Newron Pharmaceuticals

Pivotal evenamide trial looms

FY24 results

Healthcare

3 April 2025

Newron Pharmaceuticals has published its FY24 results, reflecting a rewarding period for its lead clinical candidate, evenamide, which is being developed for treatment-resistant schizophrenia (TRS). Key achievements included licensing agreements for Japan and South Korea ahead of the planned pivotal Phase III trial, expected to launch in Q225. We expect the €44m upfront payment from EA Pharma to provide operational headroom into H126, with further liquidity likely to be injected following a potential US up-listing (planned for early 2026). Reflecting Newron's FY24 results and near-term operational guidance, we adjust our valuation to CHF385.6m or CHF19.3/share (from CHF368.5m or CHF18.5/share previously).

Year end	Revenue (€m)	PBT (€m)	EPS (€)	DPS (€)	P/E (x)	Yield (%)
12/23	9.1	(16.0)	(0.90)	0.00	N/A	N/A
12/24	51.4	21.7	0.87	0.00	8.4	N/A
12/25e	7.4	(32.1)	(1.61)	0.00	N/A	N/A
12/26e	7.9	(19.0)	(0.95)	0.00	N/A	N/A

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

Deals emerge ahead of pivotal evenamide trial

Evenamide's encouraging track record in the clinic has received validation in the form of multiple licensing deals as Newron gears up for the pivotal Phase III programme. The €117m deal with EA Pharma in Japan (c 10% of evenamide's global market potential) was noteworthy, with its sizeable €44m upfront payment and committed trial cost contributions. More recently, Newron secured Myung In Pharm as its partner in South Korea, contributing 10% of the Phase III patient population and related costs (under undisclosed licensing terms), further de-risking the programme. On track for Q225, the trial launch will represent a key near-term milestone and, while we believe additional regional deals may continue to emerge, we expect that decisions regarding the US and Europe (the largest markets) will likely only be made following the completion of Phase III.

Cash runway: Funded into H126

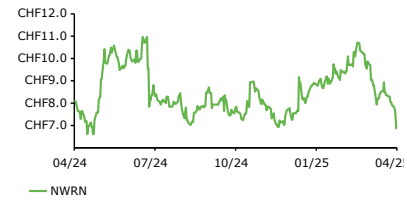
We expect Newron's end-FY24 gross cash position of €9.9m (comprising cash of €6.9m and €2.9m in short-term investments) to be bolstered by the €44.4m upfront payment from EA Pharma (realised by the company in January 2025). Based on our cash burn projections, we estimate that funds on hand will provide operational headroom into H126, after accounting for the €10m debt repayment to the European Investment Bank (EIB) due in November 2025. Newron is also seeking a secondary listing in the US in early 2026, which, if successful, will provide further liquidity.

Valuation: CHF385.6m or CHF19.3 per share

We recently published updated estimates for Newron, reflecting the latest licensing deals for evenamide in Japan and South Korea, as well as the planned Phase III trial. We keep our underlying assumptions broadly unchanged following the release of the FY24 results. We adjust our valuation to CHF385.6m or CHF19.3/share (from CHF368.5m or CHF18.5/share previously), reflecting benefits from rolling our model forward and higher pro forma cash, partially offset by further strengthening of the Swiss franc against the euro.

Price	**CHF6.93**
Market cap	**CHF138m**
	€1.05/CHF
Pro forma net cash at 31 December 2024 (including €44.4m upfront proceeds from EA Pharma)	€4.6m
Shares in issue	20.0m
Free float	95.0%
Code	NWRN
Primary exchange	SWX
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(22.3)	(14.3)	(6.7)
52-week high/low		CHF11.2	CHF6.1

Business description

Newron Pharmaceuticals is focused on the central nervous system. Xadago for Parkinson's disease is sold in Europe, Japan and the United States. Evenamide, a novel schizophrenia add-on therapy, is preparing for a Phase III trial programme targeting treatment-resistant and poorly responding schizophrenia.

Next events

Evenamide Phase III launch	Q225

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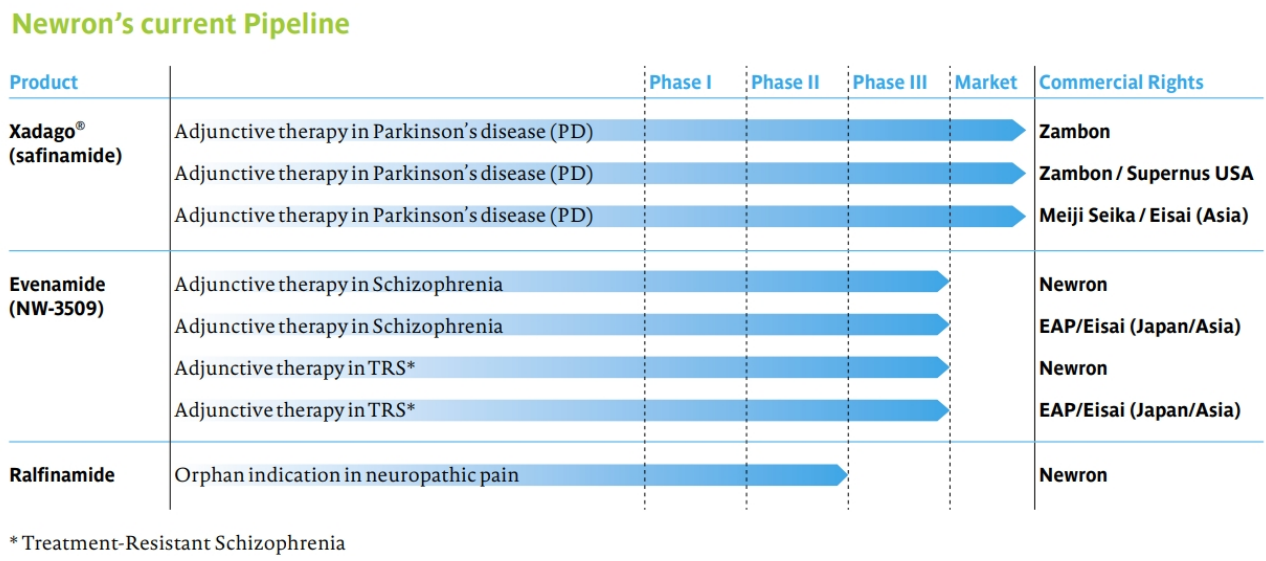
Schizophrenia-focused CNS pipeline

Newron Pharmaceuticals is a biopharmaceutical company with headquarters in Bresso (near Milan, Italy) and is listed on the SIX Swiss Exchange. It is dedicated to the clinical development of novel treatments for central nervous system (CNS) conditions (Exhibit 1). The main focus of its clinical pipeline is evenamide, a voltage-gated sodium channel inhibitor and modulator of post-synaptic glutamate release, which is currently in late-stage development for TRS (see further detail below).

Xadago (safinamide), Newron's first marketed product, is used as an add-on treatment for patients with Parkinson's disease. It has been approved in more than 20 markets (including the US, UK, EU, Switzerland and Japan), with commercial support from partners Zambon, Supernus and Meiji Seika. According to the FY24 results, the drug continues to generate steady income for Newron (>€85m in milestone payments and royalties collected to date). In particular, the company recorded €6.9m in royalty payments from Zambon in 2024 (up from €6.7m in 2023). We remind readers that Xadago is approaching the end of its market exclusivity period (in place until at least 1 December 2027). Nevertheless, we believe it showcases Newron's experience in bringing CNS drugs to the market, providing a robust foundation for evenamide, which, in our view, holds blockbuster potential, as it approaches Phase III.

We understand that the ralfinamide programme remains on clinical hold while Newron focuses on the development of evenamide as a top strategic priority.

Exhibit 1: Newron's clinical development pipeline



Source: Newron Annual Report 2024

CNS in the spotlight

As Newron's evenamide programme has garnered notable attention, exemplified by its licensing deals to date, we highlight that this reflects a resurgence of interest in CNS in the healthcare sector. In the last 18 months, there have been four multi-billion-dollar acquisitions of biotech players: Cerevel Therapeutics (by AbbVie at a 22% premium), Karuna Therapeutics (by Bristol Myers Squibb at a 53% premium), Longboard Pharmaceuticals (by Lundbeck at a 54% premium) and, most recently (announced during the JPMorgan Healthcare Conference in January 2025), Intra-Cellular Therapies (by Johnson & Johnson at a 39% premium). Of particular relevance to Newron was the Karuna deal, as it focused primarily on the schizophrenia drug candidate KarXT, which was approved by the FDA in September 2024 (with the drug now named Cobenfy). Cobenfy works via a novel mechanism of action, selectively targeting muscarinic receptors M1 and M4 (associated with cognition, learning and memory). The approval was considered a key milestone in the field of schizophrenia, which had been relatively stagnant since the 1950s, since the novel mechanism represents an advancement on the historical dopamine hypothesis of schizophrenia pathophysiology. We note that Newron does not see Cobenfy as evenamide's direct competitor, as management believes evenamide is differentiated by its favourable side effect profile and the fact that it is specifically targeting durable responses in the TRS patient population, which is not included in the label for Cobenfy.

Evenamide: Gearing up for the pivotal Phase III programme

On track to launch in Q225…

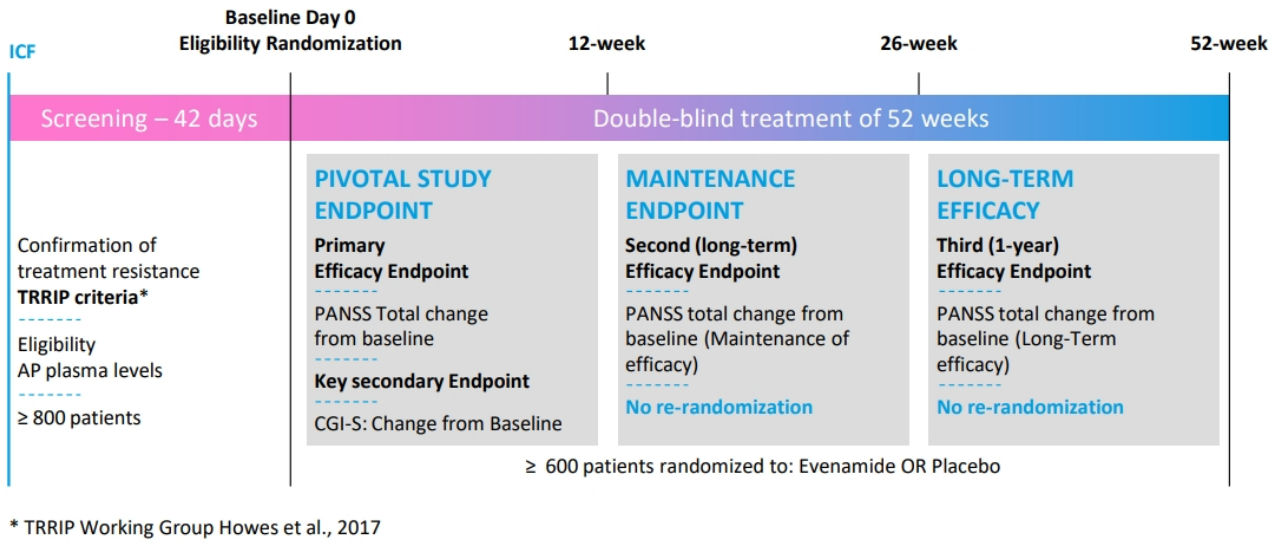
Newron announced a licence agreement with EA Pharma for evenamide in Japan in December 2024, and subsequently, an agreement with Myung In Pharm for South Korea in January 2025 (discussed in further detail in our last update note). With these regional deals in place and increased capital on hand, Newron is ready to commence the pivotal Phase III programme in Q225, in line with previously guided timelines. This has been designed as a randomised, double-blind, multinational, one-year study involving at least 600 participants, assessing evenamide as an add-on treatment in patients with TRS that is not adequately controlled by a stable therapeutic dose of current antipsychotic medication(s) including clozapine, compared to placebo. We understand that a key reason to pursue the TRS population specifically is because it may allow for regulatory approval based on just one pivotal Phase III trial. The primary endpoint measure will be based on changes from baseline in the Positive And Negative Syndrome Scale (PANSS) scores at week 12. Participants will be followed up at week 26, and at week 52, to evaluate long-term efficacy, safety and tolerability outcomes (Exhibit 2). It was noted that there will not be an opportunity for re-randomisation during treatment duration.

Key eligibility criteria for the trial include:

- Treatment resistance according to the Treatment Response and Resistance In Psychosis Working Group (Howes et al., 2017).
- Antipsychotic treatment as per standard of care, minimally one oral or depot antipsychotic at a stable therapeutic dose.
- Brief Psychiatric Rating Scale (BPRS) total score ≥ 45 at screening.
- Prominent positive symptoms as measured by BPRS.
- Clinical Global Impressions-Severity (CGI-S) rating of mildly ill to severely ill (score of 3 to 6).
- Antipsychotic plasma levels tested at screening and throughout the study to confirm adherence to the background antipsychotic therapy and evenamide therapy.

If the results (expected from H226) of this pivotal trial are positive, we expect Newron to file for regulatory approval in H127, followed by a potential commercial launch from 2028. While we do not rule out the possibility of further regional deals in the near to medium term (management has communicated that it continues to pursue further development opportunities for evenamide in other territories), we believe that any decision about the largest US and European markets will be made following completion of the planned pivotal Phase III programme.

Exhibit 2: Pivotal evenamide Phase III design



Source: Newron FY24 results and Outlook 2025 presentation

…backed by encouraging TRS data from prior clinical studies

Newron's most recent clinical readout in TRS came in January 2024, when it presented final results from the Phase II trial, study 015 (an extension of study 014). This was an open-label, rater-blinded, multi-centre trial to assess the long-term efficacy, safety and tolerability of evenamide (7.5mg, 15mg and 30mg bid) in TRS patients as an add-on treatment (to any single antipsychotic drug excluding clozapine). The data demonstrated statistically significant benefits with evenamide treatment compared to baseline, measured by PANSS scores, the CGI-S scale and Level of Functioning measures. Importantly, more than 70% of patients achieved what was considered a clinically meaningful reduction in condition severity, and it was concluded that c 50% of patients no longer met the protocol severity criteria for a diagnosis of TRS at the 12-month follow-up. Furthermore, 25% of the patients were described as achieving clinical remission, a phenomenon that, to our knowledge, has not yet been reported in the TRS population. This trial also showed that evenamide was safe and well tolerated, laying a robust foundation for the subsequent stages of clinical development, in our view.

We note that while the study 015 results were highly encouraging, they come from an open-label trial, which may be viewed as subject to biases in patient assessment. Accordingly, the pivotal Phase III TRS programme has been designed as a double-blinded trial and hence in line with the requirements for regulatory approval. Further, study 015 was based primarily in India, whereas the pivotal Phase III will be a multinational trial (across multiple key geographies).

Clozapine is the only drug that has been approved for TRS (approved in 1989, although usage remains relatively limited; it is only used by c 5% of treated schizophrenia patients, with physicians more likely to utilise polypharmacy in cases of TRS). This is believed, at least in part, to be due to the unfavourable side effect profile of the drug (such as agranulocytosis, cardiomyopathy and pneumonia), as well as the requirement for weekly blood tests (for the first 18 weeks and monthly tests thereafter) under FDA-mandated 'risk evaluation and mitigation strategy' monitoring. We therefore believe that TRS and poorly responding patients (see below) remain areas with significant unmet need, requiring new treatment modalities with a differentiated mechanism of action, such as evenamide.

Beyond TRS (poorly responding patients)

A key achievement for FY24 was the results of study 008A (n=291), presented in April/May 2024. While not focused on TRS, this trial included patients with poorly managed schizophrenia not meeting the definition of treatment-resistant (c 40% of schizophrenia patients). These results were also positive, meeting the primary endpoint (of improvement in the PANSS score from baseline) and secondary endpoint (improvement on the CGI-S scale). Notably, 31.3% of patients treated with evenamide were rated as 'much improved' compared to 17.3% in the placebo group, according to the CGI-S scale, consolidating the already robust data from study 014/015, albeit in a larger, randomised, placebo-controlled setting. While these results are highly favourable, we remind readers that the upcoming Phase III programme will focus on the TRS patient population (c 30% of schizophrenia patients) only for now, although the data from study 008A do

provide encouragement, in our view.

Financials

Top-line growth supported by licensing payment from Japan

Newron's reported revenues of €51.4m in FY24, broadly in line with our estimate of €50.9m, comprised the €44.5m upfront payment from EA Pharma (for evenamide's licensing rights in Japan) and €6.9m in royalty inflows from its on-market drug Xadago. In comparison, FY23 revenues came in at €9.1m, primarily derived from Xadago-related royalty income (€6.7m) and other payments from partners (€2.3m). Total operating expenses for the year were recorded at €25.2m (higher than our estimate of €19.5m) and were up 21.9% y-o-y. This was mainly attributed to higher G&A expenses recorded during the year, which rose by 53.7% y-o-y to €11.6m. This growth in G&A was primarily driven by higher consulting and professional fees (€6.0m versus €2.7m in FY23) related to fund-raising and out-licensing efforts by the company during the year. R&D expenses stayed broadly flat at €13.6m (€13.2m in FY23), although we had estimated these to be lower (€10.4m) given the lower levels of clinical activity on evenamide ahead of the initiation of the Phase III pivotal study in Q225. Overall, benefiting from the upfront payment, Newron reported operating income of €26.2m in FY24 versus an operating loss of €11.6m in the previous year. The company reported PBT of €21.4m in FY24, compared to a loss of €16.2m in FY23, which incorporated €4.3m in interest expenses related to accrual of the outstanding €40m loan from the EIB, secured in October 2018.

Estimate revisions

We recently presented our updated estimates for FY25, to reflect licensing deals for evenamide in Japan and South Korea, and keep our top-line estimates broadly unchanged following the FY24 results. We expect revenues of €7.4m in FY25, made up entirely of Xadago royalties. Note that these estimates do not include potential licensing inflows from other regional deals for evenamide which the company may undertake, and are therefore subject to revision. Following Newron's latest update on the commencement date of the Phase III trial (Q225), as well as the expected timeline for top-line results (Q3/Q426), we bring forward some of our estimates for R&D expenses in FY25. As noted in our previous update, we estimate total Phase III trial costs at c €45m, of which we assume EA Pharma and Myung In Pharm will contribute €10m and €3m, respectively. This translates to a net outflow of €32m required from Newron, which we now split 70:30 between 2025 and 2026, versus 40:50:10 between 2025, 2026 and 2027. Accordingly, we revise our R&D expense estimate for FY25 to €22.7m, from €13.4m previously. We also update our FY25 G&A estimate to €11.7m (from €9.2m previously) to reflect the FY24 run rate. Overall, we now forecast an operating loss of €27.0m in FY25 (loss of €15.1m previously). As we roll forward our model for the FY24 results, we introduce FY26 estimates, projecting revenues of €7.9m and an operating loss of €13.9m.

Operational headroom into H126

Newron exited FY24 with a gross cash position of €6.9m and €2.9m in other current financial and liquid assets. We also note that the company realised the €44.4m upfront payment from EA Pharma in January 2025, which adds up to a pro forma gross cash balance of €55.2m. Newron also has €49.7m of debt on its books, comprising the €40m loan from the EIB and accrued interest. Following renegotiations with the EIB in March 2024, the deal maturity for the first three tranches (of the total five) will now be in late 2025/26. The first €10m tranche is due in November 2025 (vs June 2024 previously), with the other four tranches maturing in 2026. Based on cash at end FY24, the debt repayment schedule and our burn projections, we estimate that Newron is funded into H126, a slightly more conservative estimate than management's guidance of Q326. We calculate that the company will need to raise a further €50m in capital in early 2026 to service the remaining €30m EIB debt (assuming the repayment terms are not renegotiated again) and continue to fund the Phase III study.

Valuation

We recently published an updated valuation of Newron, following the licensing deals in Japan and South Korea. Following the FY24 results, we keep our underlying assumptions unchanged. For evenamide, we continue to assume a regulatory filing in the US in 2027, factoring in top-line readouts in Q3/Q426 and around two to three months to prepare the data package, with approval in 2027 and launch in 2028. We continue to assign a 70% probability of success, with

peak sales of c €1.7bn (including the US, Europe and Japan), to be achieved in 2034.

Reflecting these underlying assumptions, forex changes, rolling our model forward and the latest pro forma cash position, we adjust our valuation for Newron to CHF385.6m or CHF19.3/share (vs CHF368.5m or CHF18.5/share previously). A breakdown of our risk-adjusted net present value (rNPV) is shown in Exhibit 3.

Exhibit 3: Newron rNPV valuation

Product	Indication	Launch	Probability	rNPV (CHFm)	rNPV/Share (CHF/share)
Xadago	Parkinson's Disease	2015	100%	22.1	1.1
Evenamide	TRS/Schizophrenia non-responders	2028	70%	421.0	21.1
Total direct product value				**443.0**	**22.2**
Direct costs to 2034 less tax				(61.8)	(3.1)
Pro-forma net cash at end-December 2024				51.5	2.6
Loans (fair value December 2024)				(47.2)	(2.4)
Valuation				**385.6**	**19.3**

Source: Edison Investment Research. Note: Per-share value is based on 19.96m shares outstanding.

Exhibit 4: Financial summary

Accounts: IFRS; year-end 31 December; €000s	2022	2023	2024	2025e	2026e
PROFIT & LOSS					
Total revenues	6,094	9,057	51,390	7,384	7,881
Cost of sales	0	0	0	0	0
Gross profit	6,094	9,057	51,390	7,384	7,881
Total operating expenses	(19,396)	(20,686)	(25,217)	(34,422)	(21,763)
Research and development expenses	(12,005)	(13,152)	(13,642)	(22,723)	(9,940)
G&A	(7,391)	(7,534)	(11,575)	(11,699)	(11,823)
EBITDA (normalised)	(12,620)	(11,231)	26,621	(26,642)	(13,622)
Operating income (reported)	(13,302)	(11,629)	26,173	(27,038)	(13,882)
Finance income/(expense)	(4,170)	(4,571)	(4,779)	(5,031)	(5,087)
Profit before tax (reported)	(17,472)	(16,200)	21,394	(32,070)	(18,969)
Profit before tax (normalised)	(16,992)	(16,003)	21,650	(32,070)	(18,969)
Income tax expense (includes exceptionals)	(21)	(24)	(5,551)	0	0
Net income (reported)	(17,493)	(16,224)	15,843	(32,070)	(18,969)
Net income (normalised)	(17,013)	(16,027)	16,099	(32,070)	(18,969)
Basic average number of shares, m	17,845	17,845	18,563	19,959	19,959
Basic EPS (€)	(0.98)	(0.91)	0.85	(1.61)	(0.95)
Adjusted EPS (€)	(0.95)	(0.90)	0.87	(1.61)	(0.95)
BALANCE SHEET					
Property, Plant and Equipment	72	53	43	35	28
Right of use assets (leases)	455	352	791	513	333
Non-current receivables (Tax credits)	8,175	5,809	1,970	2,042	2,073
Total non-current assets	8,702	6,214	2,804	2,590	2,435
Cash and equivalents	13,424	6,338	6,933	8,023	9,854
Current financial assets	9,350	6,261	2,893	0	0
Trade Accounts Receivable	5,719	7,053	51,278	9,278	9,278
Total current assets	28,493	19,652	61,104	17,301	19,132
Trade Accounts Payable	4,869	6,106	9,430	7,768	8,599
Other Current Liabilities	172	543	662	662	662
Short-term Debt	0	22,277	13,414	33,414	3,414
Total current liabilities	5,041	28,926	23,506	41,844	12,675
Long-term Debt	45,165	25,753	36,243	6,243	56,243
Leasing Obligations	325	210	673	387	201
Share-based liabilities	220	473	1,568	1,568	1,568
Long-term Provisions	474	412	460	460	460
Total non-current liabilities	46,184	26,848	38,944	8,658	58,472
Equity attributable to company	(14,030)	(29,908)	1,458	(30,612)	(49,580)
CASH FLOW STATEMENT					
Pre-tax profit	(17,472)	(16,200)	21,394	(32,070)	(18,969)
Net Financial Income	(1,183)	(1,162)	(1,847)	21	12
Tax	0	0	0	0	0
Depreciation and amortisation	202	201	192	396	260
Share-based payments	480	197	256	0	0
Other adjustments	4,996	5,311	144	(72)	(31)
Movements in working capital	1,885	1,513	(37,753)	40,338	831
Cash from operations (CFO)	(11,092)	(10,140)	(17,614)	8,614	(17,897)
Capex	(18)	(11)	(13)	(111)	(73)
Acquisitions & disposals net	0	0	0	0	0
Other investing activities	(299)	3,257	3,171	2,893	0
Cash used in investing activities (CFIA)	(317)	3,246	3,158	2,782	(73)
Loans received	0	0	0	0	50,000
Loan repayments	0	0	0	(10,000)	(30,000)
Equity issued	0	0	15,244	0	0
Other Financing Cash Flows (leases)	(186)	(192)	(193)	(307)	(199)
Cash from financing activities (CFF)	(186)	(192)	15,051	(10,307)	19,801
Cash and equivalents at beginning of period	25,019	13,424	6,338	6,933	8,023
Increase/(decrease) in cash and equivalents	(11,595)	(7,086)	595	1,090	1,831
Effect of FX on cash and equivalents	0	0	0	0	0
Cash and equivalents at end of period	13,424	6,338	6,933	8,023	9,854
Net (debt)/cash (including liquid resources)	(22,391)	(35,431)	(39,831)	(31,634)	(49,803)

Source: Company accounts, Edison Investment Research

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