EDISON

Actinogen Medical

Pipeline update

Refining the upcoming XanaMIA Phase IIb study

Pharma and biotech

Actinogen intends to start patient enrolment and dosing in H2 CY23 in the Phase IIb XanaMIA study portion assessing Xanamem in lead indication Alzheimer's disease (AD). The company expects to receive FDA approval in the coming weeks on amendments to the study design protocol and the new Xanamem tablet formulation to be used (replacing the capsule used in prior Xanamem trials). It expects to report top-line efficacy data in H2 CY25, with interim readouts projected in or around late CY24 or early CY25. We believe market participants will be keen to observe whether this study, which prospectively enrols patients with elevated pTau, will confirm the positive findings shown in a subset biomarker analysis from the earlier XanADu study. Positive Phase IIb data could introduce the possibility of material out-licensing or value realisation opportunities, in our view.

Year end	Revenue (A$m)	PBT* (A$m)	EPS* (A$)	DPS (A$)	P/E (x)	Yield (%)
06/21	2.0	(3.3)	(0.002)	0.0	N/A	N/A
06/22	3.6	(7.9)	(0.005)	0.0	N/A	N/A
06/23e	4.0	(9.4)	(0.005)	0.0	N/A	N/A
06/24e	4.1	(37.6)	(0.020)	0.0	N/A	N/A

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

Revisions to XanaMIA Phase IIb study design

The Phase IIb portion of the XanaMIA study is designed to assess Xanamem versus placebo in 330 patients with biomarker-positive AD, as determined through an elevated level of pTau-181 (phosphorylated Tau-181) protein in the blood. Patients will receive treatment (or placebo) for 36 weeks (up from the originally planned 24 weeks), which is expected to improve the ability to show differences versus placebo or possible disease-modification effects. The study will now include patients with moderate AD to match the elevated pTau subset population from the prior XanADu Phase IIa study more closely. Finally, a cognitive composite of several tests will be used as the primary endpoint, with the Clinical Dementia Rating – Sum of Boxes (CDR-SB) functional score remaining a key secondary endpoint.

Operations funded through late CY23

We believe Actinogen remains funded into Q4 CY23 (Q224) and continue to model it will raise A$60m before end-FY24 given the expected rise in expenses once the AD study commences. While the total funding requirements to bring an AD drug to market are substantial, we believe Actinogen will seek non-dilutive funding and/or partnership arrangements, which may reduce the overall funding need.

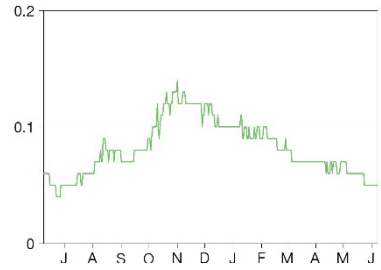
Valuation: Revisions to launch timing forecasts

Our near-term forecasts are largely unchanged but as primary efficacy readouts from the XanaMIA Phase IIb portion and the XanaCIDD trials are guided to occur a bit later than our prior assumptions, we are pushing back our expectations for potential launches of Xanamem in the AD and major depressive disorder (MDD) indications by around six months each, to CY28 (vs H2 CY27 previously) in both indications. Given these revisions, we now obtain a total equity valuation of A$640m, or A$0.35 per share, versus our prior assessment of A$702m, or A$0.39 per share.

8 June 2023

Price	**A$0.05**
Market cap	**A$91m**
	A$0.66/US$
Net cash (A$m) at 31 March 2023	12.3
Shares in issue	1,816m
Free float	90%
Code	ACW
Primary exchange	ASX
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(19.4)	(30.6)	(24.2)
Rel (local)	(18.2)	(28.2)	(24.2)
52-week high/low	A$0.14		A$0.04

Business description

Actinogen Medical is an ASX-listed Australian biotech developing its lead asset Xanamem, a specific and selective 11β-HSD1 inhibitor designed to treat cognitive impairment (CI) that occurs in chronic neurodegenerative and neuropsychiatric diseases. Currently, Actinogen is targeting CI in two indications: the early stages of Alzheimer's disease and major depressive disorder.

Next events

Start enrolment for XanaMIA Part IIb study in biomarker-confirmed early AD	H2 CY23
Results for Phase II XanaCIDD study in cognitive impairment associated with major depressive disorder	H1 CY24

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Edison profile page

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Xanamem trajectory in AD highlighted

Actinogen recently held an R&D Science Day where the company discussed recent developments relating to its lead programme for drug candidate Xanamem for the treatment of cognitive impairment (CI) associated with AD, and updated its expected timelines and study protocol for the upcoming Phase IIb portion of the XanaMIA trial in patients with AD.

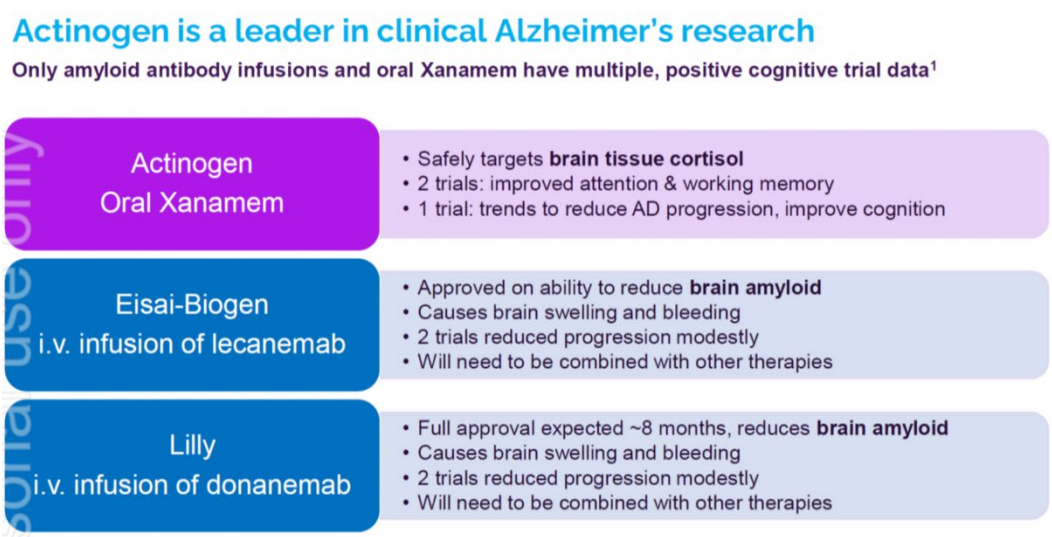
The number of people living with dementia worldwide is estimated to be 55 million, of whom approximately 60–70% have AD, including about 5.8 million people in the United States. There remains significant unmet need as no approved treatments have convincingly been shown to decelerate AD progression by more than c 30% (compared to the condition's natural evolution), as discussed below. As explained in our prior Outlook note, much scientific literature suggest that excessive cortisol is associated with CI in patients with various chronic conditions, including age-related CI and AD. The naturally present enzyme 11β-HSD1 (11β-Hydroxysteroid dehydrogenase type 1) normally converts cortisone to cortisol inside cells. Xanamem is an 11β-HSD1 inhibitor designed to penetrate the brain and thereby reduce excessive cortisol production in the brain.

Actinogen previously showed that Xanamem can provide rapid therapeutic effects on attention and working memory in the Phase Ib portion of the XanaMIA study, reported in Q2 CY22, and the CY19 XanaHES study also showed cognitive benefit in healthy elderly subjects at a higher tested dose. While initial results from the previous XanADu trial in mild AD (CY17–19) did not show significant improvements, a subset analysis reported in Q4 CY22 in 34 patients with elevated pTau blood levels, confirming AD diagnosis, provides stronger indications of activity in this population, as explained further below. We believe market participants will be keen to observe whether the upcoming Phase IIb portion of XanaMIA, which prospectively enrols patients with elevated pTau, will confirm the positive efficacy findings shown in a subset biomarker analysis from the earlier XanADu study. Given the widespread economic and social costs of AD and the limitations of current approved treatments, we believe positive Phase IIb data could introduce the possibility of material out-licensing or value realisation opportunities.

Emphasising opportunities versus anti-amyloid antibodies

Recent well-publicised clinical advances in the AD space have been the FDA-accelerated approvals of anti-amyloid beta (anti-Aβ) mABs such as Leqembi (and previously Aduhelm) and positive Phase III data for donanemab. While we view these advancements of anti-amyloid drugs as a positive for AD patients, as they have been shown to reduce disease progression using validated AD scales such as CDR-SB, we believe there remains tremendous potential for alternative AD treatment approaches (such as the 11β-HSD1 inhibition approach used by Xanamem resulting in lower brain cortisol), particularly those that can be taken orally (such as Xanamem), given better convenience and ease-of-use compared to the intravenous approach required by the anti-Aβ drugs.

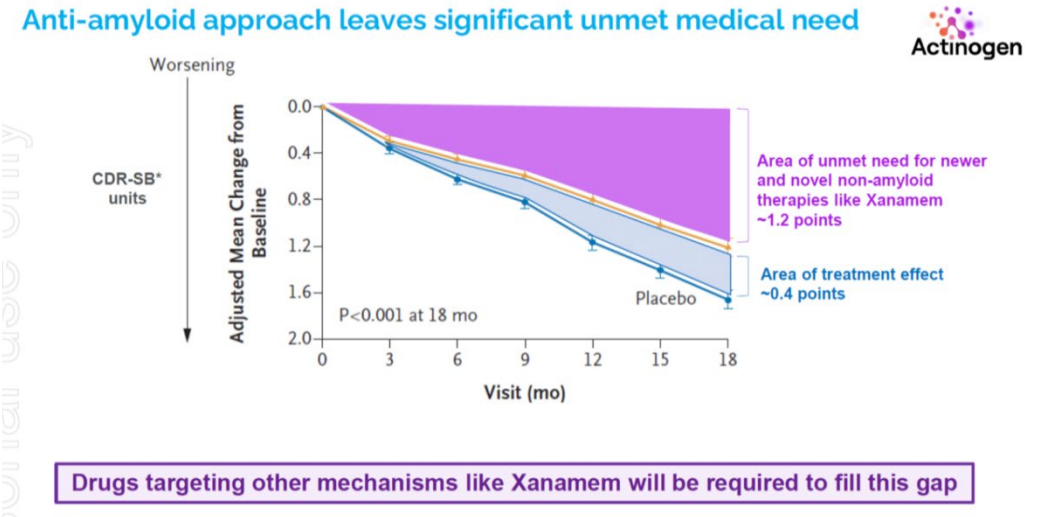
Exhibit 1: Xanamem comparison with anti-amyloid antibodies



Source: Actinogen presentation, May 2023. Note: [1]Companies claiming efficacy based on uncontrolled data, biomarkers or imaging not included in this comparison.

Further limitations or impediments of anti-Aβ drugs include the high cost of anti-amyloid mABs and the risks of severe side effects such as brain swelling/bleeding. Importantly, the latest anti-Aβ drugs, while capable of demonstrating statistically significant decelerated disease progression versus placebo, still do not fully stabilise the disease or halt disease progression.

Exhibit 2: Treatment effect of Leqembi versus placebo over 18 months



Source: Actinogen presentation, May 2023. Note: *Lecanemab is an anti-amyloid antibody given as an intravenous infusion every two weeks and largely clears brain of amyloid by 12 months, accelerated approval given by the US FDA based the ability of the drug to clear amyloid, full approval pending. Used (CDR-SB) with an effect size reported of 0.4–0.45 points at 18 months; Leqembi USPI & van Dyck et al. 2022; DOI: 10.1056/NEJMoa2212948 n=1795).

For instance, Leqembi was shown to result in a treatment difference of 0.45 points on the CDR-SB scale (p=0.000005) versus placebo after 18 months of treatment. However, over this time, this relative improvement only represented c 27% of the decline that was occurring; the placebo group declined by 1.66 points and the Leqembi arm declined by 1.21 points. Hence, there remains ample scope to build on the efficacy shown by the anti-Aβ drugs. Further, it is not yet evident, in our view, whether the improvements shown by Leqembi (and other anti-Aβ drugs) are clinically meaningful. In effect, as highlighted in a recent *Lancet* article, it was found in 2019 that for people with mild CI,

the minimally clinically important difference was 0.98 on the CDR-SB scale, and 1.63 for those with mild AD. Hence, should Xanamem demonstrate positive efficacy data in improving cognition and/or decelerating AD progression versus placebo, we believe there could be a material commercial opportunity for the drug.

Planned adjustments to XanaMIA Phase IIb trial

The Phase IIb portion of XanaMIA is a placebo-controlled study that will assess Xanamem in patients with biomarker-positive AD, as determined through an elevated level of pTau-181 protein in the blood. The study is designed to enrol 330 patients, and patients will be randomised to treatment with 5mg, 10mg or placebo once a day. As discussed below, Actinogen is making changes to the study protocol, including: (1) an additional 12 weeks of treatment, designed to improve the ability to observe disease-modification effect; (2) the use of a to-be-marketed tablet formulation instead of a capsule; and (3) the use of a cognitive composite score as the primary efficacy endpoint.

As a reminder, Actinogen reported biomarker data using blood samples from a subset of patients in the prior 185-patient XanADu study in AD patients showing clinical activity and a relatively large effect size at 12 weeks using the FDA-recognised CDR-SB in biomarker-positive AD patients (as determined through patients who had elevated pTau). Patients with pTau levels at or above 6.74pg/ml, representing 34 patients (16 on Xanamem 10mg daily, 18 on placebo), showed a 0.6 mean difference (effect size) in CDR-SB (representing a 60% relative reduction in disease progression versus placebo) at 12 weeks between the placebo and treatment arms.

Actinogen has completed development of a new tablet formulation that will be more convenient for patients to use (compared to the gelatin capsule form used in prior Xanamem studies). This tablet formulation will be used in the Phase IIb portion of XanaMIA and all subsequent Xanamem trials and is also intended to be the dosage form to be used and sold commercially if the drug is approved. The benefits of changing the drug form from capsule to tablet are a longer shelf-life, the tablet can handle a variety of colours, shapes, sizes and identifiers, and manufacturing is easier to scale up and is expected to be more cost-effective.

While the company had received initial Investigational New Drug clearance to start the Phase IIb portion of XanaMIA in Q422 and had anticipated it to begin in Q2 CY23, it must submit additional documentation regarding the tablet formulation prior to beginning the study. Further, as summarised above, Actinogen is making several changes to the study design, which it believes should improve the likelihood of demonstrating statistically significant improvements versus placebo in key endpoint measures. Given the additional updated regulatory submissions required (for the tablet formulation and trial protocol revisions), Actinogen expects to receive FDA approval for these changes in early H2 CY23 and to enrol and treat the first patient in subsequent months. The company expects to report top-line XanaMIA Phase IIb results in H2 CY25 (versus our prior estimates of H2 CY24 or H1 CY25). It also expects to provide interim Phase IIb data in late CY24 or early CY25.

The primary design change is that the study will assess patients (on treatment or placebo) for 36 weeks (versus 24 weeks previously), which is expected to improve the ability to show differences versus placebo and/or possible disease-modification effects. In addition, while the initially proposed study design was to recruit patients with ‘mild’ AD, the trial will now include patients with moderate AD to match more closely the elevated pTau subset population from the prior XanADu Phase IIa study (which was reported as having a high treatment effect, as described above).

Actinogen has also decided to change the primary endpoint to a cognitive composite of several tests. The CDR-SB functional score (the previously proposed primary endpoint measure) remains a key secondary endpoint and the company remains confident the study can demonstrate a treatment effect in this parameter, as it has in the XanADu elevated pTau subset discussed above. However, Actinogen believes that, based on its prior clinical study data, Xanamem may show a stronger effect on cognitive skills and cognitive improvement activities (such as working memory and

attention) than on the more 'functional' or broader composite measures like CDR-SB (which also assess the ability of an affected patient to complete daily tasks and maintain independence).

Mild adjustment to timelines for XanaCIDD study in MDD

The XanaCIDD study in patients with CI associated with MDD started in late 2022. It aims to enrol about 160 patients across Australia and the UK who have persistent depressive symptoms and CI despite standard-of-care anti-depression therapy. Having demonstrated the ability to improve cognition in two trials (XanaHES and the Phase Ib portion of XanaMIA) in healthy adults, Actinogen is confident that Xanamem can exert similar cognitive improvement effects in MDD patients; this study will also explore whether the drug can have effects on depression as well.

Xanamem 10mg daily or placebo will be added to patients' existing anti-depression therapy and effects on cognition (using the Cogstate Cognitive Test Battery) and depression (using the Montgomery-Asberg Depression Rating Scale) will be evaluated.

MDD is a common disorder, with a c 5% prevalence globally. CI is a feature in most MDD patients and often persists even when depressive symptoms subside. Elevated cortisol levels have been associated with depression and modification of brain cell cortisol levels has been proposed as a strategy to treat both depression and its associated CI. As Xanamem targets excess brain cortisol, and given the benefits shown in healthy adults in XanaHES and the Phase Ib portion of XanaMIA, we believe it is plausible for cognitive benefits to be shown in patients with persistent MDD. If the XanaCIDD study is successful in showing CI improvement, the company may move to advance it into pivotal studies. Actinogen now expects to report study results in H1 CY24 (versus prior guidance of late CY23 or early CY24).

Financials and valuation

Actinogen reported an operating cash burn of A$2.2m in Q323 and had a cash balance of A$12.3m at 31 March 2023. We believe the company remains funded into Q4 CY23 (Q224) and continue to model it will raise A$60m before end-FY24 given the expected rise in expenses once the Phase IIb portion of the XanaMIA study commences. Our underlying FY23 and FY24 estimates are essentially unchanged and we continue to model FY23e and FY24e free cash outflow rates of A$9.6m and A$38.4m, respectively. We expect the burn rate to ramp up significantly in FY24e due to expected rising costs to fund the XanaMIA Phase IIb and XanaCIDD studies.

Given the company's new expectations for top-line data for XanaMIA Phase IIb and XanaCIDD, we have pushed back our expectations for potential launches of Xanamem in the AD and MDD indications by around six months each, to CY28 (versus H2 CY27 previously) in both indications. As our base case projection assumes that Actinogen will independently fund all studies needed for regulatory approval in these indications, we have raised our total projected funding need to A$455m (from A$410m previously).

Our valuation continues to be based on a risk-adjusted NPV (rNPV) analysis, which includes A$12.3m in net cash at the end of March 2023. We apply a discount rate of 12.5% and include Xanamem in the two lead indications. We continue to use a probability of success of 10.0% for Xanamem to reach the market in the AD indication and 12.5% in the MDD indication. Given the changes to our commercialisation timing projections, we now obtain a total equity valuation of A$640m, or A$0.35 per share, versus our prior assessment of A$702m, or A$0.39 per share.

Exhibit 3: Actinogen rNPV valuation

Product	Market	Launch	Sales (A$m) in 2034	NPV (A$m)	Probability of success	rNPV (A$m)	rNPV/basic share (A$)
Xanamem in cognitive impairment related to Alzheimer's disease	US	CY28	3,828	3,621.1	10.0%	308.5	0.17
Xanamem in cognitive impairment related to Alzheimer's disease	EU5 & Australia	CY28	1,812	1,768.5	10.0%	176.9	0.10
Xanamem in cognitive impairment related to major depressive disorder	US	CY28	1,247	1,051.1	12.5%	103.5	0.06
Xanamem in cognitive impairment related to major depressive disorder	EU5 & Australia	CY28	728	647.4	12.5%	80.9	0.04
Corporate costs				(42.1)	100%	(42.1)	(0.02)
Net cash at 31 March 2023				12.3		12.3	0.01
Total equity value				**7,058.3**		**639.9**	**0.35**

Source: Edison Investment Research

We continue to estimate the Actinogen's funds on hand will last into Q4 CY23 (Q224). We continue to model the company will raise A$60m before the end of FY24. In total, we forecast A$455m (vs A$410m previously) in additional financing will be required before FY29 to fund the development of both the CI-MDD and AD programmes, after which, provided it receives regulatory approval, the company should be able to generate sufficient operating revenues to reach recurring profitability. Our model assumes all financing will be raised through illustrative debt, as per usual Edison methodology. If our projected funding need of A$455m is raised through equity issuances at the prevailing market price of c A$0.05, our effective value per share would decrease to A$0.10.

The amount of fund-raising estimated to be necessary for Actinogen to independently bring Xanamem to commercialisation in these indications is larger than the company's current market capitalisation, although we note that the funding intervals may be staggered over the next several years, which may alleviate potential challenges associated with raising funds in excess of a company's market capitalisation. We also believe Actinogen will seek non-dilutive funding arrangements and/or partnership arrangements (actions towards the latter would likely particularly increase after the XanaMIA Phase IIb portion is completed), which may reduce the overall funding need, but such scenarios are not included in our forecasts.

Considering that AD pivotal trials are reported to cost more per patient than studies in nearly any other therapeutic area, we believe Actinogen will likely explore partnerships or non-dilutive funding strategies if the XanaMIA Phase IIb data are positive.

Exhibit 4: Financial summary

A$(000)	2020	2021	2022	2023e	2024e
Year end 30 June	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	3,516	1,984	3,640	4,004	4,086
Cost of Sales	0	0	0	0	0
Gross Profit	3,516	1,984	3,640	4,004	4,086
Sales, General & Administrative	(2,962)	(3,111)	(4,558)	(4,999)	(4,337)
Net Research & Development	(5,537)	(2,406)	(8,215)	(9,394)	(36,364)
EBITDA	(4,983)	(3,533)	(9,133)	(10,389)	(36,614)
Amortisation of intangible assets	(314)	(313)	(313)	(313)	(313)
Depreciation & other	(99)	(74)	(88)	(93)	(279)
Normalised Operating Profit (ex. amort, SBC, except.)	(4,888)	(3,318)	(7,933)	(9,614)	(36,894)
Operating profit before exceptionals	(5,396)	(3,920)	(9,533)	(10,795)	(37,206)
Exceptionals including asset impairment	0	0	0	0	0
Other	(194)	(289)	(1,288)	(869)	0
Reported Operating Profit	(5,590)	(4,209)	(10,821)	(11,664)	(37,206)
Net Finance income (costs)	65	5	36	261	(736)
Profit Before Tax (norm)	(4,822)	(3,313)	(7,897)	(9,353)	(37,629)
Profit Before Tax (FRS 3)	(5,331)	(3,915)	(9,497)	(10,534)	(37,942)
Tax	0	0	0	0	0
Profit After Tax and minority interests (norm)	(4,822)	(3,313)	(7,897)	(9,353)	(37,629)
Profit After Tax and minority interests (FRS 3)	(5,331)	(3,915)	(9,497)	(10,534)	(37,942)
Average Basic Number of Shares Outstanding (m)	1,118.0	1,405.2	1,717.1	1,806.0	1,851.7
EPS - normalised (A$)	(0.004)	(0.002)	(0.005)	(0.005)	(0.020)
EPS - normalised and fully diluted (A$)	(0.004)	(0.002)	(0.005)	(0.005)	(0.020)
EPS - (IFRS) (A$)	(0.005)	(0.003)	(0.006)	(0.006)	(0.020)
Dividend per share (A$)	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed Assets	3,772	3,287	2,889	3,534	4,029
Intangible Assets	3,346	3,033	2,720	2,908	3,095
Tangible Assets	19	17	13	627	934
Investments in long-term financial assets	408	237	156	0	0
Current Assets	8,164	15,091	20,417	31,189	32,752
Short-term investments	0	0	0	0	0
Cash	5,040	13,457	16,370	27,556	29,119
Other	3,123	1,634	4,047	3,633	3,633
Current Liabilities	(744)	(755)	(1,480)	(1,708)	(1,708)
Creditors	(744)	(755)	(1,480)	(1,708)	(1,708)
Short term borrowings	0	0	0	0	0
Long Term Liabilities	(304)	(165)	(87)	(20,038)	(60,038)
Long term borrowings	0	0	0	(20,000)	(60,000)
Other long term liabilities	(304)	(165)	(87)	(38)	(38)
Net Assets	10,889	17,458	21,740	12,978	(24,964)
CASH FLOW STATEMENT					
Operating Income	(5,590)	(4,209)	(10,821)	(11,664)	(37,206)
Movements in working capital	(3,591)	(1,513)	(3,143)	597	0
Net interest and financing income (expense)	65	5	36	261	(736)
Depreciation & other	99	74	88	93	279
Taxes and other adjustments	6,161	3,920	4,323	2,165	313
Net Cash Flows from Operations	(2,856)	(1,724)	(9,517)	(8,548)	(37,350)
Capex	(23)	(6)	(3)	(1,051)	(1,087)
Acquisitions/disposals	0	0	0	0	0
Interest received & other investing activities	0	0	0	0	0
Net Cash flows from Investing activities	(23)	(6)	(3)	(1,051)	(1,087)
Net proceeds from share issuances	0	10,195	12,491	903	0
Net movements in long-term debt	0	0	0	20,000	40,000
Dividends	0	0	0	0	0
Other financing activities	282	(84)	(71)	(39)	0
Net Cash flows from financing activities	282	10,111	12,420	20,864	40,000
Effects of FX on Cash & equivalents	0	0	49	(80)	0
Net Increase (Decrease) in Cash & equivalents	(2,596)	8,381	2,949	11,186	1,563
Cash & equivalents at beginning of period	7,637	5,040	13,422	16,370	27,556
Cash & equivalents at end of period	5,040	13,422	16,370	27,556	29,119
Closing net debt/(cash)	(5,448)	(13,694)	(16,527)	(7,556)	30,881
Lease debt	390	236	165	127	127
Closing net debt/(cash) inclusive of IFRS 16 lease debt	(5,058)	(13,458)	(16,361)	(7,429)	31,008
Free cash flow	(2,878)	(1,730)	(9,520)	(9,599)	(38,437)

Source: Edison Investment Research, company reports

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