EDISON

Shield Therapeutics

Focus on increasing US market access

Commercial progress

Pharma & biotech

Shield Therapeutics' (STX) value stems from Accrufer's US market opportunity as the company seeks to maximise returns through self-commercialisation. Recent progress on payer coverage and prescription uplift bodes well for future US expansion, although we expect a more modest growth trajectory than previously as STX focuses on expanding market outreach. The successful execution of its commercial plans relies on adequate fund-raising, which remains challenging in the current macro environment. The recent $10m convertible shareholder loan extends the cash runway into early FY23, but a further £25m would be required to break even, according to our estimates. We have introduced more conservatism in our estimates and as a result our valuation resets to £371.0m or 172p/share (previously £631.3m or 293p/share).

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
12/20	10.4	(1.9)	(2.2)	0.0	N/A	N/A
12/21	1.5	(19.7)	(9.5)	0.0	N/A	N/A
12/22e	6.2	(20.2)	(9.3)	0.0	N/A	N/A
12/23e	16.2	(17.4)	(8.1)	0.0	N/A	N/A

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

Positive US outlook on improved payer coverage

While commercial activities for Accrufer commenced in July 2021, we expect 2022 to be the first real predictor of potential US market growth following recent coverage from pharmacy benefit managers (PBMs) and state-run Medicaid plans. STX has secured coverage that captures c 40% of the 270 million covered lives in the United States and we expect this figure to rise as coverage expands. Outreach activities from its 30-person US sales team appear to be bearing fruit, with prescription volumes doubling quarter-on-quarter in Q122 to more than 3,900. We expect the company to reach positive operating income in FY25.

Limited funding headroom

STX closed FY21 with a cash balance of £12.1m and reported £4.2m cash at the end of May 2022. This is expected to be bolstered in August with the closing of a $10m convertible debt issue to be raised from AOP Orphan International (AOP), the company's second largest shareholder. We expect these proceeds will enable the company to maintain its operations into early FY23, but we estimate the need to raise a further £25m (modelled as illustrative debt) before reaching operating profitability in FY25. STX is exploring all financing options including royalty-based funding, which in addition to being non-dilutive offers more flexibility compared to traditional capital instruments.

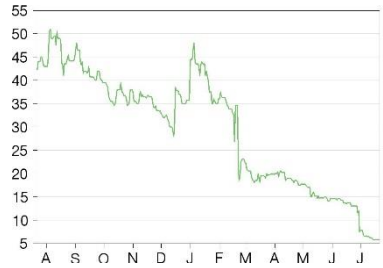
Valuation: £371.0m or 172p/share

Given trends to date, we are taking a slightly more conservative approach for Accrufer/Feraccru. Based on the slower ramp-up to peak, we estimate a valuation of £371.0m or 172p/share, down from £631.3m or 293p/share previously.

22 July 2022

Price	**5.8p**
Market cap	**£12m**
	£0.84/US$; £0.84/€
Estimated net cash (£m) at end May 2022	4.2
Shares in issue	216.2m
Free float	55%
Code	STX
Primary exchange	AIM
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(55.8)	(68.1)	(86.4)
Rel (local)	(56.6)	(66.4)	(86.5)
52-week high/low		51.0p	5.8p

Business description

Shield Therapeutics is a commercial-stage pharmaceutical company. Its proprietary product, Feraccru/Accrufer, is approved by the EMA and FDA for iron deficiency. Outside the United States, Feraccru is marketed internationally through Shield and its commercial partners.

Next events

Launches in additional EU states as covered by Norgine	H222
Further acceptance of Accrufer into key US PBM formularies	H222
Completion of China Phase III study	2023

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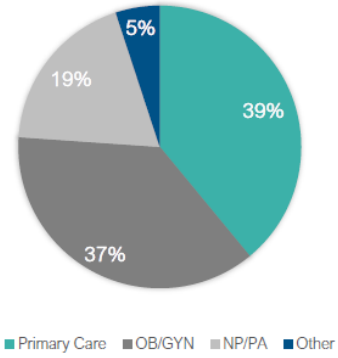
Edison profile page

Tapping the US market opportunity

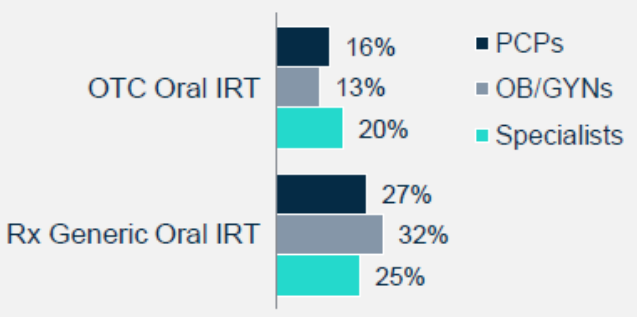
Iron deficiency (with or without anaemia) remains a key disease burden globally and STX estimates the US patient population to be in the range of 20 million with over 13.4 million prescriptions written annually for oral iron treatments, which make up 90% of the treatment volume for iron deficiencies (the remaining 10% is attributed to intravenous-IV therapies, which are required in more severe cases). Around 80% of these prescriptions are written by primary care physicians/general practitioners (GPs) and obstetrician/gynaecologists (OB/GYNs) (see Exhibit 1). The current mainstay of oral treatments is salt-based over-the-counter (OTC) iron supplements and generic prescription products, which are associated with low absorbability and severe gastrointestinal side effects (caused by the aggregation and oxidative stress of uncomplexed iron salts) leading to high treatment discontinuation rates (typically c 40% depending on the patient population). According to internal research conducted by STX, physicians report fairly low satisfaction rates with currently prescribed oral treatments (Exhibit 2), indicating high unmet need for alternate oral treatments with higher efficacy and tolerability.

Exhibit 1: Accrufer prescriptions by specialty



Source: Shield Therapeutics presentation

Exhibit 2: Clinician satisfaction rates to current SOC



Source: Shield Therapeutics presentation. Note: SOC refers to standard of care.

STX decided to self-commercialise Accrufer (oral ferric maltol for iron deficiency) in the United States, which it launched in the country in July 2021, rather than relying on commercial partners as it has done for other geographies (ie Norgine for Europe, Australia and New Zealand and ASK Pharm for China, Taiwan, Hong Kong and Macau). Hence, the company has a highly geared exposure to the potential economics of Accrufer in the United States, which is the largest potential market for the product, in our view, and will be pivotal for realising future value for investors.

We note that Accrufer was approved by the FDA with a highly broad label (encompassing iron deficiency of any cause) and in our view, carries a superior side-effect profile to conventional salt-based oral treatments. Accrufer remains a stable iron complex (where iron is complexed with sugar derivative trimaltol), until it is absorbed. Whereas man-made iron salt products contain ferrous (Fe2+) iron, ferric maltol contains ferric (Fe3+) iron, which is believed to be less toxic to the gastrointestinal tract. As a result, Accrufer provides higher absorbability but also mitigates the adverse side effects associated with OTC salt-based treatments. The current mainstay treatment for patients intolerant of these salt-based irons is an intravenously administered formulation but this requires hospital admission, which carries higher costs and a risk of anaphylaxis. The discontinuation rates for Accrufer (4.6% across randomised trials) are c 10x lower, indicating greater patient compliance and potentially lower hospital-related costs due to the reduced requirement to shift to IV formulations.

The majority of the product's current US coverage through PBMs and insurance plans is for second-line treatment (ie after the first fail on the current standard of care (SOC), which are salt-based OTC and/or generic products), hence we expect Accrufer to initially be positioned as such. However, given that Accrufer is significantly more expensive than the current SOC (its list price of $500/month with a typical three-month treatment required for most patients), gaining market share would likely require raising consumer and health provider awareness, growing prescriptions and securing broad payor coverage. While relatively slow to get off the ground, Accrufer is beginning to make progress on all these fronts.

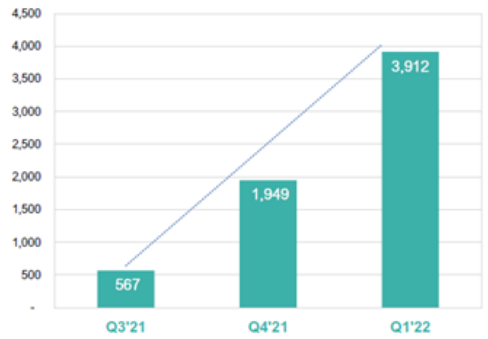
Broadening the payor coverage landscape…

The latest available information reveals that STX has secured coverage from seven PBMs including major players such as Express Scripts, Cigna, Anthem and Optum. More recently (March/April 2022) the company has started to gain traction with the state-run Medicaid plans and has received coverage in 14 US states, including the larger states of Texas, Florida and Georgia. Together (commercial plus Medicaid) these insurance plans cover 100 million of the 270 million insured patients in the United States (c 40% of all covered lives). This is up from 40 million and 60 million covered patients in December 2021 and February 2022 respectively. We estimate that the most recent additions came from recent Medicaid wins and this should continue to scale up as more state-plans are onboarded. Looking ahead, STX will need to make continued progress with other PBMs and states to capture an incrementally larger proportion of covered lives and maximise sales penetration. CVS Caremark (the biggest PBM in the United States accounting for over 30% of all prescription claims) and the state of California (the biggest US state with over 10% of the country's population) are some of the major exclusions from STX's current coverage list and expansion here would grow the potential market materially.

…should translate into higher sales per prescription

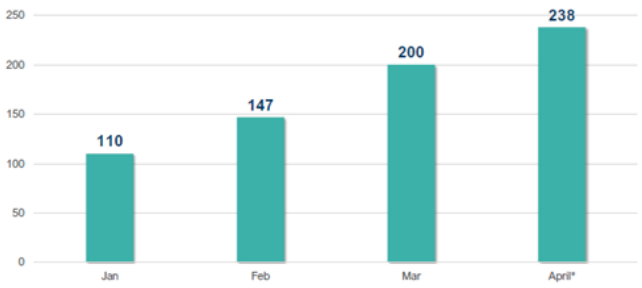
Accrufer's July 2021 launch in the United States was preceded by limited pre-marketing activities as STX was able to secure funding only in March 2021 (£27.2m in net proceeds from an equity issue), leaving it with only a couple of months to undertake pre-launch marketing activities. This resulted in relatively low market awareness for Accrufer and the associated lack or reimbursement and slower prescription growth (2,500 prescription in the six months following launch) was reflected in the relatively low revenue figure for FY21 (£0.61m). Encouragingly though, the sales outreach efforts are beginning to bear fruit, with the company reporting a strong q-o-q growth in prescription volumes in 2022 (prescriptions doubled in Q122 versus Q421 resulting in more than 3,900 prescriptions during the quarter). We also note that the company recorded 700 first-time writers of Accrufer between January and April 2022, indicating a widening market reach (Exhibits 3 and 4). Moreover, the number of new first-time writers has seen a month-on-month improvement, more than doubling from 110 writers in January to 238 in April.

Exhibit 3: Quarterly prescriptions for Accrufer



Source: Shield Therapeutics corporate presentation

Exhibit 4: First-time writers for Accrufer



Source: Shield Therapeutics corporate presentation

We expect 2022 to be a key inflection period for US sales uptake for STX and based on current trends, we expect the company to record c 26,700 prescriptions in FY22, translating to sales of c $5.2m. STX currently employs a 30-person US sales team, and we expect it to continue to invest in growing its sales and marketing team in the next few years. We estimate the need to have a 160–175-person sales team in the long term to target the 65,000 high prescribing physicians (out of a total of c 550,000) who, according to market research prepared for STX, write 60% of the oral iron prescriptions in the United States. The company also plans to supplement its field activities with digital marketing efforts, which we believe will further help in creating broader awareness and penetrating the market further.

Funding support required to action growth plans

A self-commercialisation strategy, as employed by STX, is a trade-off between the potential upside from reaching an optimal sales penetration level and the requirement for upfront expenditures to develop the needed commercial presence. STX's growth strategy hinges on recording multiple touchpoints with the target physician community, which as indicated above, is a fragmented market. This requires the company to be able to raise adequate financing in a timely manner. The current capital market tightness has made it challenging for biotech players to raise funds, as evidenced by the company's lack of success in raising its planned $30m in equity capital (which if successful could have provided access to a non-dilutive debt facility) earlier in the year. To alleviate the funding situation, STX has announced the raise of $10m (£8.4m) convertible shareholder debt from AOP, STX's second largest shareholder with a 13.1% shareholding in the company. The loan is expected to close in August 2022 and will be based at Libor+7% (payable monthly) plus a 2% fee and is secured by the US intellectual property rights associated with Accrufer. It is due for repayment by 31 December 2023 either in cash (provided STX secures at least $30m in debt or equity financing) or through conversion to equity.

We expect this bridge facility to extend the company's cash runway into early 2023 but we anticipate the need to raise a further $25m before the end of FY24, for the company to reach profitability (we anticipate positive EBIT to start in FY25). The company is exploring all avenues for further capital raises, including royalty-based financing, which can be an effective alternative financing stream, often employed in the biotech space.

European strategy being reworked

STX reported £0.9m in royalty income from Europe in FY21, 25% y-o-y growth versus the £0.7m earned in FY20 from licensing partner Norgine. The 25% y-o-y growth in Europe was driven by a 60% increase in sales volume, although this was in part offset by a lower average sale price due to

the launches in Scandinavia, Luxembourg and Belgium. While Feraccru (Accrufer's brand name in Europe) has been available in the European markets since late 2018, the ramp up in sales has seen a protracted softness; STX attributes this to Norgine focusing on the gastro-intestinal market rather than the GP and OB/GYN pools that STX is targeting in the United States. STX has been in talks with Norgine and expects the sales strategy to gradually realign to the target areas, which may result in a larger uplift in sales in the coming years. Gaining reimbursement in other European geographies (Feraccru is currently reimbursed in Germany and the UK) should also help in this scale up. Norgine completed reimbursement document submissions for Spain in late Q421 and we await further updates on this and other geographies from the company.

New partnerships expand market reach

STX has signed two new (albeit small) partnerships in the last year, highlighting its deal-making capacity and the value of Accrufer/Feraccru in global markets. The first out-licensing deal was signed with Korea Pharma (for commercialisation in South Korea) in October 2021. It came with an upfront licence fee of £0.5m (reflected in the FY21 revenues), £1.5m on first commercialisation (estimated 2024), £4m in milestone payments and a flat 15% royalty on sales. In January 2022, the company signed another partnership, with KYE Pharmaceuticals, to commercialise Accrufer in Canada. STX received an upfront payment of £0.15m and is eligible to receive a further £0.85m in development and sales milestones, including £0.25m upon regulatory approval in Canada. The company will also receive double-digit royalties on Canadian sales. In July 2022, the company announced that Health Canada has accepted the New Drug Submission (NDS) filed by KYE and it expects the Canadian regulatory review to be completed in mid-2023.

In both deals, the partner will assume all clinical and regulatory costs while STX will be responsible for manufacturing the drug. While these deals expand the market reach and scope of STX's drug, given the small market sizes, we will await commercial launches in these respective territories before introducing their potential contributions to our financial estimates and valuation.

Valuation

We have revisited our valuation for STX following the recent FY21 results, management's update on its go-to-market strategy and focus and near-term directional guidance for sales growth and profitability. We continue to evaluate the company based on a risk-adjusted net present value (rNPV) model of Feraccru/Accrufer for the treatment of iron deficiency anaemia (IDA) in Europe (as covered by Norgine), the United States (STX-led commercialisation) and China (as covered by ASK Pharm). For the United States and Europe where the drug is already launched and approved, we have used a probability of success of 100% and a 10% discount rate, while for China (where the product is not launched yet) we assume a 75% probability of success and a 12.5% discount rate. We have rolled forward our model and updated it to reflect £4.2m in net cash at end-May 2022.

The key revision to our valuation comes from the introduction of slightly more conservative assumptions for the ramp up in sales across geographies compared to our previous estimates. We now expect a flatter sales trajectory in the near to medium term with the bulk of the upside realised after 2027–28. We now assume peak US net sales of £213m ($258m) in FY30, down from our prior peak estimate of $256m (previously anticipated in 2027). We assume that the second-line label for most of its reimbursement coverage and the significant price differential between Accrufer and generic and OTC alternatives, as well as the fragmented nature of the oral iron market (and of the health care prescribers for iron products, in general), are factors that make it challenging for the product to exceed 10% overall market share among all oral iron prescriptions written to insured patients in the United States. Hence, we have pushed out our estimated timelines for peak sales achievement across the board by an average two to three years. For China, owing to COVID-19-

related delays in clinical trials, we now expect the launch to take place in 2024 versus our earlier estimate of 2023. As a result of these changes, we obtain a new valuation of £371.0m (172p/share), down from £631.3m or 293p/share previously.

Exhibit 5: Shield Therapeutics rNPV valuation

Product	Market	Launch	*Sales (£m) in 2030	NPV (£m)	Probability of success	rNPV (£m)	rNPV/basic share (£)
Accrufer in IDA	US	2021	213	398.2	100%	398.2	1.84
Feraccru in IDA	Europe	2019	36	41.6	100%	41.6	0.19
Feraccru in IDA	China	2024	64	60.7	75%	45.5	0.21
Corporate costs				(118.4)		(118.4)	(0.55)
Net cash at 31 May 2022				4.2		4.2	0.02
Total equity value				386.2		371.0	1.72

Source: Edison Investment Research. Note: *Reflects end-market net sales; Shield is expected to receive a percentage of net sales as royalty revenue in Europe and China and recognise US product sales.

We highlight that the US opportunity remains a key value driver and represents 80% of our valuation for the company (excluding corporate costs). Given that STX is self-commercialising in the United States, successful execution remains a key sensitivity. Below we provide a sensitivity analysis reflecting how our valuation per share can respond to differing assumption on US peak operating margin and peak US sales revenue.

Exhibit 6: Shield Therapeutics sensitivity analysis*

	197	227	254	279	305
47%	0.83	1.12	1.45	1.78	2.04
50%	0.90	1.24	1.58	1.85	2.18
53%	1.01	1.36	1.72	1.99	2.33
56%	1.12	1.48	1.85	2.13	2.48
59%	1.23	1.61	1.98	2.26	2.63

Source: Edison Investment Research. Note: *Left-hand column represents peak US operating margin (%) and top row represents peak US end-market sales in 2030 (in US$m)

We also note, for reference, that the debt-to-equity conversion feature of the $10m shareholder loan (expected to be closed in August 2022), if actioned and converted at the current trading price of c 6p, would result in the issuance of 140m shares and the added dilution would result in the valuation being adjusted to 107p/share. We highlight that the current share price is at a substantial discount to our reassessed valuation, which we believe is largely due to investors pricing in risks associated with the uncertainty as it relates to how future financing needs will be met. In addition, the sensitivity analysis provided above demonstrates the wide potential fluctuation in valuation that can arise based on profitability and peak revenue (or market share) metrics. That said, we believe that if the company can manage its financing needs with minimal dilution, and if it can execute on its US commercialisation strategy for Accrufer, there can be material upside in the shares, as suggested by our valuation analysis.

Financials

STX's revenues and future growth potential remain fully exposed to the success of Feraccru/Accrufer across its target geographies. The company reported FY21 revenues of £1.5m versus £10.4m in FY20 (which benefited from a significant upfront payment for licensing Feraccru to ASK Pharm for the China market). Broken down, the net product revenue from the US launch of Accrufer was £0.06m (versus no revenue in FY20). Royalty revenues from Europe totalled £0.9m versus the FY20 figure of £0.7m. The company also received £0.5m in milestone payments from the licensing of Korean commercialisation to Korea Pharma in October 2021 (£9.7m upfront payment from ASK Pharm in FY20).

Total revenue was below our prior estimates of £3.9m due to the lower-than-anticipated ramp-up in the United States and Europe. However, we believe that this can be partially attributed to the less

effective ‘go to market’ strategy employed in Europe described above, as well as lack of payor coverage in the United States in FY21, which resulted in the company selling the drug at highly subsidised prices. STX estimates its net-to-gross discount on US sales is currently c 25% (meaning that on a $500 list price it would realise net revenue of c $125) but expects to, as the product roll-out continues and as it strengthens its PBM, insurer and distributor relationships, for this discount to level off at c 50% over the coming years.

Operating expenses for the year rose sharply to £20m from £8.6m in FY20 primarily due to higher selling costs (£10.3m vs £0.3m in FY20) related to the company employing its own US sales force following the July 2021 launch. General and administrative expenses increased by 34% y-o-y to £7.6m while R&D expenses fell from £2.6m to £0.6m. This excludes £0.9m capitalised development costs related to the ongoing paediatric study.

As stated above, we now anticipate a slower ramp-up in sales across geographies as STX focuses more on building its salesforce and on customer education and market coverage in the near term. We have introduced more conservative estimates for our near-term forecasts. We now estimate FY22 revenue of £6.2m (including £4.3m of Accrufer US net sales) versus our previous estimate of £19.3m, and we introduce FY23 and FY24 revenue estimates of £16.2m and £39.7m, respectively. We highlight that Accrufer is still in the early phases of its US launch and progress with the outreach activities of its sales force and improved payor coverage may have a material impact on our sales trajectory and revenue forecasts.

We expect STX to reach positive operating profit by FY25 (versus our previous estimate of FY23) and assume that the $10m (£8.4m) convertible debt financing expected in August should, with the company’s existing cash on hand (£4.2m at end of May), fund operations into FY23. We estimate the need to raise a further £25m before the end of FY24 (modelled as illustrative debt) before STX reaches the point of generating sustained profitability from Accrufer/Feraccru-related revenue.

Exhibit 7: Financial summary

£'000s	2020	2021	2022e	2023e	2024e
31-December	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	10,387	1,519	6,162	16,215	39,688
Cost of Sales	(1,354)	(980)	(1,747)	(4,035)	(8,214)
Gross Profit	9,033	539	4,415	12,181	31,474
Sales, General & Administrative	(5,903)	(17,816)	(21,792)	(25,674)	(34,203)
Net Research & Development	(2,579)	(579)	(672)	(504)	(420)
Amortisation of intangible assets	0	0	0	0	0
EBITDA	551	(17,856)	(18,049)	(13,998)	(3,149)
Depreciation & other	(2,705)	(2,207)	(2,113)	(2,041)	(1,999)
Normalised Operating Profit (ex. amort, SBC, except.)	(2,154)	(20,063)	(20,161)	(16,039)	(5,149)
Operating profit before exceptionals	(2,154)	(20,063)	(20,161)	(16,039)	(5,149)
Exceptionals including asset impairment	0	111	0	0	0
Other	0	0	0	0	0
Reported Operating Profit	(2,154)	(19,952)	(20,161)	(16,039)	(5,149)
Net Finance income (costs)	268	387	(9)	(1,366)	(2,162)
Profit Before Tax (norm)	(1,886)	(19,676)	(20,170)	(17,405)	(7,311)
Profit Before Tax (FRS 3)	(1,886)	(19,565)	(20,170)	(17,405)	(7,311)
Tax	(744)	229	0	0	0
Profit After Tax and minority interests (norm)	(2,630)	(19,447)	(20,170)	(17,405)	(7,311)
Profit After Tax and minority interests (FRS 3)	(2,630)	(19,336)	(20,170)	(17,405)	(7,311)
Average Basic Number of Shares Outstanding (m)	117.2	204.0	216.2	216.2	216.2
EPS - normalised (p)	(2.2)	(9.5)	(9.3)	(8.1)	(3.4)
EPS - normalised and fully diluted (p)	(2.2)	(9.5)	(9.3)	(8.1)	(3.4)
EPS - (IFRS) (p)	(2.2)	(9.5)	(9.3)	(8.1)	(3.4)
Dividend per share (p)	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed Assets	27,298	27,155	26,035	24,994	24,044
Intangible Assets	27,266	26,851	25,238	23,697	22,198
Tangible Assets	32	304	796	1,296	1,846
Investments in long-term financial assets	0	0	0	0	0
Current Assets	5,230	17,258	7,280	5,068	6,207
Short-term investments	0	0	0	0	0
Cash	2,940	12,117	280	1,562	2,701
Other	2,290	5,141	7,000	3,506	3,506
Current Liabilities	(2,252)	(3,380)	(3,380)	(3,380)	(3,380)
Creditors	(2,252)	(3,380)	(3,380)	(3,380)	(3,380)
Short term borrowings	0	0	0	0	0
Long Term Liabilities	0	0	(8,400)	(25,900)	(33,400)
Long term borrowings	0	0	(8,400)	(25,900)	(33,400)
Other long-term liabilities	0	0	0	0	0
Net Assets	30,276	41,033	21,535	782	(6,529)
CASH FLOW STATEMENT					
Operating Income	(2,154)	(19,952)	(20,161)	(16,039)	(5,149)
Movements in working capital	(2,711)	(1,415)	(1,859)	3,494	0
Net interest and financing income (expense)	268	387	(9)	(1,366)	(2,162)
Depreciation & other	2,705	2,207	2,113	2,041	1,999
Taxes and other adjustments	492	2,035	672	(3,348)	0
Net Cash Flows from Operations	(1,400)	(16,738)	(19,244)	(15,218)	(5,312)
Capex	(23)	(2,064)	(992)	(1,000)	(1,050)
Acquisitions/disposals	0	0	0	0	0
Interest received & other investing activities	3	13	0	0	0
Net Cash flows from Investing activities	(20)	(2,051)	(992)	(1,000)	(1,050)
Net proceeds from share issuances	6	27,705	0	0	0
Net movements in long-term debt	0	0	8,400	17,500	7,500
Dividends	0	0	0	0	0
Other financing activities	(53)	(121)	0	0	0
Net Cash flows from financing activities	(47)	27,584	8,400	17,500	7,500
Effects of FX on Cash & equivalents	266	382	0	0	0
Net Increase/(decrease) in cash & equivalents	(1,201)	9,177	(11,837)	1,282	1,138
Cash & equivalents at beginning of period	4,141	2,940	12,117	280	1,562
Cash & equivalents at end of period	2,940	12,117	280	1,562	2,701
Closing net debt/(cash)	(2,940)	(12,117)	8,120	24,338	30,699
Lease debt	28	156	156	156	156
Closing net debt/(cash) inclusive of IFRS 16 lease debt	(2,912)	(11,961)	8,276	24,494	30,855
Free cash flow	(1,423)	(18,802)	(20,237)	(16,218)	(6,362)

Source: Company reports, Edison Investment Research

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