

Oryzon Genomics

All steady heading into 2025

FY24 results

Oryzon has reported its **FY24 results**, reflecting steady progress across its pipeline. Oryzon's highest value-driving programme remains vafidemstat in borderline personality disorder (BPD), which, following a positive end-of-Phase II (EoP2) meeting in October, is now Phase III-ready. As the company transitions into a Phase III organisation, it is reshaping its board of directors to enhance its US outreach, which we believe is a sensible strategy given that the US will be the key market for Oryzon's clinical candidates. In oncology, Oryzon continues its broad approach to bolster its data package for iadademstat in acute myeloid leukaemia (AML). FRIDA remains the top priority and the next update is expected in December 2025. Following the FY24 results, our valuation for Oryzon adjusts to €885.1m or €13.5/share (from €796m or €12.3/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	38.9	25.7	0.43	0.00	6.3	N/A
12/26e	43.3	30.8	0.50	0.00	5.3	N/A

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

Multiple inflection points on the horizon

The EoP2 meeting added confidence to Oryzon's BPD programme, with the FDA acknowledging agitation and aggression (A/A) as a therapeutic indication, and showing support for State-Trait Anger Expression Inventory 2 (STAXI-2) Trait Anger as a primary endpoint for Phase III (PORTICO-2). Encouragingly, vafidemstat showed a statistically significant benefit by this measure in Phase IIb. Oryzon also **announced** a new clinical advisory board, consisting of recognised leaders in psychiatry, to define and establish the endpoints for Phase III. In our view, the regulatory green light (expected in H125) for PORTICO-2 could be the most significant upcoming inflection point, and we estimate that PORTICO-2 could commence from H225. In oncology, the FRIDA trial (assessing iadademstat in combination with gilteritinib in AML patients with the FLT3 mutation) continues to enrol patients. After the June 2024 update, which showed antileukemic activity in the first two cohorts, we believe the next update may also be a key catalyst.

Improved headroom with convertible debt option

Oryzon closed FY24 with gross cash of €5.6m, supported by another €7m drawdown from the €45m convertible debt facility established in November 2023. The debt, unless converted, matures in 2027 and to date a total of €15m has been utilised. We expect the remaining tranches, if fully utilised, to provide a cash runway well into 2026, but expect a deal for vafidemstat in BPD to be signed before then.

Valuation: €885.1m or €13.5 per share

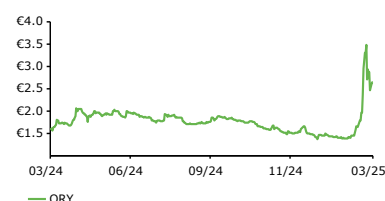
We keep our underlying assumptions for Oryzon's development programmes unchanged on the back of the FY24 results. We continue to project a market launch in BPD in 2030 under partnership and await the FDA's green light on the Phase III design. We upgrade Oryzon to €885.1m or €13.5/share (from €796m or €12.3/share previously), with the valuation reflecting the benefit from the model roll forward.

Healthcare

4 March 2025

Price	€2.67
Market cap	€164m
Net cash/(debt) at 31 December 2024	€(10.5)m
Shares in issue	65.8m
Free float	82.0%
Code	ORY
Primary exchange	MADRID
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	75.1	58.4	33.3
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 (SCLC) and neuroendocrine tumours. Central nervous system (CNS) asset vafidemstat has completed several Phase IIa trials and a Phase IIb trial in borderline personality disorder, and is in a Phase IIb trial for schizophrenia.

Next events

FDA clearance for PORTICO-2	H125
FRIDA trial update	December 2025

Analysts

Jyoti Prakash, CFA	+44 (0)20 3077 5700
Arron Aatkar, PhD	+44 (0)20 3077 5700

healthcare@edisongroup.com

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CNS and oncology pipelines going strong

Oryzon's two clinical-stage assets are vafidemstat for conditions of the central nervous system (CNS) and iadademstat for oncology indications (Exhibit 1). As Oryzon is a leader in the field of epigenetics, its drug candidates both inhibit lysine specific demethylase 1 (LSD1, or KDM1A), a histone-modifying enzyme forming parts of complexes implicated in the regulation of genes associated with various CNS conditions and cancers (Exhibit 2). The target represents, to our knowledge, a unique competitive position for Oryzon in the CNS space, with supporting proof-of-concept data from the Phase IIa REIMAGINE trial recently published in the journal *Psychiatry and Clinical Neurosciences*. In oncology, it has been validated by big pharma, with Merck acquiring Imago Biosciences for its LSD1 inhibitor for **\$1.35bn** in 2022 and Bristol Myers Squibb's CC-90011 (an LSD1 inhibitor) currently involved in a Phase II programme.

Both vafidemstat and iadademstat are involved in a wide range of active clinical programmes. Oryzon's epigenetic platform creates a growing pipeline, ultimately aiming to develop novel treatments to address unmet medical needs. The company's earlier-stage programmes include ORY-3001 (an LSD1 inhibitor targeting sickle cell disease) and ORY-4001 (an inhibitor of histone deacetylase 6 targeting neurological conditions such as Charcot-Marie-Tooth disease and amyotrophic lateral sclerosis). ORY-3001 has completed investigational new drug (IND)-enabling toxicology studies in preparation for the clinical stages of development, while IND-enabling toxicology studies are ongoing for ORY-4001.

Exhibit 1: Oryzon's clinical development pipeline

Program	Study	Preclinical Phase	Phase I		Phase II		Status	Expected Milestone(s)
			Phase Ia	Phase Ib	Phase IIa	Phase IIb		
CNS: Vafidemstat (ORY-2001) – CNS optimized LSD1 inhibitor								
Borderline personality disorder Agitation / Aggression & Overall Improvement	PORTICO						Completed. Study has results	Final Data 3Q24 ECNP-2024 EoP2 FDA meeting 3Q24 Ph III protocol submission 1H25 ★
Schizophrenia Negative Symptoms	EVOLUTION						Recruiting	Timeline updates in 2025
Kabuki Syndrome	HOPE			Phase Ib/II			IND in evaluation	IND in 2025 (subject to additional resources)
Oncology: Iadademstat (ORY-1001) – Selective LSD1 inhibitor								
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	ALICE-2 (IIS-X002)			Phase Ib			Recruiting Sponsor: OHSU	1 st cohort dosed
AML 1L Unfit Patients Combination with azacitidine and venetoclax	ALICE-3 (CRADA-AML)			Phase Ib			Recruiting Sponsor: NCI, Led by UPMC	1 st patient dosed
AML R/R-Fit3mut+ Combination with gilteritinib	FRIDA			Phase Ib			Recruiting	Initial data presented at EHA-2024 Next data update EHA-2025 ★
MDS Combination with azacitidine	IIS-X005			Phase I			Recruiting Sponsor: MCW	1 st patient dosed
Neuroendocrine High Grade R/R Combination with paclitaxel	C-X001 NET Basket						Recruiting Collab Study with FCCC	Study Updates 1H25
ED-SCLC 1L Combination with ICI	STELLAR-0 (CRADA-SCLC)				Phase I/II		IND Approved Sponsor: NCI, Led by MSKCC	FPI 1Q25
ED-SCLC 1L Combination with ICI	STELLAR				Phase II pivotal		In preparation ⁽¹⁾ Company sponsored	IND 2025
Other Programs								
ORY-3001 (LSD1) Sickle Cell Disease							IND enabling tox completed	
ORY-4001 (HDAC6) CMT, ALS							IND enabling tox ongoing	

ALS: amyotrophic lateral sclerosis; AML: acute myeloid leukemia; CMT: Charcot-Marie-Tooth disease; CRADA: Cooperative Research and Development Agreement; FCCC: Fox Chase Cancer Center; ICI: immune checkpoint inhibitor; IIS: investigator-initiated study; MCW: Medical College of Wisconsin; MDS: myelodysplastic syndrome; MSKCC: Memorial Sloan Kettering Cancer Center; NCI: National Cancer Institute; NETs: neuroendocrine tumors; OHSU: Oregon Health & Science University; SCLC: small cell lung cancer; UPMC: University of Pittsburgh Medical Center
⁽¹⁾ STELLAR trial to be informed by the data to be obtained in the CRADA-SCLC trial.
 Note: Study names indicated for IIS or CRADA trials correspond to Oryzon's internal names for these trials



Source: Company resources

Exhibit 2: Epigenetics and LSD1

Source: Oryzon corporate presentation

Strengthened board to support the advancing pipeline

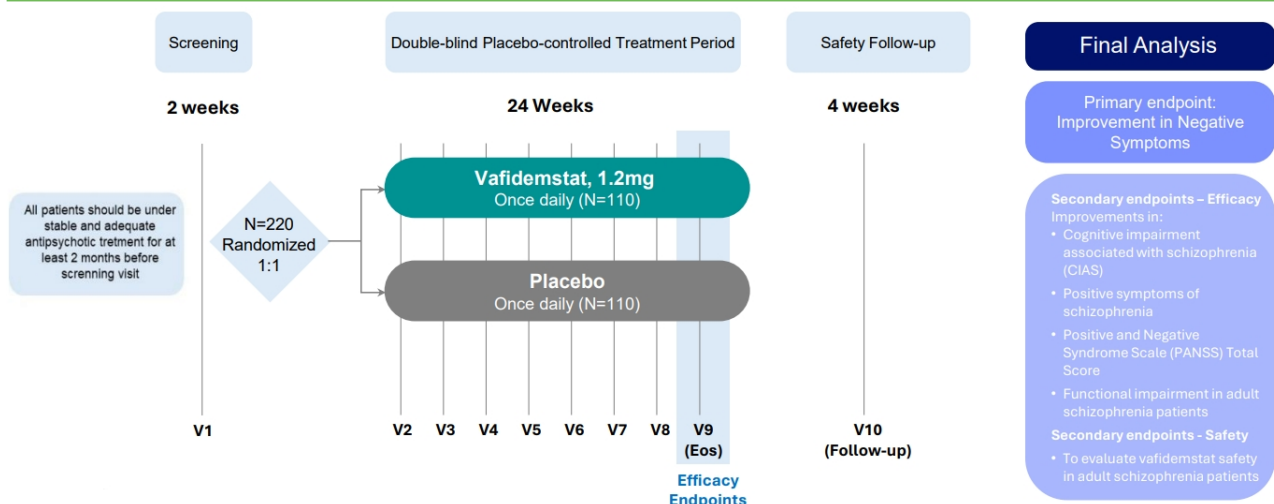
In January 2025, Oryzon [announced](#) its plans to reshape its board of directors to have more of a US focus, as the company edges closer to becoming a Phase III organisation for the first time. Management has communicated that its board will have three directors with Nasdaq and industry experience based in the San Francisco Bay Area, with the intention of expanding outreach and strengthening discussions with corporate partners and investors.

Vafidemstat: Lead BPD programme gearing up for Phase III

Oryzon continues to prepare for Phase III with its lead CNS programme in BPD. During Q424, management confirmed that it was [aligned](#) with the US FDA on its proposed plans for the Phase III PORTICO-2 trial. The company currently estimates that this will involve 350 patients randomised 1:1 to receive either vafidemstat or placebo for an 18-week treatment duration. Importantly, the FDA has acknowledged A/A as a therapeutic indication. This means that STAXI-2 Trait Anger, in which vafidemstat had previously shown a statistically significant benefit in the preceding Phase IIb PORTICO study, may be used as a primary endpoint. Secondary endpoints are likely to include both patient-rated and clinician-rated scales to assess A/A and overall BPD improvement. We note that the FDA has requested further research to show that STAXI-2 Trait Anger is a clinically meaningful endpoint, with similar supporting documentation to justify the selected secondary endpoints. Oryzon intends to carry out a qualitative research study on a subset of PORTICO-2 patients to provide validation of the endpoints used. The qualitative research study protocol will be submitted to the FDA for review and feedback before initiating PORTICO-2. In addition, psychometric properties and performance of the endpoints will be shared with the FDA before initiating Phase III. We believe these additional activities are expected given that BPD lacks clinically validated endpoints. With no approved drugs for the condition, we believe there is a sizeable opportunity for Oryzon, should the data continue to be as supportive as the prior PORTICO trial (see our [previous update note](#) for a detailed discussion of these results). Oryzon's FY24 results reaffirmed previous guidance that FDA clearance for Phase III should be within H125, potentially representing a near-term catalyst. We also believe that the [new clinical advisory board](#), which includes internationally recognised leaders in psychiatry and clinical trial research, should ensure that preparations run smoothly. We note that PORTICO-2 would be one of two registrational trials required by the FDA before Oryzon may file for regulatory approval.

Vafidemstat is also involved in the [EVOLUTION](#) trial (Exhibit 3). This is a Phase IIb clinical study assessing the candidate 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. A recent analysis of effect sizes in the BPD programme led to a re-evaluation and increase in the recruitment target for EVOLUTION (expected recruitment: 220 patients). According to the latest update from Oryzon, the trial continues to enrol patients, and it may be converted into a global trial, should suitable funding be secured. It is currently being conducted across multiple hospitals in Spain, with the programme partially funded by the Spanish Ministry of Science and Innovation.

Exhibit 3: EVOLUTION trial design



Source: Oryzon corporate presentation

Oryzon also intends to assess vafidemstat for a precision-medicine approach for Kabuki syndrome, a rare congenital

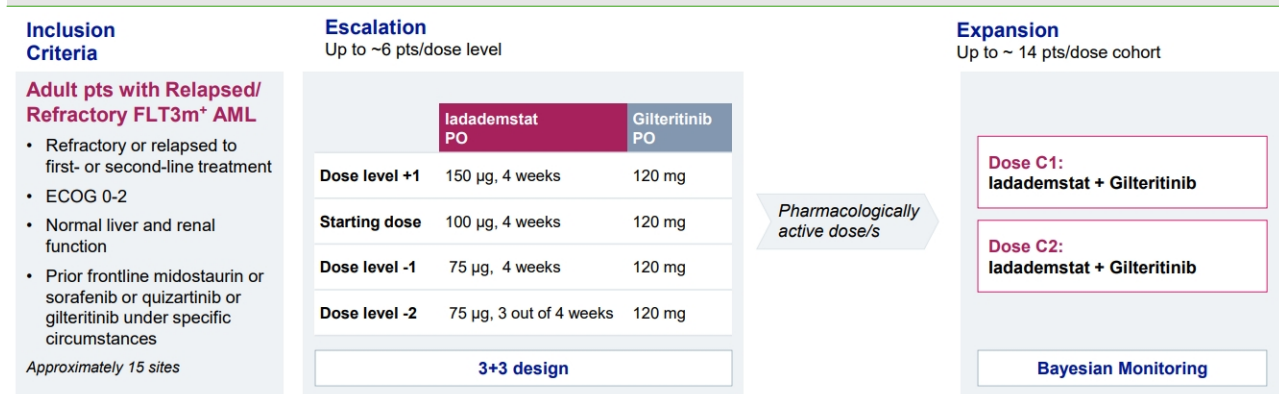
disorder. We note that this could be Oryzon’s first clinical-stage precision-medicine programme for a monogenic CNS condition, meaning a condition caused by a single genetic abnormality. For Kabuki syndrome, 55–80% of cases are caused by KMT2D gene variants and Oryzon believes it can provide an effective treatment option for this orphan indication through LSD1 inhibition. Management has communicated it will decide on a possible IND submission to the FDA for the Phase Ib/II HOPE trial in 2025.

Iadademstat: Building the data package with external backing

The ALICE trial, which evaluated iadademstat in combination with azacitidine as a potential first-line treatment for AML, presented encouraging results, with patients showing rapid, deep and durable responses; the results were published in *Lancet Haematology* in mid-2024. Oryzon is now taking a broad approach to further assess iadademstat in this indication with two new trials. The first is under a cooperative research and development agreement (CRADA) with the National Cancer Institute (NCI), and the second is an investigator-initiated trial in collaboration with Oregon Health & Science University (OHSU). Both of these studies explore a potential broadened treatment synergy, testing iadademstat in combination with azacitidine and venetoclax in the first-line AML setting. The first patient was dosed in the OHSU-sponsored study in [September 2024](#) and the first two cohorts are now fully enrolled; the NCI study also recently commenced patient dosing.

However, Oryzon’s priority in oncology remains the Phase Ib [FRIDA](#) trial (expected n=45), which is assessing iadademstat in combination with the tyrosine kinase inhibitor gilteritinib for relapsed or refractory (r/r) AML patients harbouring the FLT3 mutation in the second-line setting (Exhibit 4). The primary analysis will be focused on safety and a recommended Phase II dose, with secondary endpoint measures on efficacy and transfusion rates. Initial data, presented in June 2024, were promising and the FY24 results confirmed that the third cohort is fully enrolled with recruitment ongoing as planned. We expect the next update at the American Society of Hematology meeting (in December 2025). Should the FRIDA data be positive, Oryzon and the FDA have agreed to hold a meeting to discuss the best plan to further develop this combination, which could entail an accelerated clinical development path.

Exhibit 4: FRIDA trial design



Source: Oryzon corporate presentation

As per the FY24 report, a new investigator-initiated study, sponsored by Medical College Wisconsin (MCW), has commenced, with the first patient recently dosed. This is a Phase I dose-finding trial of iadademstat in combination with azacitidine in myelodysplastic syndrome (MDS), a rare form of blood cancer. It is currently actively enrolling patients.

Oryzon is also investigating iadademstat in combination with paclitaxel in platinum r/r small cell lung cancer (SCLC) and extrapulmonary high-grade neuroendocrine tumours in a Phase II basket trial. This is taking place in the US in collaboration with the Fox Chase Cancer Center and the programme continues to enrol patients.

As part of the CRADA agreement with the NCI, the potential synergy of iadademstat with immune checkpoint inhibitors is also being explored in SCLC patients with extensive disease. A number of prestigious cancer centres in the US will be involved, including the Memorial Sloan Kettering Cancer Center (MSKCC) as one of the main sites, alongside the JHU Sidney Kimmel Comprehensive Cancer Center and many others. A Phase I/II trial protocol has been accepted by the FDA. The programme will aim to enrol 45–50 patients and is due to commence recruitment in Q125. Should the results of the CRADA-MSKCC trial be supportive, they may inform the design of Oryzon’s STELLAR trial, which will be a randomised, multi-centre Phase II study of iadademstat in combination with a checkpoint inhibitor for first-line extensive-stage SCLC. Oryzon expects STELLAR to support an accelerated approval application.

Financials

Oryzon's FY24 results were broadly in line with our expectations. The company recorded an operating loss of €4.4m during FY24, at a similar run-rate to FY23 (€4.5m). Operating expenses for the year fell by c 38% y-o-y to €11.4m (€18.3m in FY23), with the reduction driven by materially lower R&D expenses (€5.4m vs €12.2m in the previous year), which made up 47% of the total opex for the year. The reduced R&D was not unexpected given the completion of the Phase IIb PORTICO trial in late-2023 and cost rationalisation efforts introduced by Oryzon. We note that while the company has several ongoing clinical programmes, a number of them are investigator-sponsored, where Oryzon's contribution is restricted to providing the drug candidate to the trial. We see merit in this strategy for a smaller biotech, such as Oryzon, as it allows the company to minimise capital risk, while continuing to widen the scope of commercial opportunities for its programmes. However, this also means that Oryzon has limited control of the ongoing studies and related timelines. We highlight that the company capitalises its R&D, reflected in the cash flow statement as the purchase of intangible assets (€7.7m in FY24 vs €14.5m in the previous year). Personnel expenses/SG&A were broadly stable at €3.4m and primarily consisted of salaries and wages (€2.9m), and social security expenses (€0.6m). Free cash outflow during FY24 was €13.5m, versus €15.1m in FY23.

Following the FY24 results, we have made only minor changes to our FY25 estimates and have introduced FY26 forecasts with the model roll forward. For FY25, we reduce our estimate for R&D to €8.5m (from €10.0m previously) as it now seems likely that the Phase III BPD programme will start in H225, following the expected regulatory thumbs-up in H125. We keep our SG&A projections largely unchanged at €3.5m. We continue to reflect risk-adjusted revenues and licensing inflows of €30m from a potential partner for vafidemstat in BPD in FY25 (assuming a licensing deal in H225, with the partner taking over further development work). This, alongside capitalised R&D, adds to a total revenue projection of €38.9m, versus €40.5m previously. Overall, we expect an operating income of €26.5m for the year. For FY26, we forecast revenues of €43.3m and operating income of €31.8m. We note that our estimates currently do not include potential non-dilutive inflows or grant proceeds under the Med4Cure project, which the company is entitled to receive. In its annual filings management has disclosed that, on 21 January 2025, Oryzon formally submitted documents for a €17.2m grant request, corresponding to the 1 January 2023 to 31 August 2026 period.

The company ended FY24 with net debt of €10.5m, including a €5.6m cash balance and €8.7m in short-term debt (bonds: €3.1m; credit institutions: €4.8m; other public organisations: €0.8m) and €7.4m in long-term debt (bank debt: €3.2m; other public organisations: €4.2m). We note that Oryzon had drawn down a further €7m in FY24 from the €45m convertible debt facility announced in November 2023 (€8m utilised in Q423). The facility has a maturity of 48 months and does not bear interest or have attached warrants. We expect the remaining €30m to be utilised in equal €15m tranches in FY25 and FY26, although this timing could vary according to company requirements and access to other funding sources. We reflect this inflow as illustrative debt in our model.

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%. Given limited developments since our last [update](#), we keep our underlying assumptions for Oryzon's ongoing programmes unchanged. We roll forward our model for the FY24 results and introduce the latest net debt position, with our valuation adjusting to €885.1m or €13.5 per share, from €796m or €12.3 per share previously. A breakdown of our rNPV is shown in Exhibit 5.

Exhibit 5: Valuation of Oryzon (rNPV)

Product	Indication	Launch	Peak sales (US\$m)	Value (€m)	Probability	rNPV (€m)	NPV/share (€/share)
ladademstat	2L AML	2029	548	599.1	30%	172.5	2.6
	1L SCLC	2030	709	707.6	20%	138.5	2.1
	BPD	2030	1,600	694.9	30%	301.3	4.6
Vafidemstat	Schizophrenia, negative symptoms	2031	692	513.1	15%	135.1	2.1
	Aggression related to AD	2031	892	600.0	15%	148.2	2.3
Net debt at end-December 2024				(10.5)	100%	(10.5)	(0.2)
Valuation				3,104.2		885.1	13.5

Source: Edison Investment Research. Note: Per share valuation is based on 65.8m shares outstanding.

We highlight that our model reflects a licensing deal for vafidemstat in H225, supporting cash flow positivity in FY25. As an added sensitivity, if we were to assume self-development and commercialisation by Oryzon for all its programmes, we estimate that the company would be required to raise c €100m between FY27 and FY29 (excluding the €30m convertible debt drawdown we model in FY25–26). Assuming these requirements are fulfilled through equity issues, we estimate Oryzon would need to issue 34.7m shares (at the current trading price of €2.67). This would lead to an increase in shares outstanding to 103.2m (from 65.8m currently) and will dilute our per-share valuation to €9.5 per share (from €13.5 per share currently). However, this still presents a significant upside to current trading levels.

Exhibit 6: 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%	98%	96%	99%	99%
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)	0	0
Exceptionals and adjustments	0	0	79	0	0
Reported EBITDA	(5,323)	(4,396)	(4,275)	26,626	31,900
Depreciation and amortisation	(167)	(153)	(148)	(117)	(95)
Reported EBIT	(5,490)	(4,549)	(4,423)	26,509	31,806
Finance income/(expense)	(1,067)	(1,555)	(1,148)	(798)	(965)
Other income/(expense)	0	0	0	0	0
Reported PBT	(6,557)	(6,104)	(5,571)	25,711	30,841
Income tax expense (includes exceptionals)	2,325	2,751	1,906	2,328	2,117
Reported net income	(4,231)	(3,353)	(3,665)	28,040	32,958
Basic average number of shares, m	53.3	57.6	63.4	65.8	65.8
Basic EPS (€)	(0.08)	(0.06)	(0.06)	0.43	0.50
Adjusted EBITDA	(5,323)	(4,396)	(4,355)	26,626	31,900
Adjusted EBIT	(5,490)	(4,549)	(4,502)	26,509	31,806
Adjusted PBT	(6,320)	(6,004)	(5,740)	25,711	30,841
Adjusted EPS (€)	(0.07)	(0.06)	(0.06)	0.43	0.50
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	36,320	73,096
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	38,894	75,947
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	19,081	34,067
Other current liabilities	70	11	52	52	52
Total current liabilities	18,732	16,414	11,739	22,677	37,329
Equity attributable to company	72,572	81,775	87,042	115,082	148,040
CASH FLOW STATEMENT					
Profit before tax	(6,557)	(6,104)	(5,571)	25,711	30,841
Cash from operations (CFO)	(1,848)	(575)	(5,690)	29,377	32,442
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	0	0
Movements in debt	9,642	7,901	5,374	10,249	12,584
Other financing activities	0	0	0	0	0
Cash from financing activities (CFF)	8,710	6,021	6,871	10,249	12,584
Increase/(decrease) in cash and equivalents	(7,408)	(9,060)	(6,638)	30,702	36,776
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	36,320
Cash and equivalents at end of period	21,317	12,257	5,619	36,320	73,096
Net (debt)/cash	(1,264)	(6,078)	(10,538)	9,892	34,060
Free cash flow (CFO + Net capex + Intangible assets)	(16,118)	(15,078)	(13,399)	20,452	24,192

Source: Company accounts, Edison Investment Research

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