EDISON

Paion

FY19 results and update

Positive prospects with strategic uncertainties

Pharma & biotech

By 5 July 2020, the FDA is due to announce its decision on remimazolam (ByFavo) for procedural sedation (PS). In Japan, Remimazolam (Anerem) was approved in January for general anaesthesia (GA). Paion guides to royalties of under €1m for 2020. In the EU, the possible approval for PS is due in H121. The GA European trial has closed early with 424 patients; this potentially gives launch from late 2021 with top-line data in H220. Paion is considering licensing or acquiring products to make a direct European salesforce economic. Until this happens, we base our valuation on a royalty deal. Due to a reappraisal of short- and longer-term costs, our indicative value is adjusted to €270m, formerly €317m. Paion is funded until H221 and has loan facilities to take cash until 2022 if needed.

Year end	Revenue (€m)	PBT* (€m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
12/18	2.77	(12.45)	(15.9)	0.0	N/A	N/A
12/19	8.00	(9.35)	(10.8)	0.0	N/A	N/A
12/20e	20.30	2.42	3.7	0.0	48.9	N/A
12/21e	4.21	(20.88)	(31.2)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding exceptional items.

US approval likely, with sales via Acacia

The FDA review for PS will now complete by 5 July 2020 (PDUFA). This is taking longer as more data were requested. Cosmo (Paion's US partner) sublicensed US sales to Acacia, a new company selling Barhemsys for post-operative recovery. Acacia is recruiting a US salesforce, which we presume might be affected by the viral epidemic and fewer elective operations. We expect that Paion will receive a €15m milestone on US approval and a 20% royalty on sales. ByFavo launch is expected in Q420, but royalties will only become significant from 2021 onwards.

Japan and European launch sequence

In Japan, remimazolam (Anerem) was approved for GA in January, enabling a mid-2020 launch by Mundipharma. This triggered a further milestone payment. In late 2019, Paion filed remimazolam with the EMA for PS; the outcome is now likely in H121. The EU main market is seen as GA. The GA Phase III (NCT03661489) has closed enrolment at 424 patients out of 500 planned. This will allow analysis in H220, with possible launch after an abbreviated application in Q421.

Valuation: Adjusted to €270m with cash until H221

Paion has stated that it aims to become a profitable company within five years. It has cash (€18.8m), expected milestones in 2020 (€20m) and EIB loan facilities (€20m) to cover planned expenses to H221 plus potential royalties, assuming US ByFavo approval. The company is evaluating the economics of creating a direct salesforce in Northern Europe to sell remimazolam, but a portfolio of related products is required. Given this is challenging to acquire and license, we still assume that remimazolam is outlicensed with a royalty. For 2020 and 2021, we have adjusted US royalty expectations and updated short-term cash flows. This gives a revised value of €270m (formerly €317m) or €4.23/share pre dilution. This will be further revised as market projections and strategies become better defined.

17 April 2020

Price	**€1.81**
Market cap	**€118m**
	US$1.10/€
Cash (€m) at 31 December 2019	18.8
Shares in issue (12 March 2020)	65.28m
Free float	75%
Code	PA8
Primary exchange	Frankfurt
Secondary exchange	Xetra

Share price performance

%	1m	3m	12m
Abs	19.9	(13.4)	(17.0)
Rel (local)	1.7	12.9	(2.5)
52-week high/low		€2.6	€1.4

Business description

Paion develops the fast-onset and short-recovery anaesthesia product remimazolam. This is approved in Japan and could gain US approval in July where it is sublicensed to Acacia. It is filed in the EU, China and South Korea. A European Phase III general anaesthesia has ended enrolment for a possible H121 regulatory filing.

Next events

FDA ByFavo PDUFA	5 July 2020
GA Phase III top line data	H220
Interim FY20 report	12 August 2020

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Edison profile page

Development phase moves to commercial stage

Paion already has one regulatory approval, for GA in Japan, and could receive more this year, of which the crucial one will be the US by 5 July. The current status of remimazolam is in Exhibit 1 as stated by Paion. It is possible that the viral pandemic may delay the regulatory reviews, but we assume it will not. The biggest impact will be Covid-19 viral disruption to healthcare systems with possible postponement or cancellation of discretionary procedures and elective surgery. However, this will create a backlog for 2021. This could be a long-term gain in that a more efficient anaesthesia product could be adopted more rapidly. EvaluatePharma estimates that the 2018 world injectable anaesthetics market was worth $213m.

Exhibit 1: Summary of remimazolam development status and global partners

Region/partner (brand name)	Lead indication	Clinical status	Notes
US/Cosmo-Acacia (ByFavo)	PS	PDUFA 5 July 2020	Phase III studies in PS against midazolam completed, including in colonoscopy and bronchoscopy and a safety study in higher-risk colonoscopy patients. Now sublicensed to Acacia, a UK-based company building a US direct salesforce. Launch in H220 possible but delays probable due to viral impact on US healthcare. Milestone of €15m expected on FDA approval.
EU (Aptimyda)	PS	Approval from Q121	An EMA filing in Dec 2019 for PS based on US dossier; possible commission approval from Q121.
	GA	Phase III	Phase III study in 500 GA surgery patients against propofol. Trial ended early In April 2020 at 424 patients. We expect top-line outcomes in H220 and an abbreviated filing in H121 after the PS decision by the EMA (if positive); this takes six to nine months. If so, the GA indication might be marketed from late 2021 since we assume that remimazolam will already be marketed for PS.
Japan/Mundipharma (Anerem)	GA	Approved Jan 2020	Launch mid-2020. Japan has low levels of viral infection so far, so launch probably on track. Triggered a 2020 milestone. The launch stock order was filled and paid in 2019 and will be recognised as revenue in 2020; Paion supplies the product with a small margin.
South Korea/Hana Pharm	GA	Phase III	Hana Pharm paid a €1.5m milestone in 2020 for rights to Asia (ex-China and Japan) and plans to file for market approval in 2020. It will produce remimazolam in South Korea.
China/Yichang Humanwell	PS	Filed in PS	Subject to the requirements of the SFDA. Filed for approval in procedural sedation in November 2018. Possible 2020 approval. Phase II being run in GA.
CIS, Russia, Turkey, MENA/R-Pharm	GA	File in 2020?	R-Pharm has a licence to develop, manufacture and commercialise remimazolam in these regions. In Russia, R-Pharm may file for GA approval in 2020. A trial completed in 2018.
Canada/Pharmascience	PS	File H220?	Filing based on the US dossier. However, no timeline as yet and will depend on US outcome.

Source: Paion, Edison Investment Research. Note: PS: procedural sedation, GA: general anaesthesia.

Although use in intensive care units (ICUs) is a potential indication, there are no trials running and so it is not considered. We will include this if trials are run (which is possible). It could be a better alternative to midazolam (which accumulates and causes delirium) or propofol (with respiratory and cardiovascular side effects) (Reade and Finfer (2014)). For adoption, cost could be an issue and usually a hospital has only a few ICU beds, limiting the market. The COVID-19 viral situation and possible greater long-term demand for ICU capacity with longer ICU stays may mean this indication is developed as a safer sedation agent that reduces nursing demand.

US update and market

The US sublicensee, Acacia, is now preparing a US salesforce to sell its own product, although this might be handicapped by the current virus pandemic; the company has not made any recent statements. Preparatory work for a ByFavo launch, assuming a successful FDA review, could pave the way for launch in Q420 with the first full sales year in 2021. We expect a price of about US$25 per 20mg PS vial. This is much higher (10x) than midazolam. Paion notes that, based on the US trials, if use of ByFavo saves up to 22 minutes per procedure, then a clinic could carry out perhaps three extra colonoscopies per day. As the clinic is paid per procedure, this will boost income. This assumes that the clinic has unmet demand.

Paion views the most attractive US market segment as being about 15m colonoscopies per year. At US$25 per vial, this would be a worth about US$375m at a royalty rate estimated at 20%. There are other endoscopy procedures, so the total market might be 26.7m vials/year according to Paion.

Of the colonoscopy procedures, about 50% already use propofol for deep sedation, Predmore et al (2017). Dossa et al (2020) observed that the fast onset of propofol and the deep sedation obtained gave higher levels of patient satisfaction. However, propofol has a relatively narrow therapeutic window and can cause apnea (when patients stop breathing), so the FDA requires that an anaesthesiologist or nurse anaesthetist administers the drug. The cost of sedation is included in the fixed reimbursement rate.

Paion estimates that 75–80% of procedures are done outside hospitals, for example in private ambulatory clinics. The small planned Acacia salesforce will mainly sell its post-operative product (Barhemsys) to rescue patients suffering from nausea and vomiting and unresponsive to current medications. This is only used in post-surgical recovery units in hospitals.

There remains the potential for a US GA indication. This requires that Acacia funds the study. We give this a 20% probability. We understand from Paion management that any trial would use remimazolam as an anaesthesia induction agent (vs propofol) but not extend its use to prolonged anaesthesia, as with the European Phase III. This would be a relatively simple study to run and take 18–24 months. If the study started in 2021, remimazolam could be approved in 2023 and marketed from 2024.

EU update and market

Paion has a strategic dilemma. To capture a bigger share of the profits from the disparate and complex European markets, it needs to sell direct, at least in major territories like Germany. However, running a direct salesforce is expensive, sales in Europe take time to build and many countries require economic assessments of new products. The two options are:

- build a Paion distribution structure in selected European markets provided that the portfolio can be extended by acquiring or in-licensing additional approved products; or
- Paion could out-license remimazolam for the whole of Europe.

For Paion, a small company with no salesforce, in-licensing or acquiring approved, high-value, high-growth additional products will be a challenge. The likeliest route would be branded generics, including generic reformulations, but these sell into competitive markets.

The first approved indication will be PS. The 2015 Eurostat dataset reports 4.6m colonoscopy procedures. In addition, there were about 1m bronchoscopy procedures. This gives a minimum identifiable PS market of 5.6m procedures. Most of these are in northern Europe. At €12 per PS vial and 50% assumed midazolam use, the addressable market might be €34m. We would note that we are unsure how comprehensive Eurostat data are. It probably under-records procedures and Paion has not supplied its own estimates. European launches are a slow succession of country rollouts with pricing and economic negotiations.

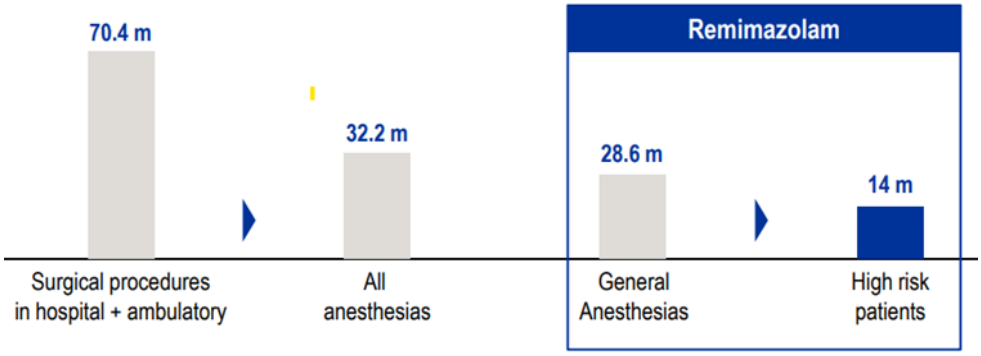
The GA trial had enrolled 424 patients as of 25 March. On 2 April, Paion announced, given a drop in the number of centres recruiting due to the COVID-19 viral situation affecting elective surgery, that the trial had been stopped early as there were enough patients to meet the endpoint. The regulatory application will be supported by data from other trials. This means that the data could be analysed from Q2 and top-line outcomes released in H220. The dossier could therefore be largely ready by the date of the PS decision, expected in Q121 now. Assuming the PS decision is for apporval, an abbreviated application could be lodged in H121 meaning a decision from Q421. As we assume that a PS indication will have been launched already, this would enable a GA indication to be launched immediately, at least in some territories like Germany.

Closing the trial early will save some cash (we assume at least €1m), but there some costs that would have been in 2021, like analysis and dossier completion, that will occur instead in 2020. Closing the trial early means that the confidence intervals on the statistical analysis could be wider and outcomes possibly less robust. Offset against that is the opportunity of potentially getting the GA indication approved 12 months or more earlier than might have otherwise been the case.

Use of remimazolam in GA

Most European surgery uses an initial sedation dose of propofol (generic, low cost) and then anaesthetic gases such as sevoflurane or desflurane (from a cylinder) to maintain anaesthesia. These are given though a mask and blended with oxygen. The amounts are easily regulated with a valve and can be quickly adjusted. Paion identifies 14 million surgical patients in Europe as high risk (Exhibit 2) and therefore who might benefit from the use of remimazolam as a safer agent.

Exhibit 2: Paion estimates of European GA market



- Patient demographics continue to evolve driven by the aging population and the differences between the functional or physical ages of patients compared to actual age
- General Anesthesia is more frequently offered to elderly patients than years ago but the choice is an individual one depending on the type of surgery, the underlying disease and assessment of the general physical health of the patient, including co-morbidities

1. Modeled data combining 2010 and 2012 national and regional statistics

Source: Paion 2019 results presentation

Remimazolam would compete in the proportion of procedures using total intravenous anaesthesia (TIVA). This currently uses a sedation dose of propofol then a steady infusion of propofol to maintain general anaesthesia. Other products and drugs are added, for example muscle relaxants, nerve blocks and opioids for pain. TIVA is suited to higher-risk patients but is more technical.

Remimazolam would have a potential advantage in higher-risk patients as propofol can cause cardiovascular problems (hypotension (low blood pressure)) and respiratory depression. The current Phase III uses TIVA and has the number of hypotension incidents during surgery as a secondary endpoint. The primary endpoint is depth of anaesthesia. It might be necessary to run a further longer-term outcomes study to show an overall benefit in terms of long-term reduced morbidity. Walsh et al (2013) surveyed over 33,000 surgery patients and found that if blood pressure dropped to under 55mm Hg, the risk of acute kidney injury or myocardial (heart muscle) injury was increased when measured after 30 days. Anaesthetists are aware of and monitor for hypotensive events.

If a GA procedure uses two 50mg vials of remimazolam at €20 each, the cost will be €40 per procedure. Based on 14 million surgical patients in Europe as high risk, the potential market is therefore €560m. The proportion of these using TIVA, rather than anaesthetic gas, is hard to determine and probably varies by country and by medical speciality. TIVA is more likely to be used

in countries like Germany (Paion data) and less used in other countries like the UK (Sury et al (2014)). If one assumes 20% of high-risk cases use TIVA, the addressable GA market on Paion data would be about €110m.

Japan – approved for GA with partner Mundipharma

In December 2017, Paion licensed the Japanese rights to remimazolam to Mundipharma.[1] In Japan, remimazolam is branded as Anerem. The deal was €1m upfront and up to €25m in milestones, mostly probably sales related. The royalty rates start at low double digits (12.5% we assume) and rise to over 20%.

Approval was announced on 23 January 2020; this will trigger milestone payments totalling €1.5–2.5m. Pricing is under negotiation. We assume, based on discussions with Paion, ¥2,000 (about €16.50) for a 20mg vial and possibly about ¥3,300 (€27.50) for a 50mg GA vial. The World Health Organization has imputed surgical numbers for Japan in 2012 of about 16–20 million, but this is all procedures, not just the addressable market.

Mundipharma has an obligation to develop remimazolam for PS and ICU sedation in Japan. We expect a decision on whether these are viable to be made once Mundipharma has initial sales data.

Financials

In FY19, Paion's main costs were associated with GA development. R&D was €13.1m (vs €12.2m FY18). The guidance for FY20 R&D is €10–12m, with the GA Phase III now ended and a paediatric study due to start. We assume a drop in R&D from 2021 as the Phase III will have closed and a paediatric study should be near completion. For regulatory purposes, the work on the dossier should be largely complete in 2020. Any further studies would be paid by partners.

General costs (SG&A) in FY19 rose to €5m (FY18: €3.4m), mainly due to investment in manufacturing supply. There were €0.7m of non-cash items (see below) associated with the €5m convertible notes from Yorkville. FY20 guidance is for €8m of expenses. In line with guidance on cash, we expect that these costs will rise significantly in FY21, perhaps to €15m, to support commercialisation. Assuming European partnering, corporate costs should drop back after 2021.

The costs should be offset in FY20 by at least €20m of income. This will be mainly the expected milestones (see below) and bulk sales of remimazolam, although the latter have only a small margin. Management guides that less than €1m will come from royalties. It appears that UK tax credits are not now available. In cash flow, about €2.5m of R&D tax credits were booked in 2019 and should be received by the company in 2020. Overall, in FY20, we expect a profit; guidance is a range from -€1m to €3m and we expect this to be towards the upper end of the range at about €2m.

Milestones available from 2020 onwards total €76.6m. Of these, €35m relate to the US, of which €15m is expected in 2020 and €22m relates to Japan, of which we expect up to €2.5m in 2020. Other 2020 milestones could be Korea and Asia (€4.2m maximum including any in 2020) and China (€0.5m). The remaining €20m of US milestones require Acacia to run and fund studies in GA and perhaps IND; we have retained the €10m GA milestone in 2023 at a 20% probability adjustment.

Cash at the FY19 year end was strong at €18.8m. Of this, some came from a €5m convertible loan issued by Yorkville; there were about €300k in transaction costs. Another €15m could be drawn down, but management has indicated that this is not planned. Another €2.5m came from the FY18

[1] Mundipharma is privately owned as part of the Sackler-Purdue Pharma business. It might be sold to enable Purdue to settle large opioid mis-selling claims. Mundipharma sell opioids and anaesthetic products.

tax credit. Amounts payable rose to €4.8m, giving a cash boost of €2.7m. We assume this is mainly incurred clinical cost, which will be paid in 2020.

Management indicates that available cash will cover operating expenses until the second half of 2021 based on the FY19 close. FY20 income is basically milestones. FY21 cash flows will derive more from royalties, basically the US and Japan as Europe will be minimal. Hence, we expect that €10m of the EIB loan might be drawn in 2021. This is shown as a long-term loan in the Edison financial forecasts. This will leave €10m of EIB loans available in 2022, if needed.

Yorkville

Paion entered a convertible loan agreement with Yorkville for up to €15m in August 2019. The first tranche of €5m was then drawn with some conversions in 2019. The face value of the loan in the balance sheet on the 31 December was €4.35m. Between 1 January and 12 March 2020, €1.8m of loans were converted, leading to 1.12m new shares being issued. As of 12 March, €2.4m of loans were outstanding so, due to conversions, we expect some further dilution in 2020; this might be about 1.5m shares at the current share price.

Paion management has no plans to draw further convertible loan tranches (€10m available).

Valuation

There are several short-term technical adjustments to the valuation model given the better information on short-term regulatory and launch timings and company operational costs. Longer term, we have not adjusted our product forecasts or assumptions so these remain consistent with previous valuations. However, we note that major adjustments are likely once the actual pricing and, in particular, the European marketing strategy have been better defined. We do not expect such model adjustments before H220, especially with the fluid situation due to the viral epidemic.

- Cash is updated to €18.8m (31 December 2019), but offset by the €2.4m of outstanding Yorkville loans as of 12 March. The loans are being converted to equity (see below).
- In 2020, €20m of milestones in line with management guidance are assumed. We have no visibility on 2021 milestones but assume about €1m from smaller countries. There is a €0.5m milestone due from R-Pharm as a receivable amount in the 2019 balance sheet; €1m was received in 2019.
- We expect very limited US royalties in 2020. However, we note that the situation in US healthcare is fluid and might change significantly after the July PDUFA date.
- In Japan, Mundipharma is a well-established player in analgesics and the product is approved. Hence, we expect some royalties after a mid-2020 launch. The Japanese market dimensions remain very opaque, however, making forecasting difficult.
- With no trials planned by Cosmo, we have removed expectations for €10m of ICU development milestones from the US. The question of if a GA indication might be developed is still open and we have included a 20% adjusted €10m milestone in 2023. However, we assume that any GA sales are within the current forecast as this market needs clearer definition.
- In Europe, we do not expect launch for PS until mid-2021. We forecast the GA indication in Europe to launch in late 2021 with 2022 as the first full sales year. We base the forecast, as before, on our expectation of a partnering strategy using one or more regional companies and a 30% royalty rate (as post-approval). This is a high rate, but the marketing partner(s) bear no development or regulatory risk so a range of 25–30% seems realistic, in our view. If Paion brings in new products to make a direct salesforce economic, this could boost returns but also create short-term cost; we do not model this.

- We now assume that core cash costs from 2023 drop to €7m. This is based on a royalty model and would change if direct sales were started due to extra products. This more realistic assumption assumes minimal R&D as product support. This does reduce the overall value as the cost assumption has increased.
- We have adjusted the probability in Japan to 100% but not changed other probabilities.
- We have added a new royalty stream from PS sales in Europe.
- Paion sources and sells on remimazolam to its partners. This has a cost of goods and a small margin, now included in the model and valuation.

The above changes give a revised indicative value of €270m vs €316.8m previously (Exhibit 3). The new indicative value is based on a valuation date of 1 January 2020. This equates to €4.23 per share based on 65.28m shares in issue as of 12 March 2020.

Exhibit 3: Summary valuation

	Current indicative value (€m)	Former indicative value (€m)
Current value of risk-adjusted royalties	364.3	372.1
Risk-adjusted milestones	21.9	41.2
Profit on supply of remimazolam	2.1	
Expenses	(70.9)	(22.8)
Tax	(63.5)	(83.2)
Cash at 31 December 2019	18.8	9.4
Debt (12 March face value)	(2.4)	
Total	**270.3**	**316.8**

Source: Edison Investment Research

The changes to potential royalties are minimal, about -2% due to short-term revised sales expectations. The biggest impact on our current valuation vs previous expectations is the inclusion of higher costs but with reductions in the longer term as R&D expenses are expected to be much lower. These are offset by lower expected tax bills. The milestone amount in the valuation has been adjusted as discussed above.

Exhibit 4: Financial summary

€'000s	2018	2019	2020e	2021e
Year end 31 December				
PROFIT & LOSS				
Revenue	2,766	8,000	20,295	4,207
Cost of sales	0	0	(120)	(1,284)
Gross profit	2,766	8,000	20,175	2,924
Operating profit	(12,711)	(9,346)	2,210	(21,096)
Depreciation and amortisation	(256)	(120)	(214)	(214)
Share-based payments	0	0	0	0
Exceptionals	0	0	0	0
EBITDA	(12,455)	(9,226)	2,424	(20,882)
Operating profit (before amort. and except.)	(12,455)	(9,226)	2,424	(20,882)
Net Interest	6	(122)	0	0
Profit Before Tax (norm)	(12,449)	(9,348)	2,424	(20,882)
Profit before tax (reported)	(12,449)	(9,448)	2,230	(21,076)
Tax	2,510	2,432	0	0
Profit after tax (norm)	(9,939)	(6,916)	2,424	(20,882)
Profit after tax (reported)	(9,939)	(7,016)	2,230	(21,076)
Average number of shares outstanding (m)	62.5	63.9	66.0	67.0
EPS - normalised (c)	(15.9)	(10.8)	3.7	(31.2)
EPS - reported (c)	(15.9)	(11.0)	3.4	(31.5)
Dividend per share (c)	0.0	0.0	0.0	0.0
Gross margin (%)	NA	NA	NA	NA
EBITDA margin (%)	NA	NA	NA	NA
Operating margin (before GW and except.) (%)	NA	NA	NA	NA
BALANCE SHEET				
Fixed assets	2,286	2,262	2,068	1,874
Intangible assets	2,212	2,137	1,943	1,749
Tangible assets	74	46	46	46
Refund from assumption of dev costs	0	0	0	0
Other	0	79	79	79
Current assets	22,037	22,650	23,048	12,165
Stocks	0	0	0	0
Debtors	1,500	500	0	464
Cash	17,227	18,787	22,252	10,905
Other	3,311	3,363	796	796
Current liabilities	(3,501)	(10,179)	(3,800)	(3,800)
Trade payables	(2,218)	(4,843)	(2,843)	(2,843)
Short-term borrowings	0	(4,354)	0	0
Provisions	(630)	(956)	(956)	(956)
Other current liabilities	(654)	(26)	0	0
Long-term liabilities	0	0	0	(10,000)
Long-term borrowings	0	0	0	(10,000)
Provisions	0	0	0	0
Long-term deferred income	0	0	0	0
Deferred taxes	0	0	0	0
Other long-term liabilities	0	0	0	0
Net assets	20,822	14,733	21,316	240
CASH FLOW				
Operating cash flow	(16,547)	(5,274)	944	(21,326)
Net interest	5	(8)	0	0
Tax	3,729	2,435	2,567	0
Capex	0	(15)	(20)	(20)
Purchase of intangibles	0	0	0	0
Acquisitions/disposals	(13)	1	0	0
Equity Financing	5,214	0	4,354	0
Dividends	0	0	0	0
Other	0	4,421	(4,380)	10,000
Net cash flow	(7,612)	1,560	3,465	(11,346)
Opening net debt/(cash)	(24,839)	(17,227)	(14,433)	(22,252)
Effect of exchange rate changes	(0)	0	0	0
Other	0	(4,354)	4,354	(10,000)
Closing net debt/(cash)	(17,227)	(14,433)	(22,252)	(905)

Source: Edison Investment Research, company accounts

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