Oryzon Genomics

Q325 results

Progression across the pipeline in Q3

Healthcare

11 November 2025

Oryzon Genomics has reported its Q325 results, a period characterised by tangible progress across its ongoing clinical programmes. Anticipation builds for vafidemstat in borderline personality disorder (BPD) following the receipt of feedback from the FDA for the proposed Phase III PORTICO-2 programme; interactions with the regulators have been constructive and Oryzon plans to resubmit a revised protocol. Oryzon's oncology-haematology candidate, iadademstat, reported positive clinical data in acute myeloid leukaemia (AML) and further details are due to be presented at ASH 2025. We note that management aims to build the data package for iadademstat to support its efforts in seeking a partner, as part of a renewed strategy to become a central nervous system (CNS) specialist. Following the Q3 results, our valuation shifts to €909.3m or €11.4 per share (from €887.2m or €11.3 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	9.5	(4.7)	(0.02)	0.00	N/A	N/A
12/26e	48.3	35.9	0.48	0.00	6.9	N/A

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

Strategic focus specifically in the CNS space

As highlighted in the Q325 results, with its renewed strategy, Oryzon aims to position itself as a CNS-focused company, and the priority continues to be vafidemstat in BPD. Following submission of the protocol for a registrational Phase III programme (PORTICO-2) earlier this year, Oryzon received feedback from the FDA regarding various components of the programme in October 2025. It has since strengthened its clinical, strategic and regulatory teams (following a recently strengthened clinical advisory board) and intends to continue incorporating experts, to fortify its capabilities in the field. Leveraging these capabilities, and based on its dialogue with the regulators, Oryzon plans to resubmit the PORTIO-2 protocol.

Iadademstat – seeking partnership opportunities

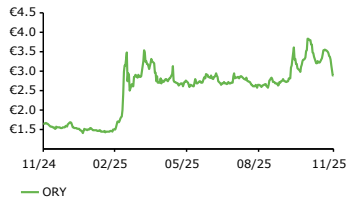
We highlight that iadademstat is being investigated across a broad range of oncology-haematology indications through multiple collaborative programmes. These serve as a cost-effective approach to building the data package for the asset, while the strategy has shifted to seeking potential partnerships. Following the recently announced positive clinical data, alongside a robust history in the clinic, we believe Oryzon is in a good position to explore such opportunities, while allowing it to pursue its focus in CNS conditions.

Valuation: €909.3m or €11.4 per share

Following the Q3 results, we have made only modest adjustments to our long-term estimates, with our valuation shifting to €909.3m or €11.4 per share (from €887.2m or €11.3 per share previously). The termination of the €45m convertible debt facility with Nice & Green in July 2025 has strengthened the balance sheet, and we continue to see the company funded into 2027 with current cash on hand of €34.4m at end-Q325.

Price	**€3.28**
Market cap	**€262m**
	US$1.16/€
Net cash at 30 September 2025	€20.7m
Shares in issue	79.9m
Free float	82.0%
Code	ORY
Primary exchange	MADRID
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	0.4	29.2	106.9
52-week high/low		€4.0	€1.4

Business description

Spanish biotech Oryzon Genomics is focused on epigenetics. Iadademstat is being explored for haematological malignancies, 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

FRIDA and other iadademstat updates at ASH 2025	December 2025
PORTICO-2 protocol re-submission (Edison estimate)	Late-2025 or early-2026

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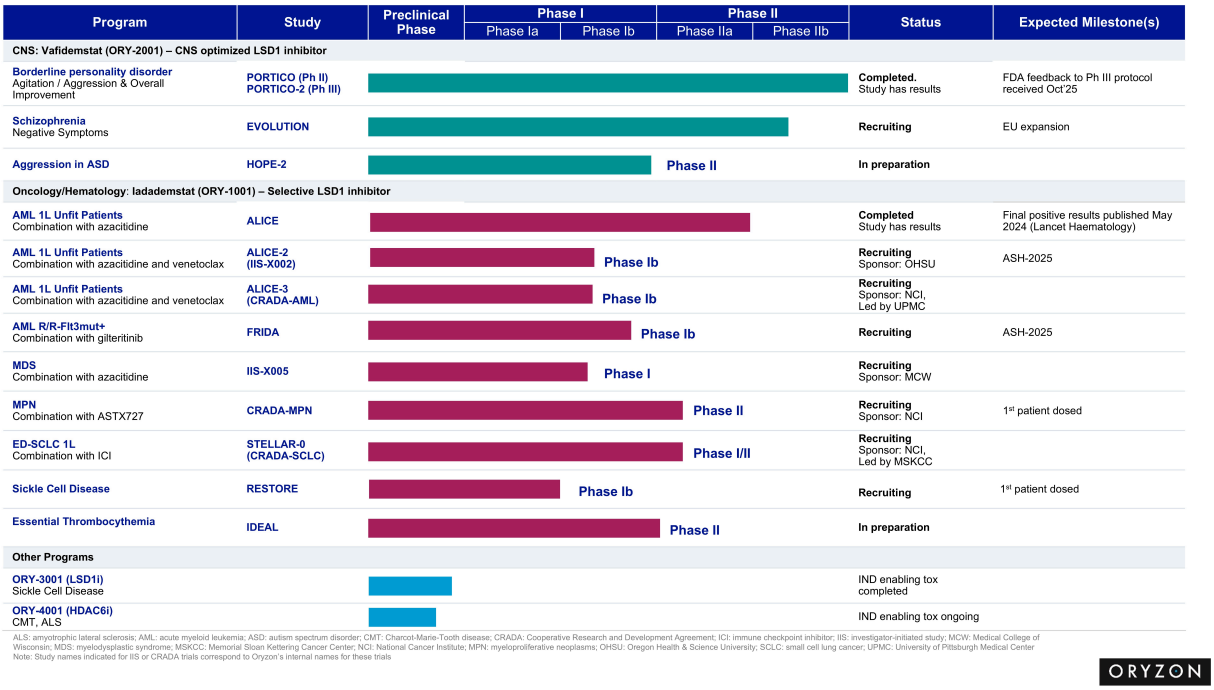
Encouraging pipeline progress in Q325

Oryzon Genomics continues to operate through self-funded studies, alongside investigator-sponsored and collaborative programmes, aiming to maximise the value propositions for vafidemstat and iadademstat, in a cost-effective manner. The company has made tangible progress across the pipeline in recent periods, for both of its clinical candidates (Exhibit 1). We discuss each of these in detail below. Oryzon's third asset, ORY-4001, is a selective histone deacetylase 6 inhibitor in preclinical development, with investigational new drug (IND)-enabling studies ongoing. Potential indications for ORY-4001 include, but are not limited to, neurological conditions such as Charcot-Marie-Tooth disease and amyotrophic lateral sclerosis.

Exhibit 1: Oryzon's clinical development pipeline



Source: Company resources

Vafidemstat (CNS conditions)

BPD: this continues to be Oryzon's most clinically advanced programme, developing vafidemstat as a treatment to address agitation and aggression (A/A) in BPD patients. We highlight that BPD is a relatively neglected CNS condition, despite having a global prevalence of c 1–2%, with no FDA-approved drugs at present. Therefore, there could be a sizeable commercial opportunity for Oryzon, in our view, should the company be successful in bringing an effective new treatment option to market. Prior clinical data have been encouraging, with the previous Phase IIb PORTICO trial showing that vafidemstat was favoured over placebo in all efficacy measures. Vafidemstat was also found to be safe and well tolerated, consistent with multiple other clinical studies involving the candidate. Oryzon had prepared a protocol for a registrational Phase III programme, PORTICO-2, and this was submitted to the FDA in June 2025, following multiple discussions with the regulators, as well as leading US psychiatry experts.

While regulatory clearance for PORTICO-2 was initially expected within Q325, according to the latest update, Oryzon received written feedback on various aspects of the proposed programme, including trial endpoints, alongside some non-clinical considerations. Management confirmed that its ongoing dialogue with the FDA has been constructive, and plans to resubmit a revised protocol based on the feedback. We note that such interactions with regulators are usual in drug development, especially in a case like this, where there is no precedent for BPD. We expect Oryzon to keep the market up to date regarding next steps, including when the protocol is resubmitted and when subsequent interactions with the FDA are underway.

Schizophrenia: the Phase IIb EVOLUTION trial is ongoing, evaluating vafidemstat in schizophrenia, another CNS

condition where A/A is a common characteristic. EVOLUTION is a double-blinded, randomised, placebo-controlled study, primarily looking to address the negative symptoms of schizophrenia, with outcomes related to positive symptoms and cognitive impairment as secondary focuses. While the programme had previously planned to enrol 220 participants, insights from PORTICO led to a revised protocol for EVOLUTION, where it was deemed that only 84 participants would be required to demonstrate a meaningful benefit. While the precise number of participants currently enrolled has not been reported, Oryzon's Q325 report confirmed that recruitment is ongoing as planned. We highlight that EVOLUTION was previously limited to hospital sites across Spain (as it was funded by the Spanish Ministry of Science and Innovation), however, with increased funding at hand, the trial is being expanded to include additional sites across Europe. We view this as a positive update for the programme, including a wider demographic and offering potential to accelerate recruitment.

Autism spectrum disorder (ASD): the most recent newly announced programme for vafidemstat is HOPE-2, which will include both genetically defined ASD subpopulations, such as Phelan-McDermid syndrome (PMS), as well as sporadic (non-genetic) subpopulations. The decision to pursue ASD as an additional indication for vafidemstat stems from prior clinical research, notably the Phase IIa REIMAGINE trial. HOPE-2 will be a Phase II trial, financially supported by the Important Project of Common European Interest (EU-IPCEI) grant (Med4Cure project). HOPE-2 will be based at sites in Spain, and we understand that preparations are still underway. It is our opinion that this could represent an attractive opportunity for Oryzon, with potential to maximise the value proposition for lead CNS asset vafidemstat should the clinical data continue to be supportive.

We note that, separately to the clinical programme, Oryzon is sponsoring the first PMS burden of illness study, strengthening its presence in this space. The study, which was recently launched, and is being led by CureShank (a research advocacy organisation focused on expediting life-changing therapies for PMS), is collecting data from families of PMS patients and health insurance companies, and taking insights from clinical experts. The ultimate aim is to quantify the economic impact of PMS, while informing the development of new treatment options and guiding future market access strategies.

Iadademstat (oncology and expanded indications)

AML: Oryzon's strategic priority in oncology remains AML, in which it has multiple ongoing programmes. The lead programme is FRIDA (self-funded), a Phase Ib trial testing iadademstat in combination with gilteritinib in relapsed/refractory AML patients with FLT3 mutations, targeting the second-line setting. Post period-end, in November 2025, Oryzon confirmed that 34 patients had been enrolled and that four dose-level cohorts had been evaluated as part of the escalation stage of the trial. Following confirmation that the combination was tolerated at the dose levels tested, the study had progressed to the expansion stage at a selected dose, involving 14 participants. According to the latest announcement, of the 12 evaluable patients, an overall response rate (ORR) of 67% was reported (8/12 patients), alongside a complete response (CR) rate of 58% (7/12 patients). In our view, the data compares favourably to the response rates for gilteritinib alone (CR rates less than 50%), highlighting the opportunity for this synergistic combination. Further details are due to be presented at the American Society of Hematology (ASH) Annual Meeting (6–9 December 2025). We also highlight that 42% of patients involved in the FRIDA trial had previously been treated with venetoclax, a group known to exhibit poor responses to gilteritinib monotherapy, and are therefore in urgent need of more effective therapies.

Beyond FRIDA, iadademstat is also being investigated in the first-line AML setting in two distinct Phase I studies, both testing the triple combination of iadademstat plus venetoclax and azacitidine, standard of care AML treatments. One of these studies is being run as an investigator-initiated trial in collaboration with Oregon Health & Science University (OHSU), for which an interim update was recently shared. The interim data, corresponding to the first eight patients involved in the trial, showed an ORR of 100%, with 88% achieving complete remission, and 12.5% achieved a morphological leukaemia-free state (meaning that there was no visible evidence of leukaemia cells in the bone marrow under a microscope). Importantly, there were no dose-limiting toxicities reported, and after a median follow-up of nine months, the six-month overall survival was 88%. The study continues to actively enrol patients, and OHSU will also be presenting an update at ASH 2025, adding further context to this promising combination. The other of these studies is under a cooperative research and development agreement (CRADA) with the National Cancer Institute (NCI), and the latest update confirmed that this programme continues to actively recruit patients.

Small cell lung cancer (SCLC): the company is also exploring the potential of iadademstat in extensive-stage SCLC. Under a CRADA with the NCI, iadademstat is being assessed in combination with immune checkpoint inhibitors in a Phase I/II trial. Patient recruitment started in April 2025, and the study has been designed to enrol a total of 45–50 patients. Primary outcome measures are based on safety, tolerability, dose-finding and efficacy, and multiple leading US-

based cancer centres are involved in this trial, including the Memorial Sloan Kettering Cancer Center. As communicated in the Q325 results, this programme continues to enrol patients. If successful, the results may support Oryzon's plans for its STELLAR programme, which will be a randomised, multi-centre Phase II trial of iadademstat in combination with a checkpoint inhibitor for extensive-stage SCLC, targeting the first-line setting.

Additional myeloid malignancies: emergent trials are evaluating iadademstat combinations in other myeloid malignancies, including myelodysplastic syndrome (MDS), myeloproliferative neoplasms (MPNs) and essential thrombocythemia (ET).

In MDS, an investigator-initiated Phase I programme (led by the Medical College of Wisconsin) dosed its first patient in January 2025; this study continues to enrol patients.

More recently, it was announced that a new trial will be taking place to explore potential synergy between iadademstat and ASTX727 (oral decitabine and cedazuridine) in MPNs. 50 patients will be randomised (25 patients in each arm) to recieve either ASTX727 alone or in combination with iadademstat, and we understand that further details will also be presented at ASH 2025. We note that this study is also being sponsored and conducted by the NCI, and it recently started enrolling patients. Since iadademstat has been shown to be safe and well tolerated in c 200 participants in prior clinical studies, we view these new investigator-initiated trials as cost-effective approaches to leverage iadademstat's full potential.

In ET, management is preparing a clinical trial application, which it intends to submit to the EMA within Q425.

Sickle cell disease (SCD): this is a relatively new programme, and the first to explore iadademstat in a non-malignant haematological indication. Regulatory clearance was provided by the EMA in August 2025 for RESTORE (a multi-centre, open-label, Phase Ib study), and Oryzon announced in November that the first patient had been enrolled. RESTORE has been designed to enrol 40 participants, and while safety and tolerability have been set as the primary outcome measure, it will be used to determine a recommended dose for Phase II and, importantly, will assess the extent to which iadademstat induces foetal haemoglobin expression (an FDA-recognised outcome measure for SCD treatment). We see SCD as a potentially promising area for Oryzon to tap into, broadening the applicability of iadademstat beyond malignant haematological indications, though we acknowledge that it is currently an early-stage programme. The SCD treatment market is projected to reach c $9.8bn by 2030 (according to Fortune Business Insights), with the US dominating the market with a share of c 64% (in 2022), where it is the most common inherited blood disorder. We note that the field has evolved significantly in recent years with the approval of gene therapies for the condition. Since these are associated with expensive price tags, we believe the opportunity for Oryzon may lie in an effective treatment option at a more accessible price point.

Strengthened intellectual property positions

Oryzon continues to strengthen its intellectual property portfolio for both of its clinical-stage candidates. Should vafidemstat and iadademstat be successful with regulatory approval, this robust intellectual property position should provide protection across multiple key geographies, meaning maximum value can be extracted from the assets by Oryzon, or any potential partners.

For vafidemstat:

- A 'decision to grant' communication was received from the European patent office in October 2025. This protects the use of vafidemstat for treating aggression and social withdrawal in CNS conditions, including BPD and ASD. It also covers its use for treating social withdrawal in conditions such as schizophrenia, actively covering the company's current active programmes. Once granted, this patent remains in place until at least 2038 (excluding any other further patent term extensions).
- Additional related patents have already been granted in Europe, Australia, Canada, Hong Kong, Israel, South Korea, Malaysia, the Philippines and Russia. Other applications are also pending in additional countries.

For iadademstat:

- 'Decision to grant' communications were received from the Australian patent office in September 2025, and from the European patent office in October 2025. These protect the use of iadademstat in combination with PD1 or PD-L1 inhibitors for the treatment of cancer, including SCLC, in which Oryzon has an active clinical programme. Once granted, these patents remain in place until at least 2040 (excluding any other further patent term extensions).

- A corresponding patent has already been granted in Russia. Other applications are also pending in the US, Japan, China and various additional countries.

Financials

Operating performance: R&D expenses trending higher, reflecting increased clinical activity

In Q325, Oryzon reported R&D expenses (c 76% of total operating expenses for the quarter) of €3.3m ($3.9m), up c 100% over the Q324 figure of €1.7m ($1.9m) and up 30–40% over the past two quarters in FY25. We believe this is attributed to increased clinical activities by the company as it seeks to broaden its CNS footprint and focus. In particular, we estimate the increased cost to be related to the ongoing EVOLUTION trial in schizophrenia (where the trial is being expanded to include four additional EU countries) and preparatory activities for the upcoming Phase IIb trial (HOPE-2) in aggression in specific genetically defined subpopulations of ASD, such as Phelan-McDermid syndrome. Note that the company capitalises a part of the R&D expenses, which is reflected as other income in the profit and loss account (€2.9m in Q325 versus €1.7m in Q324 and €2.2m in Q225). SG&A expenses for the quarter were €0.9m, up c 7% from €0.8m in Q324. Overall, operating loss for the period was €1.0m, on par with the figure in Q324. Net financial income improved to €0.07m from a loss of €0.26m in Q324, which we believe was largely driven by the termination of the €45m convertible debt facility with Nice & Green in July 2025, resulting in a significant decline in interest expenses recorded during the quarter (€0.15m versus €0.30m in Q324). This, along with recorded tax benefits, resulted in a net profit of €0.34m in Q325 versus a loss of €1.2m in Q324.

Balance sheet – funded into 2027

Oryzon ended Q325 with a net cash balance of €20.7m. This includes €34.4m in gross cash and cash equivalents, €7.8m in long-term debt (credit institutions – €4.1m; others – €3.7m) and €5.7m in short-term debt (credit institutions – €5.1m; others – €0.7m). Note that the company has reported €8.4m as other short-term financial liabilities on the balance sheet in Q325, of which €7.7m relates to advance financing received under the €13.26m (US$15m) non-dilutive grant as part of the Med4Cure initiative, EU-IPCEI framework. We have excluded this €7.7m payment from our calculation of net debt. Based on our cash burn projections, we continue to estimate the company to be funded into 2027.

Minor changes to estimates

Following the Q325 results, we make only minor adjustments to our FY25 R&D forecasts, which we raise to €10m, from €8.5m previously, to reflect the nine-month run-rate. Correspondingly, the other income estimate for FY25 increases to €9.5m (€8.9m previously). Overall, we now expect an operating loss of €4.7m for FY25 versus a loss of €3.8m previously. We maintain our estimates for FY26.

Valuation

We value Oryzon using a risk-adjusted net present value (rNPV) approach to value its ongoing clinical programmes, forecasting to the end of the patent lives and using a flat discount rate of 12.5%. While we await further clarity on the FDA feedback on the Phase III PORTICO-2 trial in BPD and additional time required for the revision and resubmission for the clinical trial protocol, we keep our launch timelines for the programme unchanged to 2030. We also maintain our estimates for the other ongoing clinical programmes. Given the moving parts with the recent strategic repositioning towards vafidemstat and CNS, and the newly announced investigator sponsored trials for Iadademstat, we will revisit our assumptions as further information on the plans becomes available.

Reflecting the model roll forward and updated net cash position, our valuation for Oryzon adjusts to €909.3m or €11.4 per share from €887.2m or €11.3 per share previously.

A breakdown of our risk-adjusted net present value (NPV) valuation is shown in Exhibit 2.

Exhibit 2: Oryzon rNPV valuation

Product	Indication	Launch	Peak sales (US$m)	Value (€m)	Probability	rNPV (€m)	NPV/share (€/share)
Iadademstat	2L AML	2031	548	431.0	30%	118.6	1.5
	1L SCLC	2032	778	659.3	20%	127.5	1.6
Vafidemstat	BPD	2030	1,600	735.7	40%	353.4	4.4
	Schizophrenia, negative symptoms	2031	692	545.7	20%	149.8	1.9
	Aggression related to AD	2031	892	640.1	15%	139.2	1.7
Net cash at end-September 2025				20.7	100%	20.7	0.3
Valuation				**3,032.5**		**909.3**	**11.4**

Source: Edison Investment Research

Exhibit 3: 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**	**9,500**	**48,250**
Cost of sales	(464)	(244)	(302)	(317)	(333)
Gross profit	15,234	13,948	7,057	9,183	47,917
Gross margin %	*97.0%*	*98.3%*	*95.9%*	*96.7%*	*99.3%*
SG&A (expenses)	(3,163)	(3,390)	(3,447)	(4,137)	(4,178)
R&D costs	(13,681)	(12,177)	(5,369)	(10,000)	(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)**	**(4,590)**	**36,589**
Depreciation and amortisation	(167)	(153)	(148)	(130)	(101)
Reported EBIT	**(5,490)**	**(4,549)**	**(4,423)**	**(4,721)**	**36,488**
Finance income/(expense)	(1,067)	(1,555)	(1,148)	53	(568)
Other income/(expense)	0	0	0	0	0
Reported PBT	**(6,557)**	**(6,104)**	**(5,571)**	**(4,667)**	**35,921**
Income tax expense (includes exceptionals)	2,325	2,751	1,906	3,326	2,117
Reported net income	**(4,231)**	**(3,353)**	**(3,665)**	**(1,341)**	**38,038**
Basic average number of shares, m	53.3	57.6	63.4	76.4	79.9
Basic EPS (€)	(0.08)	(0.06)	(0.06)	(0.02)	0.48
Adjusted EBITDA	(5,323)	(4,396)	(4,355)	(4,588)	36,589
Adjusted EBIT	(5,490)	(4,549)	(4,502)	(4,718)	36,488
Adjusted PBT	(6,320)	(6,004)	(5,740)	(4,665)	35,921
Adjusted EPS (€)	(0.07)	(0.06)	(0.06)	(0.02)	0.48
BALANCE SHEET					
Property, plant and equipment	611	481	356	249	174
Intangible assets	75,843	89,895	97,096	106,572	114,796
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**	**110,336**	**118,485**
Cash and equivalents	21,317	12,257	5,619	17,494	44,706
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**	**20,068**	**47,558**
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	117,239	155,277
CASH FLOW STATEMENT					
Profit before tax	**(6,557)**	**(6,104)**	**(5,571)**	**(4,667)**	**35,921**
Cash from operations (CFO)	**(1,848)**	**(575)**	**(5,690)**	**10**	**37,528**
Capex	(76)	0	0	0	0
Acquisition of intangible assets	(14,195)	(14,503)	(7,710)	(9,500)	(8,250)
Other investing activities	(1)	(1)	(102)	0	0
Cash used in investing activities (CFIA)	**(14,271)**	**(14,504)**	**(7,811)**	**(9,500)**	**(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)**	**11,876**	**27,212**
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**	**17,494**
Cash and equivalents at end of period	**21,317**	**12,257**	**5,619**	**17,494**	**44,706**
Net (debt) cash	(1,264)	(6,078)	(10,538)	(1,826)	27,778
Free cash flow (CFO + Net capex + Intangible assets)	(16,118)	(15,078)	(13,399)	(9,490)	29,278

Source: Company documents, Edison Investment Research

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