Oryzon Genomics

Making headway rolling into H225

Q225 results

Healthcare

31 July 2025

Oryzon Genomics has reported its Q225 results, summarising an active period. Its programme focused on vafidemstat in borderline personality disorder (BPD) remains a strategic priority, with the Phase III protocol submitted to the FDA in June. Clearance is anticipated in Q325, most likely in September, and could represent the most significant upcoming inflection point for the company. Trials relating to Orzyon's lead oncology candidate, iadademstat, continue to progress, with the next FRIDA update in acute myeloid leukaemia (AML) expected in December 2025. Oryzon has also expanded iadademstat's potential application to new non-malignant haematological indications; a clinical trial application (CTA) for a Phase Ib study in sickle cell disease (SCD) has been submitted to the EMA. Following the Q225 results update, our valuation adjusts to €887.2m or €11.3 per share (from €862.4m or €11.0 per share previously).

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	8.9	(3.9)	(0.01)	0.00	N/A	N/A
12/26e	48.3	35.9	0.48	0.00	5.5	N/A

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

FDA clearance for PORTICO-2 expected in Q325

In June 2025, Oryzon submitted the Phase III protocol to the FDA to initiate the PORTICO-2 trial. PORTICO-2 has been designed to target agitation and aggression (A/A) in BPD patients. The selected primary endpoint measure is the STAXI-2 Trait Anger score, a patient-reported measure in which vafidemstat demonstrated statistically significant improvements in the prior Phase IIb trial. The key secondary endpoint will be the score on the clinician-rated Modified Overt Aggression Scale (OAS-M). As discussed at the company's key opinion leader event, the use of these two endpoints in parallel should effectively capture both how patients feel at any given time and how their A/A changes over time. We anticipate FDA clearance for PORTICO-2 in September 2025, and expect the trial to start in 2026.

Iadademstat presents expanding opportunities

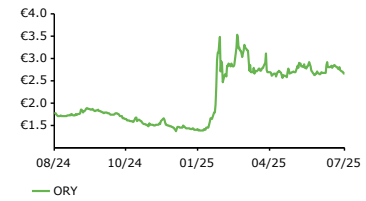
Iadademstat is being evaluated across a range of cancers, including AML, small cell lung cancer (SCLC) and myelodysplastic syndrome (MDS). In its Q225 update, Oryzon announced the expansion of iadademstat into non-malignant haematological indications, with an initial focus on SCD, based on encouraging preclinical research and the role of LSD1 (the target of iadademstat) in the disease. A response on the CTA for Phase Ib is also expected in September.

Valuation: €887.2m or €11.3 per share

We raise our probability of success for vafidemstat in BPD to 40% (30% previously) following the Phase III protocol submission. As a slight offset, we now conservatively assume a licensing deal in H126 versus H225 previously. All other long-term assumptions for Oryzon's clinical programmes remain unchanged. After updating for the latest pro-forma net cash position and rolling our model forward, our valuation stands at €887.2m or €11.3/share (from €862.4m or €11.0/share previously).

Price	**€2.67**
Market cap	**€213m**
Pro forma net cash/(debt) at 30 June 2025 (including the €13.3m grant income received in July 2025)	€26.3m
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	1.9	0.9	44.5
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 additional indications. Central nervous system asset vafidemstat has completed several Phase IIa trials and a Phase IIb trial in borderline personality disorder (Phase III clinical trial protocol submitted to the FDA). It is also currently involved in a Phase IIb trial for schizophrenia, and management is preparing for an additional Phase II trial in autism spectrum disorder.

Next events

FDA clearance for PORTICO-2	September 2025
EMA clearance for sickle cell disease trial	September 2025
FRIDA update	December 2025

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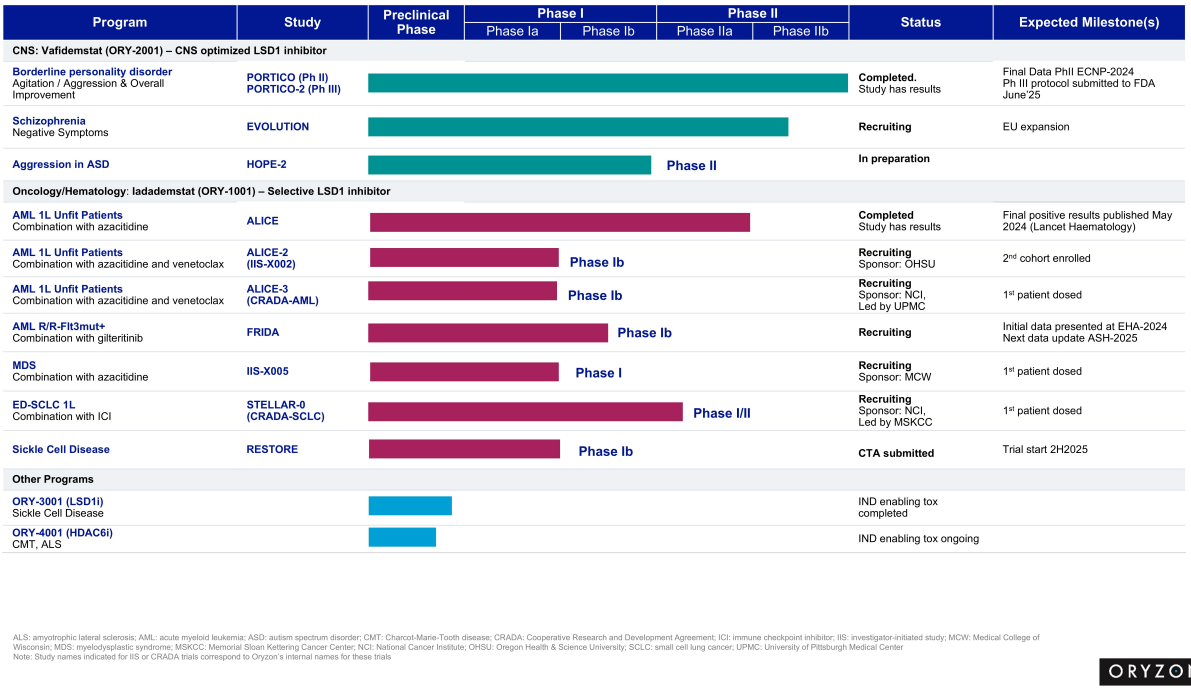
Broad clinical development pipeline continues to progress

Oryzon continues to boast a diverse clinical development pipeline, with assets focused on both central nervous system (CNS) conditions (vafidemstat) and oncology/haematology indications (iadademstat), somewhat offsetting the company's exposure to binary risk events, such as the outcome of clinical trials. The programmes comprise a mix of self-funded trials, as well as investigator-initiated studies and collaborations. Orzyon is a leader in the field of epigenetics, and management remains confident that its two proprietary candidates (both inhibitors of lysine-specific demethylase 1, LSD1, also known as KDM1A) may effectively address unmet needs across the range of indications being targeted (Exhibit 1).

Exhibit 1: Oryzon's pipeline focused on CNS conditions and oncology/haematology indications



Source: Company resources

Vafidemstat: Optimised to address CNS conditions

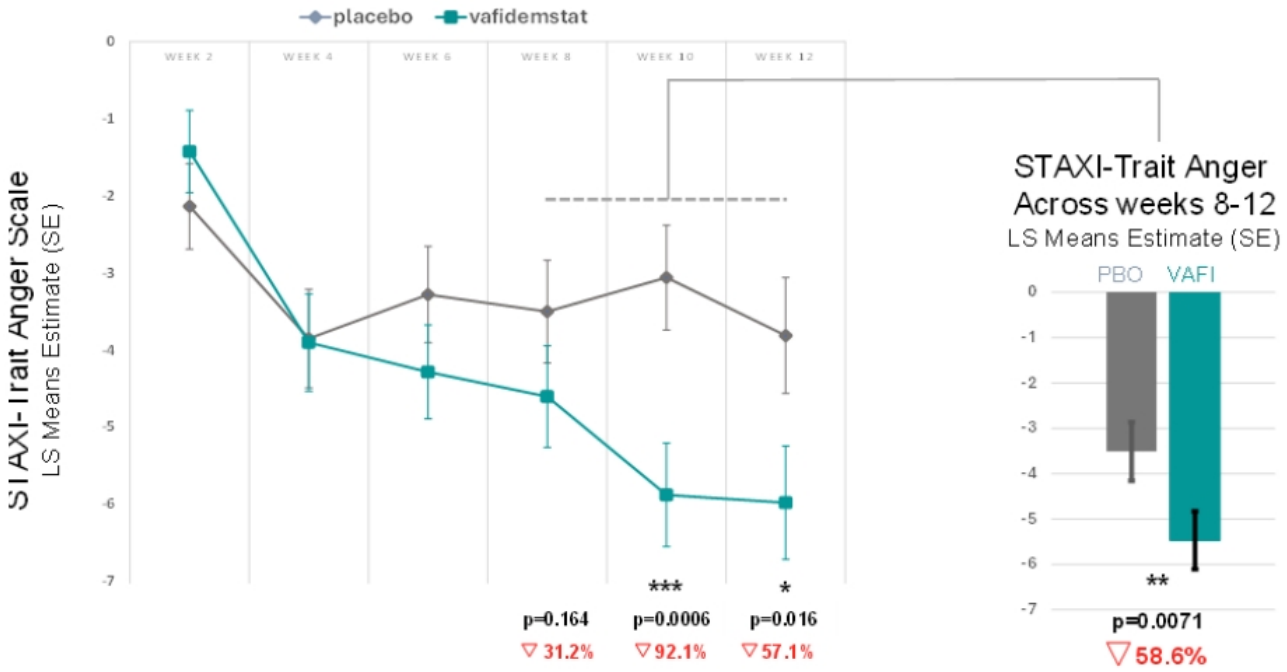
Borderline personality disorder

Oryzon's most advanced clinical programme is focused on vafidemstat's potential to address A/A in BPD patients, a neglected condition with no FDA-approved drugs, despite its global prevalence of c 1–2%. Clinicians are currently limited to prescribing medications, such as antipsychotics and/or mood stabilisers, off-label, though this approach often has limited durability and is associated with undesirable side effects. Hence, we see a potentially sizeable opportunity in this space for Oryzon, should subsequent clinical data be supportive. Most recently in the clinic, the drug candidate completed a Phase IIb trial (PORTICO), and although the primary endpoints were not met with statistical significance, vafidemstat was favoured over placebo in all measures, and the key secondary endpoint, STAXI-2 Trait Anger score, was met with statistical significance (Exhibit 2). Following a productive end-of-Phase II meeting with the FDA, Oryzon has been focused throughout late-2024 and H125 on preparing to submit a formal protocol to the regulators for PORTICO-2. This was finalised based on discussions with the FDA, as well as input from leading US psychiatry experts, and submitted in June 2025.

PORTICO-2 has been designed as a randomised, double-blinded, placebo-controlled, multi-centre Phase III trial (expected n=350), which aims to evaluate the safety and efficacy of vafidemstat in BPD patients. While the STAXI-2 Trait Anger score had been previously defined as the primary endpoint, we note that the key secondary endpoint, OAS-M,

is a clinician-rated scale used to assess aggression in psychiatric conditions. Beyond these two key endpoints focused specifically on A/A, additional secondary outcome measures will be utilised to evaluate more general improvements in BPD symptoms and quality of life. As discussed above, we expect a regulatory outcome for PORTICO-2 in September 2025, which we anticipate will be followed by a trial launch from 2026, potentially under a partnering agreement.

Exhibit 2: Phase IIb PORTICO STAXI-2 Trait Anger data



Source: Company resources

We note that Oryzon has continued to make headway in strengthening its intellectual property profile for the candidate. In July 2025, the company announced that it had received new 'decision to grant' communications from the Canadian Intellectual Property Office and the Israel Patent Office. This is for its patents, titled 'Methods of treating behavior alterations', for vafidemstat as a potential treatment to address aggression and social withdrawal. Once granted, these patents will remain in force until at least 2038 in Canada and Israel, excluding any potential patent term extensions (which have the potential to add additional years of protection). Management also noted that corresponding patents have been granted or allowed in Europe, Australia, Hong Kong, South Korea, Malaysia, the Philippines and Russia, and additional applications are pending in other countries, fortifying the protection of the candidate.

Schizophrenia

Vafidemstat is involved in the EVOLUTION programme, focused on schizophrenia. This is a double-blind, randomised, placebo-controlled Phase IIb trial exploring the drug candidate as a potential treatment for the negative symptoms of schizophrenia as the primary focus, with secondary outcome measures based on positive symptoms and cognitive impairment. While the precise number of patients currently enrolled in the trial has not been disclosed, management has communicated that, based on insights from the PORTICO trial in BPD, it has been determined that 84 patients (previously 220) should be sufficient to demonstrate any potential clinically meaningful effect of vafidemstat. The programme was previously limited to hospital sites across Spain, as it was partially funded by the Spanish Ministry of Science and Innovation. However, according to the latest update, thanks to increased funding at hand, Oryzon is expanding the trial to additional European countries. In our view, this represents a positive update to the programme, offering the potential to include a wider demographic and accelerate the pace of patient recruitment. We await further details on the next update for EVOLUTION.

Potential to expand

Given the promise that vafidemstat has shown in treating A/A in BPD, Oryzon has taken steps to expand the application of the candidate to other neurological conditions where A/A is common. Prior research (notably, the Phase IIa REIMAGINE trial) has highlighted vafidemstat's potential to address A/A in conditions such as autism spectrum disorder (ASD) and attention deficit hyperactivity disorder, as well as in Alzheimer's disease (REIMAGINE-AD trial). As per the Q225 update, Oryzon has confirmed that it is taking further action in this area, with plans to initiate a new Phase

II programme to evaluate vafidemstat in aggression associated with ASD, which will be financially supported by the 'Important Project of Common European Interest' (EU-IPCEI) grant (Med4Cure project). This new Phase II trial, named HOPE-2, will include both genetically-defined ASD subpopulations, such as Phelan-McDermid Syndrome patients, as well as sporadic (non-genetic) ASD subpopulations. Given vafidemstat's track record in the clinic to date, including its favourable safety profile and efficacy in A/A in BPD, we believe this could represent a potentially sizeable opportunity for Oryzon, should efficacy in these additional indications be sustained.

In the recently recorded executive interview below, Carlos Buesa, CEO of Oryzon Genomics, provides a detailed overview of the company's current activities in the CNS space.

Oryzon Genomics – executive interview (July 2025)

Source: Edison Investment Research

Iadademstat: Potential in oncology (and additional) indications

Acute myeloid leukaemia

Oryzon's lead oncology programme, the self-sponsored Phase Ib US-based FRIDA trial (expected n=45), is assessing iadademstat in combination with gilteritinib in patients with relapsed/refractory AML harbouring the FLT3 mutation, targeting the second-line setting. The primary analysis is focused on safety and a recommended Phase II dose, while secondary endpoint measures are focused on efficacy. Preliminary data have been encouraging, and the next update is due to be presented at the American Society of Hematology meeting in December 2025, potentially representing an upcoming catalyst for Oryzon. Should the results of the FRIDA programme be positive, Oryzon has an agreement with the FDA to conducting a meeting to discuss the most effective plan for further development efforts in this indication, which could include an accelerated pathway.

In addition to FRIDA, iadademstat is also being evaluated in the first-line setting for AML in two separate dose-finding Phase I studies, both of which explore potential synergy of the drug candidate in combination with venetoclax and oral azacitidine (standard of care treatments in AML). One of these studies is under a cooperative research and development agreement (CRADA) with the National Cancer Institute (NCI), and the other is an investigator-initiated trial in collaboration with Oregon Health & Science University. Both studies are underway, and we expect updates as information becomes available.

Small cell lung cancer

Iadademstat, in combination with immune checkpoint inhibitors (ICIs), is being assessed in SCLC as part of a CRADA with the NCI, in patients with extensive disease, targeting the first-line setting. Patient recruitment commenced in April 2025, and the programme ultimately aims to enrol 45–50 patients. Primary objectives are focused on safety, tolerability, dose-finding and efficacy. Multiple leading US-based cancer centres are involved in this trial (expected to include over 30 sites), including the Memorial Sloan Kettering Cancer Center (MSKCC) as one of the main sites. Should the results of this programme be positive, they may support Oryzon's plans for its STELLAR programme, a randomised, multi-centre Phase II study of iadademstat in combination with an ICI for first-line extensive-stage SCLC.

Additional indications

Oryzon is also exploring iadademstat in MDS, a rare form of blood cancer, in an investigator-initiated Phase I programme, with patient dosing having commenced in January 2025. The programme, led by the Medical College of Wisconsin, continues to actively enrol patients. We await further updates.

In its Q225 results update, Oryzon laid out its plans to expand the potential application of iadademstat, by exploring its potential in non-malignant haematological indications, such as SCD and essential thrombocythemia (ET). It was announced that the initial focus will be on SCD, with a CTA submitted to the EMA for this indication. The trial, named RESTORE, will aim to enrol 40 patients, with the primary endpoint relating to safety and tolerability, while determining the recommended dose for Phase II. One of the key secondary endpoints will measure the activity of iadademstat in inducing foetal haemoglobin. A regulatory decision is anticipated in September 2025. Management believes that the commercial potential could be sizeable in this indication, given the performance of Pfizer's Oxbryta (generic name: voxelotor), before it was withdrawn from the market due to safety concerns. The field has evolved significantly in recent years with the approval of gene therapies for the condition, however, given their large price tags, we believe the opportunity remains for effective treatments that may come in at a more accessible price point. Management has also noted that a second trial, to assess iadademstat in ET, is in preparation, with the intention to submit the CTA to the EMA within H225.

Financials

Oryzon's Q225 and H125 results were broadly in line with our expectations. R&D expenses for the quarter were €2.5m, up c 14% from €2.2m in Q224, and at a similar run-rate to the Q125 figure of €2.4m. The H125 R&D expenses were €4.9m (H124: €4.6m) of which €4.2m have been capitalised, which management accounts for as other income in the profit and loss statement. Personnel expenses rose materially in H125, up 40% y-o-y to €2.4m, with a 64% y-o-y jump in H2. Management has attributed this primarily to the accrual of a provision (€435k) related to the long-term incentive plan (2023–25) in H125, as well as lower salary and wage expenses in H124 (due to the reversal of a €198k provision). Overall, operating loss for the period was €2.9m versus a loss of €2.4m in H124.

Notably, Oryzon reported a net financial income of €4.1m in H125 versus a loss of €454.6m in H124. This material difference was driven by lower implicit interest related to the November 2023 €45m convertible bond programme with Nice & Green (Oryzon has drawn down €15m to date), resulting in lower interest expenses (€335.5k vs €528.8k in H124) and higher interest income (€380.1m vs €62.2m in H124). We note that this convertible financing agreement has subsequently been terminated (as of July 2025). Of the €15m drawn down, €9.52m had been converted to equity by June 2025 and a further €1.97m was converted in early July (against an issue of 1.3m shares), prior to the termination of the agreement. As part of the agreement closure, Oryzon has paid a total of €4.7m to Nice & Green as consideration for the convertible debt outstanding at end-H125 (c €3.0m), as well as in exchange for the 1.3m shares issued under the latest July conversion (these shares will be deemed as treasury shares). Net loss for the period was €1.6m, up from €1.0m in H124. The free cash outflow for H125 was €5.3m, an improvement over the €8.1m recorded in H124, supported by €1.7m in tax benefits recognised in H225.

Oryzon ended H125 with a net cash balance of €13.0m. This includes €31.1m in cash and cash equivalents, €9.4m in short-term debt (bonds – €3.0m; credit institutions – €5.7m; other – €0.7m) and €8.7m in long-term debt (credit institutions – €5.0m; other – €3.6m). The cash position was supported by a €30m equity issue in April 2025 against an issue of 12.8m new shares, at €2.35 per share. As highlighted above, this allowed the company to prematurely close out the €45m convertible debt facility. With this new financing, management plans to accelerate patient recruitment (n=84) in the ongoing Phase II EVOLUTION trial in schizophrenia by expanding test centres into five other European countries (it was previously conducted exclusively in Spain).

Post-period, on 25 July 2025, Oryzon received the €13.26m (US$15m) non-dilutive grant under the Med4Cure initiative, part of the EU-IPCEI framework, launched in May 2024. The grant represents c 64% of the €20.68m accepted budget for the project, which will run until August 2026. As part of this initiative, Oryzon has announced its plans to initiate a new Phase IIb trial (HOPE-2) to evaluate vafidemstat as a treatment for aggression in specific genetically-defined subpopulations of ASD, such as Phelan-McDermid Syndrome. The trial will be conducted in Spain initially.

Estimates revision

Based on the H125 results and improved pipeline visibility, we have made certain adjustments to our near-term estimates. For FY25, while we had previously assumed a partnering deal for vafidemstat in H225, with a risk-adjusted upfront payment of €30m, we now conservatively move this timeline to H126. This is based on the update by management that the FDA decision on the clinical trial protocol submission in BPD is now expected in late Q325. Our R&D estimate for FY25 is unchanged at €8.5m. With the clinical trial protocol for vafidemstat in BPD submitted to the FDA in June 2025 (a decision is anticipated in H225 with Phase III likely to commence in H126), R&D expenses related to the BPD programme will potentially decrease in H2, although we expect this to be offset by the expansion of the EVOLUTION trial into other European geographies as well as preparatory activities for the new trials planned, including HOPE-2. For personnel expenses, we raise our FY25 expectations to €4.1m (from €3.5m previously) to reflect the H125 figure. We note that while our last published estimates had accounted the entire €13.26 Med4Cure grant as income, we now understand that this would be capitalised and amortised over a longer duration (€0.4m to be recognised in the FY25 P&L). We therefore adjust our other income estimate for FY25 to reflect this. Overall, we now project an operating loss of €3.8m in FY25 versus an operating profit of €39.8m previously. For FY26, we estimate an operating profit of €36.5m versus €31.8m previously. We continue to see the company funded through 2027 with the current capital on books (excluding trial costs related to the BPD programme, which we assume will be borne by the licensing partner).

Valuation

We value Oryzon using a risk-adjusted net present value (rNPV) approach to its ongoing clinical programmes, forecasting to the end of the patent lives and using a flat discount rate of 12.5%. Following the H125 results, we keep our underlying long-term estimates unchanged across all clinical programmes, save for BPD, where we raise our probability of success to 40% (from 30% previously) after the successful submission of the Phase III clinical trial protocol to the FDA in June. This raises our rNPV of the programme to €343.3m (from €308.7m previously) with the increase partially offset by the slight timeline change we have introduced in relation to the expected licensing deal for vafidemstat (we now expect this in H126 versus H225 previously).

This, along with the latest pro-forma net cash position (€26.3m, including the €13.26m grant payment received in July 2025), results in our valuation for Oryzon adjusting to €887.2m or €11.3 per share, from €862.4m or €11.0 per share previously.

A breakdown of our rNPV valuation is shown in Exhibit 3.

Exhibit 3: Oryzon rNPV valuation

Product	Indication	Launch	Peak sales (US$m)	Value (€m)	Probability	rNPV (€m)	NPV/share (€/share)
Iadademstat	2L AML	2031	548	416.9	30%	114.7	1.5
	1L SCLC	2032	778	637.7	20%	123.3	1.6
Vafidemstat	BPD	2030	1,600	713.0	40%	343.3	4.4
	Schizophrenia, negative symptoms	2031	692	527.9	20%	144.9	1.8
	Aggression related to AD	2031	892	619.2	15%	134.7	1.7
Pro-forma net debt at end-June 2025				26.3	100%	26.3	0.3
Valuation				**2,941.0**		**887.2**	**11.3**

Source: Edison Investment Research

As noted above, we now model a licensing deal for vafidemstat in H126, supporting profitability and cash flow positivity in FY26. As an added sensitivity, if Oryzon were to self-develop and commercialise all its programmes, we estimate it needing to raise c €90m between FY27 and FY29. If these requirements are fulfilled through equity issues, we calculate Oryzon needing to issue 33.7m shares (at the current trading price of €2.67). This would lead to an increase in shares outstanding to 112.3m (from 78.5m currently) and would dilute our per-share valuation to €8.7 per share (from €11.3 per share currently).

Exhibit 4: 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**	**8,925**	**48,250**
Cost of sales	(464)	(244)	(302)	(317)	(333)
Gross profit	15,234	13,948	7,057	8,608	47,917
Gross margin %	*97.0%*	*98.3%*	*95.9%*	*96.4%*	*99.3%*
SG&A (expenses)	(3,163)	(3,390)	(3,447)	(4,137)	(4,178)
R&D costs	(13,681)	(12,177)	(5,369)	(8,500)	(7,500)
Other operating income/(expense)	(3,714)	(2,777)	(2,596)	366	350
Exceptionals and adjustments	0	0	79	(2)	0
Reported EBITDA	**(5,323)**	**(4,396)**	**(4,275)**	**(3,665)**	**36,589**
Depreciation and amortisation	(167)	(153)	(148)	(117)	(95)
Reported EBIT	**(5,490)**	**(4,549)**	**(4,423)**	**(3,781)**	**36,494**
Finance income/(expense)	(1,067)	(1,555)	(1,148)	(148)	(556)
Other income/(expense)	0	0	0	0	0
Reported PBT	**(6,557)**	**(6,104)**	**(5,571)**	**(3,929)**	**35,939**
Income tax expense (includes exceptionals)	2,325	2,751	1,906	3,326	2,117
Reported net income	**(4,231)**	**(3,353)**	**(3,665)**	**(603)**	**38,056**
Basic average number of shares, m	53.3	57.6	63.4	75.4	78.5
Basic EPS (€)	(0.08)	(0.06)	(0.06)	(0.01)	0.48
Adjusted EBITDA	(5,323)	(4,396)	(4,355)	(3,663)	36,589
Adjusted EBIT	(5,490)	(4,549)	(4,502)	(3,780)	36,494
Adjusted PBT	(6,320)	(6,004)	(5,740)	(3,927)	35,939
Adjusted EPS (€)	(0.07)	(0.06)	(0.06)	(0.01)	0.48
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	3,388	3,388
Total non-current assets	**78,535**	**92,624**	**99,969**	**109,775**	**117,930**
Cash and equivalents	21,317	12,257	5,619	18,794	46,017
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**	**21,368**	**48,869**
Deferred tax liabilities	2,050	2,222	2,390	3,388	3,388
Long term debt	10,346	6,335	7,455	15,653	13,251
Other non-current liabilities	0	155	91	91	91
Total non-current liabilities	**12,396**	**8,711**	**9,935**	**19,132**	**16,730**
Trade and other payables	5,742	4,210	2,878	3,544	3,211
Short term debt	12,920	12,194	8,809	3,701	3,687
Other current liabilities	70	11	52	52	52
Total current liabilities	**18,732**	**16,414**	**11,739**	**7,297**	**6,950**
Equity attributable to company	72,572	81,775	87,042	117,978	156,033
CASH FLOW STATEMENT					
Profit before tax	**(6,557)**	**(6,104)**	**(5,571)**	**(3,929)**	**35,939**
Cash from operations (CFO)	**(1,848)**	**(575)**	**(5,690)**	**735**	**37,540**
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	28,678	0
Movements in debt	9,642	7,901	5,374	(7,313)	(2,416)
Other financing activities	0	0	0	0	350
Cash from financing activities (CFF)	**8,710**	**6,021**	**6,871**	**21,365**	**(2,066)**
Increase/(decrease) in cash and equivalents	**(7,408)**	**(9,060)**	**(6,638)**	**13,175**	**27,224**
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**	**18,794**
Cash and equivalents at end of period	**21,317**	**12,257**	**5,619**	**18,794**	**46,017**
Net (debt) cash	(1,264)	(6,078)	(10,538)	(526)	29,090
Free cash flow (CFO + Net capex + Intangible assets)	(16,118)	(15,078)	(13,399)	(8,190)	29,290

Source: Company documents, Edison Investment Research

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