EDISON

Immutep

Clinical update

A big year ahead for efti

Pharma & biotech

We expect Immutep to deliver on a number of important milestones in the year ahead. The AIPAC Phase II study of its APC activator eftilagimod alpha (efti) plus chemo in breast cancer is expected to complete recruitment in H119 and report top-line data before the end of the year. The TACTI-002 study of efti plus Keytruda in lung and head and neck cancers in collaboration with US Merck will start shortly and report first data mid-year, whereas TACTI-mel will report first data from melanoma patients dosed with efti from the start of Keytruda therapy. Other in-house and partnered programmes are also likely to produce significant news. We maintain our valuation of A$510m ahead of these milestones.

Year end	Revenue (A$m)	PBT* (A$m)	EPS* (c)	DPS* (c)	P/E (x)	Yield (%)
06/17	4.1	(8.4)	(0.4)	0.0	N/A	N/A
06/18	6.9	(10.9)	(0.5)	0.0	N/A	N/A
06/19e	10.9	(6.8)	(0.2)	0.0	N/A	N/A
06/20e	2.8	(14.9)	(0.5)	0.0	N/A	N/A

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

AIPAC to report top-line data in 2019

The 226-patient AIPAC study of efti plus paclitaxel in first-line metastatic breast cancer is now over 70% recruited and is expected to fully recruit in H119. Top-line data from the event-driven progression free survival (PFS) analysis is expected to mature in 2019. This will be the first efficacy read-out for efti from a randomised study, so it will be a significant event for the company. The trial could potentially support filing in Europe if it achieves certain (undisclosed) clinical endpoints.

TACTI-002 ready to go

The TACTI-002 Phase II study in collaboration with Merck and Company is on track to recruit the first subjects in early 2019. It will evaluate efti plus Merck's Keytruda in up to 110 patients with non-small cell lung cancer (NSCLC) or squamous cell carcinoma of the head and neck (SCCHN) at 12–15 sites in the UK, Spain, the US and Australia. Initial data are expected from mid-2019 onwards.

Efti/avelumab combo nears starting line

The INSIGHT-004 study of avelumab plus subcutaneous (SC) efti in 12 patients with a range of advanced solid tumours is expected to start in Q119. The study, in collaboration with Merck KGaA and Pfizer, will be added as the fourth arm of the INSIGHT study (NCT03252938), which is underway at a single site in Germany.

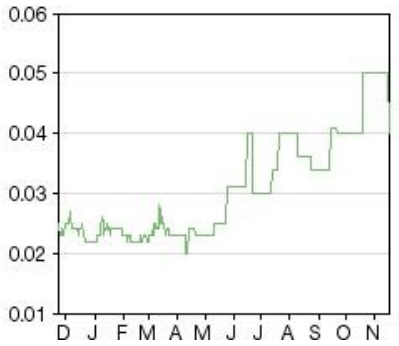
Valuation: Unchanged at A$510m, 17c per share

Our valuation is unchanged at A$510m, equal to 17c per share on an undiluted basis or 12c per share after diluting for options, warrants and convertible notes. We note that our valuation includes a modest allowance for new indications for efti beyond the ongoing studies in melanoma, lung and head and neck cancers. Gross cash at the end of September 2018 was A$21.3m. Our forecasts assume that Immutep receives a risk-adjusted US$6m (A$8m) IMP731 milestone payment from GSK in FY19, which would extend its cash reach to the end of FY20.

21 November 2018

Price	**A$0.038**
Market cap	**A$117m**
	US$0.76/A$
Gross cash (A$m) at 30 September 2018	21.3
Shares in issue	3,080.5m
Free float	93%
Code	IMM
Primary exchange	ASX
Secondary exchange	NASDAQ

Share price performance



%	1m	3m	12m
Abs	(20.8)	8.6	58.3
Rel (local)	(16.9)	21.3	65.7
52-week high/low	A$0.06		A$0.02

Business description

Immutep is an ASX-listed biotechnology company focused on cancer immunotherapy. Its pipeline is based on four products using a LAG-3 immune control system: IMP321 for cancer chemo-immunotherapy, partnered products IMP731 (GSK) and IMP701 (Novartis), and IMP761 (preclinical).

Next events

TACTI-002 Phase II first patient in	Q119
Initiate INSIGHT-004	Q119
Fully recruit AIPAC breast cancer Phase II	H119

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Edison profile page

Durable TACTI-mel responses confirmed

Professor Adnan Khattak, consultant medical oncologist at Fiona Stanley Hospital and a principal investigator of the ongoing Phase I TACTI-mel study, provided an update on the trial in oral and poster presentations at the 33rd Annual Meeting of the Society for Immunotherapy of Cancer (SITC) in Washington, DC, earlier this month.

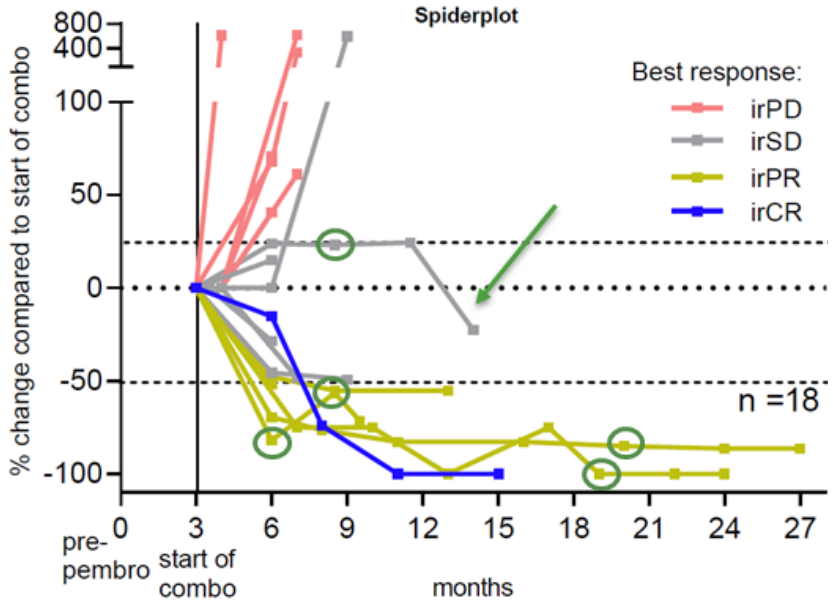
The response rate was consistent with previous reports, namely a 33% (6/18) overall response rate (ORR) from the start of efti/Keytruda combination therapy, and 61% (11/18) when measured from the start of the 12-week Keytruda monotherapy screening period. These are very encouraging results in a patient population in which 78% (14/18) subjects had M1c (late-stage) metastatic melanoma.

Importantly, the updated data in Exhibit 1 confirm that the tumour responses following efti/Keytruda combination therapy were long lasting. To highlight the new data, we have added green circles to the response plots for selected patients in Exhibit 1 to show the last data point included in the previous data set reported in the investor update in May. None of the patients who achieved a tumour response (50% shrinkage) has experienced significant tumour growth during the period of follow up.

It is interesting to note that one patient with stable disease has seen their tumour start to shrink, 12 months after starting therapy (indicated by a green arrow in Exhibit 1). There is the potential for this patient to develop into a late responder if tumour shrinkage continues.

Part A of the study tested three doses of efti (1, 6 and 30mg/kg) in combination with the anti-PD-1 immune checkpoint inhibitor Keytruda (pembrolizumab, Merck) in 18 patients with advanced melanoma who have had a suboptimal response to initial treatment with Keytruda. In Part A, efti/Keytruda combination therapy was preceded by 12 weeks of Keytruda monotherapy.

Exhibit 1: Spider plots of tumour responses from cohorts 1–3 of TACTI-mel Part A



Source: SITC poster. Note: pembro = pembrolizumab (Keytruda). We have added green ovals to indicate the last data point for selected patients as shown at the Advances in Immuno-oncology Congress in May. The green arrow indicates the patient with stable disease who is experiencing tumour shrinkage.

Immutep has fully recruited the six-patient cohort that forms Part B of the study. These patients are treated with 30mg efti every two weeks starting at the same time as Keytruda therapy. No dose-

limiting toxicities have been observed, which has given Immutep and collaborator Merck and Company confidence that this dose combination is safe to use in the upcoming TACTI-002 study.

No efficacy data from Part B have been reported to date. We expect final TACT-mel data, including Part B efficacy, to be reported in H119.

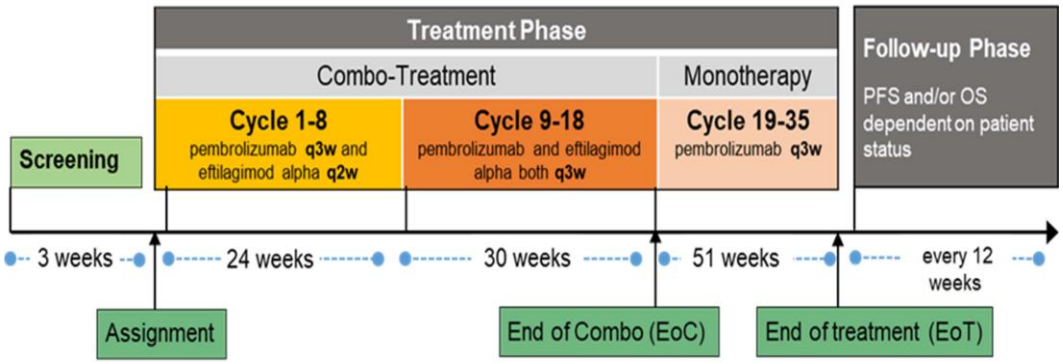
TACTI-002 to start early 2019; design details presented

The company is finalising its preparations for its TACTI-002 Phase II study in collaboration with Merck, which is on track to recruit the first subjects in early 2019.

TACTI-002 will evaluate efti plus Keytruda in up to 110 patients with NSCLC or SCCHN at 12–15 sites in the UK, Spain, the US and Australia. Treatment with efti (30mg by subcutaneous injection) will start on the same day as Keytruda treatment in this study, just like in TACTI-mel Part B.

The company presented details of the TACTI-002 trial design in a poster at SITC (Exhibit 2). Patients will receive 18 three-week cycles of efti/Keytruda combination therapy. For the first nine treatment cycles (27 weeks), patient will be injected with efti every two weeks. For the next nine cycles, efti will be administered every three weeks, to align with the Keytruda treatment regimen. At the completion of 54 weeks of combination therapy, patients can receive a further 12 months of Keytruda monotherapy.

Exhibit 2: TACTI-002 trial design



Source: SITC poster. Note: One cycle = three weeks; q2w = every two weeks; q3w = every three weeks

The open-label TACT-002 study will utilise Simon's two-stage design. For each of the three treatment indications, an initial cohort of 17–23 patients will be treated. For each indication, if the number of patients with tumour responses exceeds the threshold shown in Exhibit 3, additional patients will be recruited to take the total up to ~37 for that indication.

Part A will recruit first-line advanced/metastatic NSCLC patients, who are PD-1/L-1 naive and have not undergone systemic therapy for advanced/metastatic disease.

Part B will recruit second-line advanced/metastatic NSCLC patients who have experienced treatment failure (disease progression) following treatment with any PD-1/PD-L1 regimen.

Part C will recruit second-line SCCHN patients who are PD-1/L1 naive.

The primary endpoint will be ORR (as per irRECIST). The TACTI-002 study will make an important contribution towards building the evidence base to assess whether efti combo therapy can improve response rates to PD-1/L-1 therapy. First data are expected from mid-2019 onwards.

Exhibit 3: Patient numbers and response thresholds for TACTI-002

Indication	Threshold number of responses	Initial number of patients	Threshold response rate	Additional patients	Total patients
Part A: NSCLC first line	4	17	24%	19	36
Part B: NSCLC second line	1	23	4%	13	36
Part C: HNSCC	2	18	11%	19	37

Source: Immutep. Note: HNSCC = head and neck squamous cell carcinoma.

AIPAC data expected H219

The AIPAC Phase IIb breast cancer study is over 70% recruited, with enrolment reaching 160 out of the target of 226 as of the AGM on 16 November. Recruitment passed the halfway mark (113/226) in June and reached 126 (56%) in early August. The company expects recruitment to continue into H119, and the event-driven PFS readout to report in H219 (after 152 PFS events).

The trial is testing the efti soluble LAG-3 fusion protein combined with paclitaxel in women with hormone receptor positive metastatic breast cancer who have not previously received chemotherapy for metastatic disease. The European Medicines Agency has indicated that this trial could be sufficient to support a marketing authorisation if it achieves certain (undisclosed) clinical endpoints. A confirmatory Phase III study would likely be required before filing for approval in the US.

LAG525 retained in cutting edge Novartis pipeline

On 30 October Novartis disclosed it was culling 20% of programmes from its pipeline to focus its resources on only the most cutting-edge drug candidates. This reduced its drug programmes from 430 to 340. Although Novartis has not disclosed a list of the culled programmes to the best of our knowledge, all indications are that development of LAG525, which it in-licensed from Immutep, is ongoing.

For example, while the presentation at the Novartis R&D day held the following week (on 5 November) did not specifically mention LAG525, development of its anti-PD-1 drug PDR001[1] in multiple combinations in metastatic melanoma was listed among programmes with anticipated filings in 2022 or later. In its Q318 results presentation on 18 October, this description referred to trial NCT03484923 in which PDR001 is being trialled in combination with LAG525 or either of two other drugs (Tafinlar or Mekinist) in advanced melanoma patients.

Although the R&D day presentation did not specifically mention the other PDR/LAG525 combination studies in other advanced cancers, including breast cancer, according to both the Novartis website and the clinicaltrials.gov database, four trials of LAG525 in combination with PDR001 are recruiting patients, as shown in Exhibit 4. Three of the four studies started recruiting patients in 2018.

LAG525 combo studies are ongoing, which indicates that Novartis considers it has the potential to change the standard of care in high burden disease areas. LAG525 inhibits LAG-3 signalling by blocking the binding of LAG-3 to the MHC class II molecule. Blockade of LAG-3 restores activity of effector T cells, reduces suppressor activity of regulatory T cells and enhances the anti-tumour activity of PD-1 inhibition.

1 PDR001 is also known as spartalizumab

Exhibit 4: Four Novartis PDR001/LAG525 combo studies are currently recruiting subjects

Description	clinicaltrials.gov identifier	Phase	Subjects	Start date	Primary completion	Status
LAG525 +/- PDR001 in advanced solid tumours	NCT02460224	I/II	515	June 2015	July 2019	Recruiting
LAG525 + PDR001 in advanced solid and hematologic cancers	NCT03365791	II	160	January 2018	January 2020	Recruiting
PDR001 + LAG525 or Tafinlar or Mekinist in melanoma	NCT03484923	II	135	September 2018	January 2021	Recruiting
LAG525 +/- PDR001 +/- Carboplatin in TNBC	NCT03499899	II	96	July 2018	December 2019	Recruiting

Source: clinicaltrials.gov. Note: TNBC = triple negative breast cancer

Competing anti-LAG-3 antibodies show further potential

Additional evidence supporting the potential efficacy of anti-PD-1/anti-LAG-3 combo therapy was presented by Novartis's competitor Merck at SITC.

Merck reported results from a study of its MK-4280 anti-LAG-3 antibody +/- Keytruda in metastatic solid tumours where there was not a clinically effective alternative treatment (clinicaltrials.gov identifier NCT02720068). MK-4280 showed modest activity as a monotherapy (6% ORR, 1/18). The combination of MK-4280 with Keytruda showed promising efficacy, achieving a 27% ORR (4/15) in a range of solid tumours.

Last year BMS reported encouraging results from a Phase I study of its anti-LAG-3 antibody relatlimab (BMS-986016) in melanoma patients who had not responded to or had become resistant to checkpoint inhibitor therapies. In that study, 18% of LAG-3 positive patients responded to combination therapy with relatlimab plus Opdivo, vs a 5% response rate in patients with low tumour LAG-3 expression.[2] BMS is undertaking a Phase III study of relatlimab plus Opdivo vs Opdivo alone in 700 patients with untreated advanced melanoma. Top-line results are expected in July 2020.

As we previously noted, Novartis itself reported[3] encouraging signs of efficacy from the LAG525 in combination with PDR001 from the Phase I component of its ongoing Phase I/II study (NCT02460224) at ASCO in June. Among the 121 patients with solid tumours treated with LAG525 plus PDR001 at a wide range of doses there were 13 durable responses, including 3/8[4] mesothelioma patients and 2/5 triple-negative breast cancer patients.

We expect Novartis to continue to aggressively pursue its LAG525 clinical trial programme as it seeks to ensure it does not allow BMS or Merck to gain a dominant position in the anti-LAG-3 antibody space.

It is important to note that although MK-4280, relatlimab and LAG525 all have a similar mechanism of action (blockade of the LAG-3 immune checkpoint), and are potential competitors to each other, they are not potential competitors to efti, which has a very different mechanism of action.

INSIGHT and the Merck KGaA/Pfizer extension

In September Immutep entered into a clinical trial collaboration and supply agreement with Merck KGaA/Pfizer to investigate the combination of its APC activator efti with their anti-PD-L1 immune

2 Ascierto et al 2017 https://academic.oup.com/annonc/article/28/suppl_5/mdx440.011/4109923

3 Hong et al 2018. http://novartis.medicalcongressposters.com/Default.aspx?doc=e07a1

4 3/8 includes an additional partial response after the data cut-off date for the conference abstract

checkpoint inhibitor avelumab (Bavencio) in patients with advanced solid tumours. Although avelumab gained FDA approval in 2017 for use in bladder cancer and in the aggressive skin cancer Merkel cell carcinoma, it has not yet been approved in any other cancers.

The study of avelumab plus subcutaneous (SC) efti in 12 patients with a range of advanced solid tumours will be included as an arm of the investigator-sponsored INSIGHT study (NCT03252938), which is underway at a single site in Germany. The combination would fit neatly into INSIGHT, which already includes arms investigating intra-tumoural and intraperitoneal administration of efti, as well as a third arm investigating SC efti in combination with chemo in solid tumours. The avelumab combination therapy arm (INSIGHT-004) is expected to start in Q119 and to report first data in mid-2019.

The principal investigator of the INSIGHT study, including the INSIGHT-004 arm, Professor Dr Salah-Eddin Al-Batran, is a member of Immutep's clinical advisory board. The main INSIGHT study has already recruited 10 of the target of 38 patients; a status update is expected in coming months.

IMP761 LAG-3 agonist in preclinical development

Immutep has started cell line development and the associated manufacturing steps for IMP761. IMP761 is the first known therapeutic antibody with agonist properties that enable it to activate the LAG-3 receptor on the surface of activated T cells, and thereby downregulate T cell activation and proliferation. In contrast, LAG525 and the other known anti-cancer LAG-3 antibodies are antagonist antibodies that block LAG-3 signalling and thereby prevent the downregulation of T cell immune responses.

The mechanism of action of IMP731 is also different to the company's partnered IMP731/GSK2831781 cytotoxic antibody, which aims to treat autoimmune disease by killing LAG-3 positive T cells. IMP761 offers the opportunity to fine-tune immune responses, which could benefit sufferers of autoimmune diseases by temporarily switching off activated LAG-3 positive T cells that are damaging tissue or causing inflammation.

Immutep reported in September that preclinical studies of IMP761 in cynomolgus monkeys produced encouraging results that demonstrate the immunosuppressive activity of IMP761 in vivo. Immutep intends to present the preclinical results at a future scientific conference.

Valuation

We maintain our valuation of Immutep at A$510m or 17c per share (undiluted). On a fully diluted basis, our valuation is 12c per share, after taking into account the options, warrants and convertible notes on issue. Exhibit 5 summarises the constituent parts of our valuation, which is based on a discount rate of 12.5%. Our valuation assumptions and financial forecasts are unchanged.

Exhibit 5: DCF valuation of Immutep

Value driver	Launch date	Likelihood of success	Peak sales (US$m)	Royalty	Value (A$m)	Value per share (A$)
efti-mBC*	2021 (EU), 2024 (US)	35%	971	17.5%	215.3	0.07
efti+anti-PD1 ICI melanoma	2025	15%	480	17.5%	33.3	0.01
efti+Keytruda NSCLC	2025	15%	2,300	17.5%	202.0	0.07
efti+Keytruda ovarian	2027	15%	500	17.5%	24.0	0.01
efti+Keytruda head and neck	2025	15%	470	17.5%	32.6	0.01
efti milestones - assume partnered post PII in MBC	US$225m estimated risk-adjusted milestones from out-licensing North American and European rights.				55.60	0.02
IMP731-autoimmune disease	2023	20%	1,079	8%	64.8	0.02
Potential IMP731 milestones from GSK	US$90m of total US$100m in risk-adjusted milestones from GSK				23.9	0.01
IMP701-solid tumours (lung cancer)	2025	20%	2,440	5%	67.1	0.02
Potential IMP701 milestones from Novartis	US$20m in risk-adjusted milestones from Novartis				3.4	0.00
Grants					2.8	0.00
R&D expenses					(22.1)	(0.01)
Admin expenses					(17.0)	(0.01)
Capex					(0.0)	(0.00)
Tax					(185.7)	(0.06)
Net cash	End FY18 net cash (including A$13.75m convertible note at face value)				9.7	0.00
Total					**509.7**	**0.17**

Source: Edison Investment Research. Note: mBC = metastatic breast cancer; ICI = immune checkpoint inhibitor

Exhibit 6 shows that in addition to the 3,081m Immutep shares in issue, there are a further 1,498m potential shares that could be issued on the exercise of options, warrants, performance rights and convertible notes, all of which would be in the money at our 17c per share undiluted valuation. Exhibit 6 shows that after taking into account these potential shares, our diluted valuation is 12c per share. Depending on trial progress and the timing of milestone payments from partners, Immutep may require additional funding to complete the efti clinical trials; our diluted valuation of 12c per share does not take into account potential dilution from any future capital raising.

Exhibit 6: Potential further dilution and value per share

	Average exercise price (A$)	m
Current number of shares		3,081
Ridgeback convertible note potential shares	0.020	688
Ridgeback warrants	0.024	380
Unlisted warrants*	0.033	155
Unlisted options	0.050	149
Performance rights**	0.000	126
Total in-the-money potential shares		1,498
Total potential diluted number of shares		4,579
Net cash raised from options and CN exercise		A$35
Valuation (above plus additional cash)		A$545
Diluted value per share		**A$0.12**

Source: Edison Investment Research. Note: *1.553m ADS warrants converted to ordinary shares at the long term exchange rate. **Both vested and unvested performance rights have been included.

We include risk-adjusted milestones payable by current partners GSK for IMP731 and Novartis for IMP701, plus milestones from prospective deals for efti. The breadth of the LAG-3 pipeline means there could be further upside if Immutep or its partners launch additional products into the clinic or broaden the indications being studied.

Exhibit 7: Financial summary

A$'000s	2016	2017	2018	2019e	2020e
Year end 30 June	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	1,949	4,117	6,854	10,898	2,778
R&D expenses	(7,060)	(7,526)	(9,990)	(10,990)	(10,440)
SG&A expenses	(6,983)	(4,347)	(7,242)	(7,459)	(7,683)
EBITDA	(12,093)	(7,756)	(11,435)	(7,551)	(15,345)
Operating Profit (before GW and except.)	(12,275)	(7,770)	(11,446)	(7,554)	(15,350)
Intangible Amortisation	(1,993)	(1,688)	(1,798)	(1,650)	(1,501)
Exceptionals	(47,468)	0	0	0	0
Operating Profit	(61,736)	(9,458)	(13,244)	(9,204)	(16,851)
Other	(1,716)	(752)	323	0	0
Net Interest	256	104	177	704	498
Profit Before Tax (norm)	(13,735)	(8,417)	(10,946)	(6,850)	(14,851)
Profit Before Tax (IFRS)	(63,196)	(10,105)	(12,744)	(8,500)	(16,352)
Tax	1,181	737	(2)	0	0
Profit After Tax (norm)	(12,554)	(7,680)	(10,948)	(6,850)	(14,851)
Profit After Tax (IFRS)	(62,015)	(9,368)	(12,746)	(8,500)	(16,352)
Average Number of Shares Outstanding (m)	2,016.6	2,072.5	2,079.7	3,026.1	3,080.5
EPS - normalised (c)	(0.6)	(0.4)	(0.5)	(0.2)	(0.5)
EPS - IFRS (c)	(3.1)	(0.5)	(0.6)	(0.3)	(0.5)
Dividend per share (c)	0.0	0.0	0.0	0.0	0.0
Gross Margin (%)	N/A	N/A	N/A	N/A	N/A
EBITDA Margin (%)	N/A	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)	N/A	N/A	N/A	N/A	N/A
BALANCE SHEET					
Fixed Assets	20,883	19,045	18,356	16,715	15,223
Intangible Assets	20,852	19,020	18,329	16,680	15,178
Tangible Assets	32	24	26	36	45
Other	0	0	0	0	0
Current Assets	21,671	15,919	28,643	21,784	6,924
Stocks	0	0	0	0	0
Debtors	168	2,194	3,432	3,432	3,432
Cash	20,880	12,237	23,476	16,616	1,756
Other	623	1,488	1,736	1,736	1,736
Current Liabilities	(1,472)	(2,632)	(3,853)	(3,853)	(3,853)
Creditors	(1,444)	(2,589)	(3,664)	(3,664)	(3,664)
Short term borrowings	(0)	(0)	0	0	0
Short term leases	0	0	0	0	0
Other	(28)	(43)	(190)	(190)	(190)
Long Term Liabilities	(5,765)	(5,799)	(9,623)	(9,623)	(9,623)
Long term borrowings incl. conv. note	(5,027)	(5,779)	(6,646)	(6,646)	(6,646)
Long term leases	0	0	0	0	0
Other long term liabilities	(737)	(20)	(2,978)	(2,978)	(2,978)
Net Assets	35,317	26,532	33,522	25,022	8,670
CASH FLOW					
Operating Cash Flow	(11,594)	(8,611)	(7,954)	(7,551)	(15,345)
Net Interest	284	104	177	704	498
Tax	0	0	0	0	0
Capex	(27)	(7)	(12)	(12)	(13)
Acquisitions/disposals	130	0	0	0	0
Financing	27,229	(9)	18,898	0	0
Dividends	0	0	0	0	0
Other	0	0	(493)	0	0
Net Cash Flow	16,022	(8,522)	10,616	(6,859)	(14,860)
Opening net debt/(cash)	(5,251)	(15,852)	(6,458)	(16,830)	(9,970)
HP finance leases initiated	0	0	0	0	0
Other	(5,421)	(872)	(244)	0	0
Closing net debt/(cash)	(15,852)	(6,458)	(16,830)	(9,970)	4,889

Source: Company accounts, Edison Investment Research

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