neuroendocrine cancer indications.

Estimates revision

Given that Oryzon's Q125 results were in line with our expectations, we maintain our previous estimates for revenues (including €30m in a risk-adjusted upfront payment for a licensing deal for vafidemstat, which we model in H225) and operating expenses in FY25. We also incorporate the expected €13.26m in grant income, reflecting it as other income in our FY25 projections. Overall, we now project operating profit of €39.8m in FY25 versus €26.51m previously. For FY26, our estimated operating profit is unchanged at €31.8m. Based on pro forma gross cash at hand (c €47m), we estimate that the company has enough headroom to fund operations through 2027, excluding the Phase III trial costs for vafidemstat in BPD. We estimate this to be in the range of c €80m for the two Phase III trials (each with 350) required by regulators for approval. We have modelled that these trials will be undertaken under an out-licensing agreement, with the partner taking responsibility for funding the studies and subsequent commercialisation. For FY26, our revenue estimates include a projected milestone payment from vafidemstat's out-licensing partner, related to potential label expansion opportunities into aggression/agitation related to Alzheimer's disease. Note that this is subject to modification with greater clarity on the company's growth plans and activities for vafidemstat.

Valuation

We use a risk-adjusted net present value (rNPV) approach to value Oryzon's ongoing clinical programmes, forecasting to the end of the patent lives and using a flat discount rate of 12.5%. The most significant near-term value driver for Oryzon remains the BPD programme, under its CNS-focused initiatives. Following the Q125 results, our underlying assumptions for this programme are unchanged and we continue to project a 2030 market launch and peak sales of c €1.6bn. Vafidemstat in BPD constitutes c 35% of our valuation for Oryzon. We also continue to model label expansion opportunities in schizophrenia and Alzheimer's disease, with market launches in 2031 under both labels. This is subject to revision on further clarity on the BPD programme and management's plans for its CNS pipeline. Overall, vafidemstat contributes c 67% to our valuation for Oryzon.

As noted previously, Oryzon has several ongoing clinical trials for its oncology-focused asset, iadademstat although, barring the ongoing Phase Ib FRIDA study, all other trials are either investigator sponsored or undertaken under the company's CRADA agreement signed in July 2022 with the NCI, the sponsor for the studies. Although this minimises capital risk for Oryzon, it may potentially affect timelines, given the company's limited control and oversight. While we are encouraged that several of these trials commenced patient recruitment and dosing in Q125, given the early stages of clinical development we conservatively adjust the launch timelines for the AML and SCLC programmes, previously reflected in our valuation (to 2031 for AML vs 2029 previously and 2032 for SCLC vs 2030 previously). We keep all other underlying assumptions (peak sales, probability of success) broadly unchanged. Overall, iadademstat contributes c 29% to our valuation for Oryzon.

Adjusting for the aforementioned changes, as well as the latest pro forma net cash position (€31.2m, including the €30m equity raise and €13.3m in grants), we adjust our rNPV for Oryzon to €862.4m (vs €885.1m previously). The per-share valuation resets to €11.0 per share (€13.5/share previously), reflecting the increased number of shares outstanding following the issue of an additional 12.8m shares as part of the €30m equity issue (total shares outstanding increases to 78.5m from 65.8m previously).

A breakdown of our risk-adjusted net present value (NPV) valuation is shown in Exhibit 1.

Exhibit 1: Oryzon rNPV valuation

Product	Indication	Launch	Peak sales (US$m)	Value (€m)	Probability	rNPV (€m)	NPV/share (€/share)
Iadademstat	2L AML	2031	548	406.7	30%	111.9	1.4
	1L SCLC	2032	778	622.0	20%	120.3	1.5
Vafidemstat	BPD	2030	1,600	712.0	30%	308.7	3.9
	Schizophrenia, negative symptoms	2031	692	525.6	15%	138.4	1.8
	Aggression related to AD	2031	892	614.7	15%	151.8	1.9
Net debt at end-December 2024				31.2	100%	31.2	0.4
Valuation				**2,912.2**		**862.4**	**11.0**

Source: Edison Investment Research

Note that our model assumes a licensing deal for vafidemstat in H225, supporting cash flow positivity in FY25. If we assume self-development and commercialisation by Oryzon for all its programmes, we estimate that it would need to

raise c €90m between FY27 and FY29. Assuming these requirements are fulfilled through equity issues, we calculate that Oryzon needs to issue 34.2m shares (at the current trading price of €2.63) This would lead to an increase in shares outstanding to 112.8m (from 78.5m currently) and will dilute our per-share valuation to €8.4/share (from €11.0/share currently).

Exhibit 2: Financial summary

Accounts: Spanish GAAP. Year end 31 December (€000s)	2022	2023	2024	2025e	2026e
INCOME STATEMENT					
Total revenues	**15,698**	**14,192**	**7,359**	**38,925**	**43,250**
Cost of sales	(464)	(244)	(302)	(317)	(333)
Gross profit	15,234	13,948	7,057	38,608	42,917
Gross margin %	*97.0%*	*98.3%*	*95.9%*	*99.2%*	*99.2%*
SG&A (expenses)	(3,163)	(3,390)	(3,447)	(3,482)	(3,516)
R&D costs	(13,681)	(12,177)	(5,369)	(8,500)	(7,500)
Other operating income/(expense)	(3,714)	(2,777)	(2,596)	13,260	0
Exceptionals and adjustments	0	0	79	0	0
Reported EBITDA	**(5,323)**	**(4,396)**	**(4,275)**	**39,886**	**31,900**
Depreciation and amortisation	(167)	(153)	(148)	(117)	(95)
Reported EBIT	**(5,490)**	**(4,549)**	**(4,423)**	**39,769**	**31,806**
Finance income/(expense)	(1,067)	(1,555)	(1,148)	(498)	205
Other income/(expense)	0	0	0	0	0
Reported PBT	**(6,557)**	**(6,104)**	**(5,571)**	**39,271**	**32,011**
Income tax expense (includes exceptionals)	2,325	2,751	1,906	2,328	2,117
Reported net income	**(4,231)**	**(3,353)**	**(3,665)**	**41,600**	**34,128**
Basic average number of shares, m	53.3	57.6	63.4	75.4	78.5
Basic EPS (€)	(0.08)	(0.06)	(0.06)	0.55	0.43
Adjusted EBITDA	(5,323)	(4,396)	(4,355)	39,886	31,900
Adjusted EBIT	(5,490)	(4,549)	(4,502)	39,769	31,806
Adjusted PBT	(6,320)	(6,004)	(5,740)	39,271	32,011
Adjusted EPS (€)	(0.07)	(0.06)	(0.06)	0.55	0.43
BALANCE SHEET					
Property, plant and equipment	611	481	356	263	194
Intangible assets	75,843	89,895	97,096	105,997	114,221
Investments	31	26	127	127	127
Deferred tax assets	2,050	2,222	2,390	2,390	2,390
Total non-current assets	**78,535**	**92,624**	**99,969**	**108,777**	**116,932**
Cash and equivalents	21,317	12,257	5,619	64,880	87,826
Trade and other receivables	3,709	1,909	3,019	2,464	2,742
Inventories	10	6	3	3	3
Other current assets	129	104	107	107	107
Total current assets	**25,165**	**14,276**	**8,748**	**67,454**	**90,678**
Deferred tax liabilities	2,050	2,222	2,390	2,390	2,390
Long term debt	10,346	6,335	7,455	7,432	5,030
Other non-current liabilities	0	155	91	91	91
Total non-current liabilities	**12,396**	**8,711**	**9,935**	**9,913**	**7,511**
Trade and other payables	5,742	4,210	2,878	3,544	3,211
Short term debt	12,920	12,194	8,809	4,081	4,067
Other current liabilities	70	11	52	52	52
Total current liabilities	**18,732**	**16,414**	**11,739**	**7,677**	**7,329**
Equity attributable to company	72,572	81,775	87,042	158,642	192,770
CASH FLOW STATEMENT					
Profit before tax	**(6,557)**	**(6,104)**	**(5,571)**	**39,271**	**32,011**
Cash from operations (CFO)	**(1,848)**	**(575)**	**(5,690)**	**42,937**	**33,613**
Capex	(76)	0	0	0	0
Acquisition of intangible assets	(14,195)	(14,503)	(7,710)	(8,925)	(8,250)
Other investing activities	(1)	(1)	(102)	0	0
Cash used in investing activities (CFIA)	**(14,271)**	**(14,504)**	**(7,811)**	**(8,925)**	**(8,250)**
Net proceeds from issue of shares	(932)	(1,880)	1,497	30,000	0
Movements in debt	9,642	7,901	5,374	(4,751)	(2,416)
Other financing activities	0	0	0	0	0
Cash from financing activities (CFF)	**8,710**	**6,021**	**6,871**	**25,249**	**(2,416)**
Increase/(decrease) in cash and equivalents	**(7,408)**	**(9,060)**	**(6,638)**	**59,262**	**22,946**
Currency translation differences and other	1	(3)	(9)	0	0
Cash and equivalents at start of period	**28,725**	**21,317**	**12,257**	**5,619**	**64,880**
Cash and equivalents at end of period	**21,317**	**12,257**	**5,619**	**64,880**	**87,826**
Net (debt) cash	(1,264)	(6,078)	(10,538)	53,452	78,790
Free cash flow (CFO + Net capex + Intangible assets)	(16,118)	(15,078)	(13,399)	34,012	25,363

Source: Company accounts, Edison Investment Research

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