EDISON

Oryzon Genomics

Q324 results

Q3 results recap key upcoming inflection points

Pharma and biotech

Oryzon has reported its Q324 results, the highlight of which was the borderline personality disorder (BPD) programme, with the final Phase IIb PORTICO data demonstrating vafidemstat's potential to offer meaningful results in a condition with no approved drugs currently. A further boost was the positive FDA feedback for Phase III, and the next step will be the submission of a full trial protocol for PORTICO-2 (expected in Q125). Oryzon also made strides in strengthening its intellectual property (IP) profile, extending vafidemstat's patent protection up to at least 2040. In oncology, the first patient was dosed in the investigator-initiated Phase Ib study of iadademstat with venetoclax and azacitidine in acute myeloid leukaemia (AML). For FRIDA (iadademstat with gilteritinib in AML), the strategic priority in oncology, the next update will be at EHA 2025. Our valuation adjusts to €796m or €12.3/share (from €775m or €12.1/share).

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/22	15.7	(6.6)	(0.07)	0.0	N/A	N/A
12/23	14.2	(6.1)	(0.06)	0.0	N/A	N/A
12/24e	7.6	(4.9)	(0.03)	0.0	N/A	N/A
12/25e	40.5	25.5	0.44	0.0	3.8	N/A

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

Progress toward a meaningful treatment for BPD

While the top-line results for PORTICO were reported in January 2024, the final data (presented at the 37th ECNP annual conference in September) revealed improved statistical significance across the key secondary efficacy measures. Although the primary endpoints were not met with significance, encouragement should be taken from the global treatment effect favouring vafidemstat by the global statistical test, especially given the complexity of BPD as a multifactorial condition. The momentum was maintained with the swift news of a positive end-of-Phase II (EoP2) meeting with the FDA, supporting Oryzon's plans for a Phase III programme, where STAXI-2 Trait Anger, a secondary endpoint in PORTICO, will likely be used as the primary endpoint. Management intends to submit a full trial protocol within Q125, which, contingent on regulatory clearance, could support a trial launch from H225.

Valuation: Adjusts to €796m or €12.3 per share

We adjust our valuation to reflect the Q324 performance and our revised estimates for the time-to-market for vafidemstat across the CNS pipeline. For BPD, we increase our probability of success to 30% (from 20%) following the positive feedback from the FDA EoP2 meeting. However, we adjust the launch timeline to 2030 (from 2028) given the requirement to conduct two Phase III studies. This is offset by increased times to patent expiry following recent extensions. We also update launch timelines for schizophrenia and Alzheimer's disease given overlaps with the BPD programme, although we keep our assumptions for the oncology pipeline unchanged for now. Overall, our valuation adjusts upwards to €796m or €12.3/share, from €775m or €12.1/share previously. With the current gross cash at hand of €7.5m, we see the company funded into FY25 (not accounting for further drawdowns from the convertible debt facility or grants under the Med4Cure project).

30 October 2024

Price	**€1.68**
Market cap	**€109m**
Net debt (€m) at 30 September 2024	5.3
Shares in issue	64.7m
Free float	82%
Code	ORY
Primary exchange	Madrid Stock Exchange
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(9.1)	(10.3)	(16.9)
Rel (local)	(7.8)	(15.5)	(37.2)
52-week high/low		€2.22	€1.60

Business description

Oryzon Genomics is a Spanish biotech focused on epigenetics. Iadademstat is being explored for acute leukaemias, small-cell lung cancer and neuroendocrine tumours. Vafidemstat, its central nervous system asset, has completed several Phase IIa trials and a Phase IIb trial in borderline personality disorder (now the lead programme), and is in a Phase IIb trial in schizophrenia.

Next events

PORTICO-2 protocol submission	Q125
FRIDA trial update	June 2025

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Multiple inflection points coming in CNS and oncology

Oryzon's two lead assets, vafidemstat (central nervous system (CNS)) and iadademstat (oncology), are in active clinical programmes spanning a range of indications (Exhibit 1). The company is a European leader in the field of epigenetics, and as such, both vafidemstat and iadademstat are inhibitors of LSD1, a histone-modifying enzyme that forms part of complexes responsible for the regulation of genes implicated in CNS disorders and cancer.

Vafidemstat in CNS

In CNS, the BPD programme remains a top strategic priority for Oryzon. The final analysis from the Phase IIb PORTICO trial demonstrated robust improvements per State-Trait Anger Expression Inventory 2 (STAXI-2) trait anger measures (assessing agitation/aggression) at weeks 8–12. The results were more marked compared to the initial top-line results, with nominal statistical significance now recorded as p=0.0071 (vs p=0.0259 previously). The other key secondary efficacy measure showed an improvement in Borderline Evaluation of Severity (BEST), an overall assessment of BPD disease severity, at weeks 8–12 compared to the top-line data; nominal statistical significance is now recorded as p=0.0260 (vs p=0.0423 previously). With key opinion leaders claiming that improvements of 25% or over across measures of overall severity and agitation/aggression would mark a clinically meaningful benefit, we believe the fact that PORTICO achieved this provides a strong foundation for the subsequent stages of development. (For a more detailed discussion of the final analysis, we direct readers to our prior update note.) Following a productive EoP2 meeting with the FDA, management is in preparations for a Phase III PORTICO-2 trial. The estimated total population size for PORTICO-2 is 350 patients (randomised 1:1 to receive either vafidemstat or a control), with a study duration of 18 weeks. The next inflection point will be regulatory clearance for this Phase III study. Management plans to submit the protocol to the FDA in Q125, and expects approval in late Q125 or early Q225. We note that PORTICO-2 would be one of two registrational trials required by the FDA before Oryzon could file for regulatory approval.

Oryzon is also assessing vafidemstat as a potential treatment for the negative symptoms of schizophrenia and is involved in the Phase IIb EVOLUTION trial. According to the Q324 update, an assessment of effect sizes in the BPD programme has resulted in a re-evaluation and increase in the recruitment target for EVOLUTION. The programme continues to enrol participants across multiple hospitals in Spain, and we highlight that it is partially financed by the Spanish Ministry of Science and Innovation.

Vafidemstat is also being considered for a precision medicine approach for Kabuki syndrome, a rare congenital disorder, and management has communicated it will decide on a possible Investigational New Drug submission for the Phase Ib/II HOPE trial in 2025.

Iadademstat in oncology

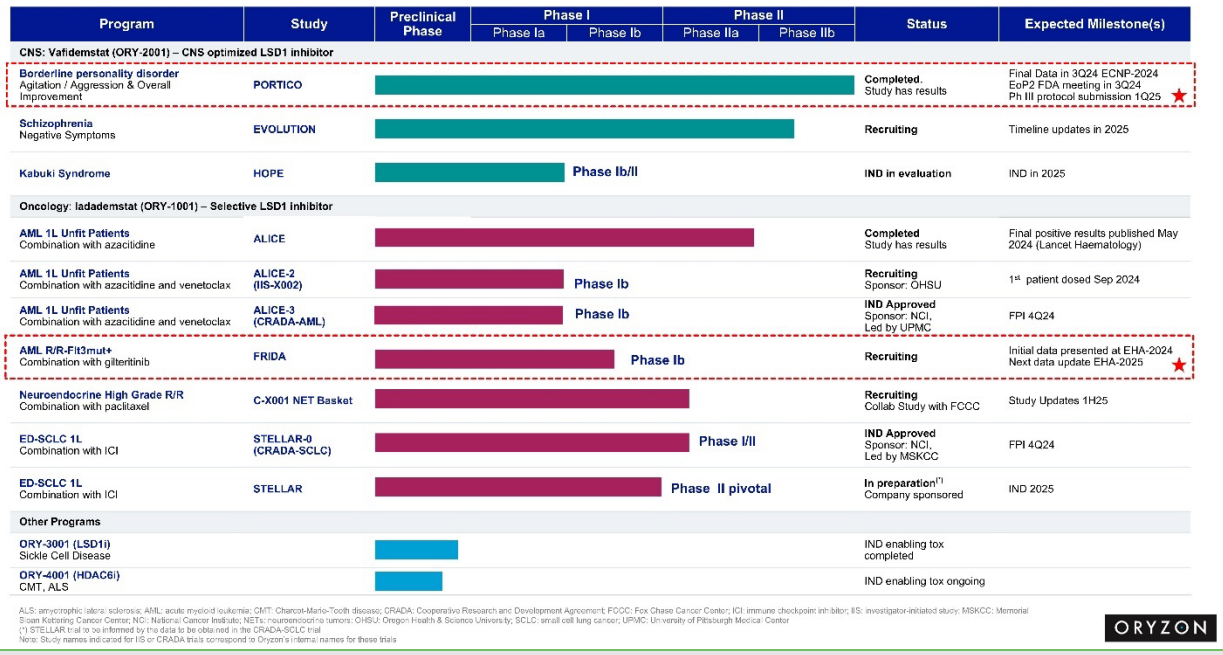
In oncology, following the positive results of ALICE (iadademstat in combination with azacitidine for the treatment of first-line AML), Oryzon is taking a broadened approach involving two new trials to evaluate the potential of the candidate in this patient population. The first is under the company's cooperative research and development agreement (CRADA) with the National Cancer Institute (NCI), while the second is an investigator-initiated study in collaboration with Oregon Health & Science University (OHSU). Both trials are exploring a potential broadened treatment synergy, assessing 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 cohort is now fully enrolled, while the NCI study is expected to start enrolment in Q424. The programme in focus, however, is 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 (second-line setting). A promising update was shared in June 2024, demonstrating strong antileukemic activity in the first two cohorts (13 patients) of the study, with encouraging response rates and a shorter time to response compared to historical data for gilteritinib. According to the Q324 update, enrolment for the third cohort is now complete, and management intends to share updated results once the data mature. We anticipate the next update to be at the next European Hematology Association (EHA) conference (in June 2025). We highlight that if this trial is successful, the company and the FDA have agreed to hold a meeting to discuss the best plan to further develop this combination.

Beyond AML, Oryzon is also assessing 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 being conducted in the US in collaboration with the Fox Chase Cancer Center, and continues to enrol patients.

Under the CRADA agreement with the NCI, iadademstat will also be explored in combination with immune checkpoint inhibitors in patients with SCLC. The protocol has been approved by the FDA, and patient enrolment will commence in Q424 with the Memorial Sloan Kettering Cancer Center (MSKCC) as one of the main sites. It is intended that the results of the CRADA-MSKCC trial will inform the design of Oryzon's STELLAR trial, which will be a randomised, multicentre Phase II study of iadademstat plus a checkpoint inhibitor in first-line extensive-stage SCLC. Management believes that STELLAR may support an application for accelerated approval.

Exhibit 1: Oryzon's clinical pipeline



Source: Oryzon Genomics

Incremental patents add to the vafidemstat value proposition

FY24 to date has been highly rewarding for Oryzon in terms of strengthening its IP portfolio for vafidemstat, with numerous announcements relating to the candidate:

- October 2024: Oryzon announced the formal grant of a key European patent for vafidemstat, titled: 'Methods of treating behavior alterations', relating to both BPD and schizophrenia as conditions characterised by aggression and social withdrawal. The patent covers 40 European countries and will not expire until at least 2038, excluding any potential patent term extensions that may provide additional years of protection.

- September 2024: Oryzon received an 'Intention to grant' communication from the European Patent Office relating to a patent application for vafidemstat entitled 'Methods of treating borderline personality disorder'. Once granted, it will provide protection in Europe until at least 2040, excluding any potential patent term extensions that may provide additional protection.
- September 2024: Oryzon received 'Decision to grant' communications for patents related to vafidemstat in Australia and Malaysia ('Methods of treating behaviour alterations'), as well as in Mexico ('Methods of treating borderline personality disorder'). Once granted, these patents will not expire in these regions until at least 2038 and at least 2040, respectively, excluding any potential patent term extensions that may provide additional protection in these regions.
- July 2024: Oryzon received 'Decision to grant' communications from the Japanese Patent Office for two patents entitled 'Methods of treating borderline personality disorder' and 'Methods of treating attention-deficit hyperactivity disorder using KDM1A inhibitors such as the compound vafidemstat'. Once granted, these patents will not expire until at least 2040, excluding any potential patent term extensions that may provide additional protection.
  - It was noted in this release, that the company had already been granted patents in Europe, Korea and Russia relating to the use of vafidemstat to treat aggression and social withdrawal, key characteristics of both BPD and schizophrenia.

Collectively, we believe these patents bolster the value proposition of the company's CNS pipeline and note that similar patent applications are pending in other relevant markets. Provided the drug candidate is successful in subsequent clinical trials, it will be well-protected across various key geographies. Oryzon also holds composition-of-matter patents for vafidemstat, expected to expire in the US and EU in 2037 and 2036, respectively, including patent term extension/supplementary protection certificates.

Financials

Following the completion of the Phase IIb PORTICO trial in late-2023 and cost rationalisation by the company, R&D expenses have continued to come down, with Q324 recording expenses of €1.7m, more than 50% lower than the Q323 figure of €3.6m. R&D as a percentage of opex declined to 69% (vs 85% in Q323). Total R&D expenses in the first nine months of FY24 (9M24) were €6.3m, materially lower than the €11.5m booked in the first nine months of FY23. We note that €5.6m of the €6.3m in R&D expenses in 9M24 has been capitalised by the company, reflected as other income in the accounts. Personnel expenses stayed broadly in line with the trend in the previous quarter, coming in at €0.77m (vs €0.82m in Q224 and €0.87m in Q124). Net loss was reported at €1.2m in Q324, a c 16% increase over the Q323 figure of €1.1m.

Following the positive EoP2 meeting with the FDA on the BPD programme, management expects to file the study protocol by early 2025, with anticipated FDA clearance for the Phase III trial within Q125. If approval is received, Oryzon plans to commence the first Phase III trial in H225. We therefore expect the R&D expenses to stay low until at least H125. As indicated previously, management anticipates the need for two Phase III trials for the New Drug Application and has guided for a clinical trial cost of less than €50m for each trial, recruiting 350 patients each. For reference, the Phase II PORTICO trial, which had enrolled around 200 patients, cost the company around €25m in R&D expenses. For our model we assume that the Phase III programme would be advanced under a licensing agreement, with the partner taking over R&D-related responsibilities.

Based on the Q324 results and near-term visibility, we have made minor adjustments to our FY24 and FY25 estimates. We have reduced our R&D expenses estimate for FY24 to €8m, from €9m previously, to reflect the nine-month run rate. This also has an impact on the other income estimate (remember that the company capitalises a large proportion of its R&D expenses, reflecting the capitalised portion as income), which goes down to €7.6m, from €8.6m previously. For FY25,

however, our revenue estimate goes up to €40.5m, from €31.6m previously, due to higher risk-adjusted income assumed as we increase the probability of success (PoS) for the BPD programme from 20% to 30% following the positive FDA feedback from the EoP2 meeting. Overall, we now project an operating loss of €4.1m in FY24 (€4.2m previously) and an operating profit of €26.7m in FY25 (€16.8m previously). We note that our estimates currently do not include potential non-dilutive inflows/grant proceeds under the Med4Cure project, which the company is entitled to receive. Management has recently indicated that the budget for Oryzon under the project will be in the range of €20–25m and it expects to receive 60–70% of this (c €14–17.5m) between Q424 and Q125.

The company ended Q324 with net debt of €10.0m, including a €7.5m cash balance and €9.8m in short-term debt (bonds: €4.7m; credit institutions: €5.0m; other public organisations: €1.2m) and €6.6m in long-term debt (bank debt: €3.0m; other public organisations: €3.6m). Based on our projected cash burn rates and assuming no incremental cash inflows in Q424 (or debt repayment), we expect the gross cash at hand to be sufficient to fund operations into FY25. We remind readers that Oryzon had announced a €45m convertible debt facility in November 2023, of which €14m has been drawn down until the end of H124. Our model assumes that another €6m will be utilised in H224 and the remaining €25m in FY25, which we reflect as illustrative debt in our projections. We note that the timing of inflows is subject to change based on receipt of grant proceeds under the Med4Cure project.

Valuation

Following Oryzon's positive EoP2 meeting with the FDA and further clarity on the Phase III trial protocol, we have made certain adjustments to our launch timelines for the vafidemstat CNS programme. For BPD, we increase our probability of success to 30% (from 20% previously), given the transition to a Phase III-ready programme. The valuation upside from this has been partially offset by a more protracted timeline to approval which we now assume. This is based on our understanding that two Phase III studies will be required to meet the requirements of a regulatory filing. As per management guidance, we anticipate the first Phase III study to commence in H225 and expect it to take three years to complete, given the trial design and size (350 patients and treatment period of 18 weeks). While the possibility of running two Phase III trials in parallel cannot be ruled out, we believe a more feasible scenario (keeping funding and other requirements in mind) would be for the company to initiate the second study after interim readouts from the first. We therefore expect the combined Phase III programme in BPD to now be completed in 2029, followed by a launch in 2030 (versus 2028 previously).

In terms of the underlying market assumption and commercial potential, while we understand that the trial will focus on agitation/aggression related to BPD as a primary endpoint, we continue to forecast the entire BPD population as the target population given the high propensity of agitation/aggression in BPD patients (over 70% of all BPD patients). We continue to assume a peak penetration of 10%, to be achieved in 2036, versus 2034 previously (peak sales estimate remains unchanged at US$1.6bn), but now project a longer tail to sales erosion following the recent patent extensions for vafidemstat (patent protect to 2040 in Europe and 2041 in the US for treatment of BPD, excluding possible patent term extensions). Overall, we revise our risk-adjusted net present value (rNPV) for vafidemstat in BPD to €271.4m, versus €245.0m previously.

We also note that based on observations from the Phase II PORTICO trial, management now plans to increase the enrolment in the Phase IIb EVOLUTION trial (previously c 100 patients) evaluating vafidemstat in schizophrenia (with a primary focus on improving negative symptoms). Based on this update, we conservatively push out our estimates for a launch timeline to 2031, from 2029 previously. The downside from this has also been offset by the longer lead time to sales erosion

following the recent strengthening of vafidemstat's IP position. Our revised rNPV for this indication is €119.6m (€120.8m previously).

Finally, for agitation/aggression related to Alzheimer's disease (AD), we continue to expect it to be pursued as a label extension opportunity. Concurrent to the revised timelines for BPD and schizophrenia, we also push out the launch timeline in AD to 2031, from 2029 previously. This again has had a limited impact on our valuation, given the longer patent life, which still provides over a decade of protection, assuming these launch timelines. Our updated rNPV for AD stands at €132.0m, from €137.8m previously.

For the oncology programme (iadademstat in AML and SCLC), our underlying assumption remains unchanged for now, but we will reassess our estimates as more information on trial progression and development plans becomes available.

Based on the aforementioned changes, and reflecting the adjustments from model roll forward and updated net debt position, our overall valuation for Oryzon increases to €796m or €12.3/share, from €775m or €12.1/share previously.

A breakdown of our rNPV is shown in Exhibit 2.

Exhibit 2: Valuation of Oryzon (rNPV)

Product	Indication	Launch	Peak sales (US$m)	Value (€m)	Probability	rNPV (€m)	NPV/share (€/share)
Iadademstat	2L AML	2029	555	557.8	30%	159.0	2.5
	1L SCLC	2030	720	653.8	20%	123.5	1.9
Vafidemstat	BPD	2030	1,625	658.8	30%	271.8	4.2
	Schizophrenia, negative symptoms	2031	702	484.6	15%	119.8	1.9
	Aggression related to AD	2031	907	567.2	15%	132.2	2.0
Net debt at end-September 2024				(10.0)	100%	(10.0)	(0.2)
Valuation				**2,911.9**		**796.2**	**12.3**

Source: Edison Investment Research. Note: Per share valuation is based on 64.7m shares outstanding.

We note that our model reflects licensing deals in FY25e and FY26e, associated with cash inflows that should support break-even in FY26e. If Oryzon does not finalise a partnership deal, and self-commercialises all programmes, the company will be required to raise sizeable external capital; we estimate c €30m annually between 2026 and 2029 for a total of €150m. Assuming all funding requirements across FY24–29 (c €181m) are realised through equity raises, Oryzon would have to issue 107.7m shares (assuming the current price of €1.68/share). Our per-share valuation would therefore be diluted to €5.7/share, from €12.3/share currently (shares outstanding would increase from 64.7m to 172.3m).

Exhibit 3: Financial summary

Accounts: Spanish GAAP. Year end 31 December (€000s)	2021	2022	2023	2024e	2025e
INCOME STATEMENT					
Total revenues	10,615	15,698	14,192	7,600	40,500
Cost of sales	(746)	(464)	(244)	(268)	(281)
Gross profit	9,869	15,234	13,948	7,332	40,219
Gross margin %	93%	97%	98%	96%	99%
SG&A (expenses)	(3,782)	(3,163)	(3,390)	(3,424)	(3,458)
R&D costs	(9,746)	(13,681)	(12,177)	(8,000)	(10,000)
Other income/(expense)	(3,203)	(3,714)	(2,777)	74	0
Exceptionals and adjustments	(4)	0	0	55	0
Reported EBITDA	(6,866)	(5,323)	(4,396)	(3,963)	26,760
Depreciation and amortisation	(144)	(167)	(153)	(129)	(110)
Reported EBIT	(7,011)	(5,490)	(4,549)	(4,092)	26,650
Finance income/(expense)	(169)	(1,067)	(1,555)	(825)	(1,141)
Other income/(expense)	0	0	0	0	0
Reported PBT	(7,180)	(6,557)	(6,104)	(4,917)	25,509
Income tax expense (includes exceptionals)	2,493	2,325	2,751	3,005	2,878
Reported net income	(4,687)	(4,231)	(3,353)	(1,912)	28,387
Basic average number of shares, m	53.1	53.3	57.6	62.9	64.7
Basic EPS (€)	(0.09)	(0.08)	(0.06)	(0.03)	0.44
Adjusted EBITDA	(6,862)	(5,323)	(4,396)	(4,018)	26,760
Adjusted EBIT	(7,007)	(5,490)	(4,549)	(4,148)	26,650
Adjusted PBT	(6,896)	(6,320)	(6,004)	(4,972)	25,509
Adjusted EPS (€)	(0.08)	(0.07)	(0.06)	(0.03)	0.44
BALANCE SHEET					
Property, plant and equipment	682	611	481	379	298
Intangible assets	60,254	75,843	89,895	97,468	107,939
Investments	29	31	26	26	26
Deferred tax assets	1,812	2,050	2,222	2,222	2,222
Total non-current assets	62,778	78,535	92,624	100,095	110,485
Cash and equivalents	28,725	21,317	12,257	7,008	47,905
Trade and other receivables	3,645	3,709	1,909	2,809	2,359
Inventories	104	10	6	6	6
Other current assets	132	129	104	104	104
Total current assets	32,606	25,165	14,276	9,927	50,374
Deferred tax liabilities	1,812	2,050	2,222	2,222	2,222
Long term debt	13,354	10,346	6,335	3,172	3,148
Other non-current liabilities	285	0	155	155	155
Total non-current liabilities	15,451	12,396	8,711	5,549	5,525
Trade and other payables	3,518	5,742	4,210	2,986	3,598
Short term debt	4,306	12,920	12,194	16,194	38,056
Other current liabilities	847	70	11	11	11
Total current liabilities	8,672	18,732	16,414	19,190	41,664
Equity attributable to company	71,262	72,572	81,775	85,283	113,670
CASH FLOW STATEMENT					
Profit before tax	(7,180)	(6,557)	(6,104)	(4,917)	25,509
Cash from operations (CFO)	(3,626)	(1,848)	(575)	(3,906)	29,559
Capex	(175)	(76)	0	0	0
Acquisition of intangible assets	(11,586)	(14,195)	(14,503)	(7,600)	(10,500)
Other investing activities	37	(1)	(1)	0	0
Cash used in investing activities (CFIA)	(11,724)	(14,271)	(14,504)	(7,600)	(10,500)
Net proceeds from issue of shares	0	(932)	(1,880)	5,420	0
Movements in debt	4,123	9,642	7,901	838	21,838
Other financing activities	0	0	0	0	0
Cash from financing activities (CFF)	4,123	8,710	6,021	6,258	21,838
Increase/(decrease) in cash and equivalents	(10,880)	(7,408)	(9,060)	(5,249)	40,897
Currency translation differences and other	348	1	(3)	0	0
Cash and equivalents at start of period	39,605	28,725	21,317	12,257	7,008
Cash and equivalents at end of period	28,725	21,317	12,257	7,008	47,905
Net (debt)/cash	11,065	(1,948)	(6,272)	(12,358)	6,701
Free cash flow (CFO + Net capex + Intangible assets)	(15,388)	(16,118)	(15,078)	(11,506)	19,059

Source: Company reports, Edison Investment Research

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