EDISON

Shield Therapeutics

Interim results

2021 focus on Accrufer

Pharma & biotech

Shield Therapeutics (STX) successfully launched its key asset, Accrufer (oral ferric maltol for iron deficiency), in the US market on 1 July, in line with previous guidance. The US commercialisation of Accrufer is key to unlocking value (the US iron market is a huge market at ~10 million patients per year and is the key value driver) and FDA approval in 2019 led to the broadest possible label, which encompasses iron deficiency from any cause. The H121 results reported total revenue of £0.5m entirely from royalties on Feraccru sales from European partner Norgine (versus £8.9m in H120, of which £8.7m related to a milestone payment from ASK Pharm for China rights). We value STX at £631.3m or 293p/share.

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
12/19	0.7	(9.1)	(7.5)	0.0	N/A	N/A
12/20	10.4	(1.9)	(2.2)	0.0	N/A	N/A
12/21e	3.9	(23.6)	(11.7)	0.0	N/A	N/A
12/22e	19.3	(13.0)	(5.1)	0.0	N/A	N/A

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

Accrufer now launched in the US

With Accrufer now available in the US market, the immediate focus for STX is to continue to build on market access coverage (STX expects over the next six to 12 months to increase formulary coverage by signing reimbursement agreements with numerous payors) and physician awareness of Accrufer's benefits to drive sales in the US. In Europe, Feraccru sales volumes increased 51% versus H220, however royalties received from partner Norgine were flat at £0.5m. We revise our FY21 revenue forecasts to reflect slower sales momentum in Europe. Launches in additional countries could aid uplift, albeit slowly. The product was launched in Belgium and Luxembourg in early 2021. We maintain our European peak sales forecasts of €130m in 2028 and will monitor this as uptake develops. Post period, STX signed a licensing deal with Korea Pharma for South Korea (£0.5m upfront, £5.5m in sales and development milestones and 15% royalties on sales). Negotiations with potential partners in other territories are ongoing and could provide further upside to our current forecasts.

Financials: Cash runway to FY23

STX raised net funds of £27.7m in March 2021, extending the cash runway to forecast break-even in FY23. The primary use of these funds is to support the commercialisation of Accrufer in the US. The appointment of a US-based CEO (Greg Madison) highlights the focus on the key US market.

Valuation: £631.3m or 293p/share

Our revised valuation is £631.3m or 293p/share, versus £505.7m or 234p/share previously. The main changes are a slower sales evolution in Europe offset by reflecting the product's launched status in the US. Our other underlying assumptions are unchanged. We have rolled our model forward and include net cash of £22.6m at 30 June 2021. Our NPV calculation is based on Feraccru achieving peak sales of €130m in Europe, $256m in the US and $126m in China.

23 August 2021

Price	**43.5p**
Market cap	**£94m**
	£0.72/US$; £0.87/€
Reported net cash (£m) at 30 June 2021	22.6
Shares in issue	215.9m
Free float	55%
Code	STX
Primary exchange	AIM
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	1.2	(24.7)	(62.4)
Rel (local)	(2.6)	(26.2)	(69.1)
52-week high/low		139p	33p

Business description

Shield Therapeutics is a commercial-stage pharmaceutical company. Its proprietary product, Feraccru, is approved by the EMA and FDA for the treatment of iron deficiency. Outside of the United States, Feraccru is marketed through partners Norgine, AOP Orphan and Ewopharma.

Next events

Launches in additional EU states as covered by Norgine	End 2021/ early 2022
Start of Phase III paediatric study	H221
Completion of China Phase III study	End 2022

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Edison profile page

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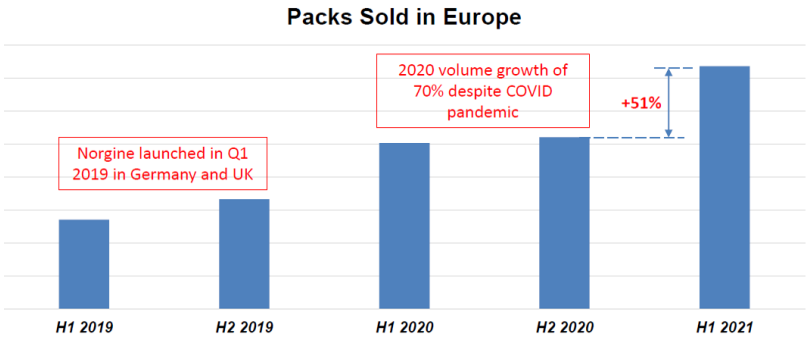
Accrufer launches in the United States

Following launch of Accrufer in the United States in July 2021, STX is working to increase physician awareness and expand market access. The COVID-19 pandemic has provided some headwinds to the initial phase of launch, limiting face-to-face contact with physicians. Importantly, STX market research demonstrates that US prescribers believe there is unmet need and Accrufer is viewed positively in terms of a clinically meaningful profile and improvement versus existing oral iron salts (good tolerability and efficacy). While 460,000 US physicians prescribe mostly oral iron tablets, STX is specifically targeting 11,000 physicians who write approximately 30% of all US prescriptions initially, through a salesforce of 30 reps in FY21 rising to 60 reps in FY22. Accrufer could offer an improved value proposition to patients and payors compared to existing oral treatments or the alternative, an intravenous treatment in the hospital setting.

The commercialisation of Feraccru in Europe, Australia (recently approved) and New Zealand is in the hands of partner Norgine, and the product is now marketed in Germany, the UK, Scandinavia (taken over from AOP Orphan), Belgium and Luxemburg. Despite the significant headwind from the pandemic, sales volumes increased by 51% in H121 versus H220 (Germany and the UK accounted for 87% of packs sold), Exhibit 1. We have lowered our forecast sales trajectory in Europe due to the lack of visibility on additional launches (ex Germany and UK) by Norgine. This has affected our royalty expectations from Norgine and we now forecast £1.4m in FY21 (vs £3.2m) and £2.9m in FY22 (vs £9.8m). Launching and obtaining pricing and reimbursement in additional European countries (key markets include France, Italy and Spain) is paramount to driving adoption in future years. Based on Feraccru's competitive profile in our view, we maintain our European peak sales forecast of €130m in 2028 and will monitor this as uptake develops. Timely sales growth over the next few quarters is critical to achieving this.

Exhibit 1: European sales evolution of Feraccru



- Number of Feraccru® packs sold in Europe increased by 51% in H1 2021 compared to H2 2020
- UK and Germany account for 87% of packs sold (H2 2020: 93%)
- Norgine (European license partner) continues to seek commercial adoption in other major European markets (e.g., Scandinavia, Benelux, France, Italy, and Spain)

Source: STX company presentation

Feraccru is not yet approved in China, and this territory is covered by partner ASK Pharm (the deal covers China, Hong Kong, Macau and Taiwan). The Chinese regulatory authority (CDE) has approved the IND for a short (12-week) Phase III study in c 120 inflammatory bowel disease (IBD) patients and a pharmacokinetic/pharmacodynamic study (to be conducted in parallel) that will be sufficient to support an NDA application. ASK Pharm has started to screen patients for the IBD study, which is expected to complete by the end of 2022, leading to potential approval and launch in 2023. STX is eligible to receive a further $11.4m milestone upon regulatory approval in China, plus royalties of 10% or 15% on net sales (depending on the level), and up to $40m in cumulative sales-related milestones. Furthermore, in August 2021 STX out-licensed the Accrufer development and

commercial rights in South Korea to Korea Pharma, netting an upfront payment of £0.5m, and is due a £1.5m milestone on first sales in the territory plus 15% royalties on sales and up to £4m in sales milestones. Negotiations with potential partners in other territories are ongoing and could provide further upside to our current forecasts.

Valuation

Our revised STX valuation of £631.3m or 293p/share (versus £505.7m or 234p/share previously) is based on a risk-adjusted net present value (NPV) model of Feraccru/Accrufer (Exhibit 2) 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). We have increased the probability of success to 100% in the United States following launch and use a discount rate of 10% for Europe and the United States, where the product is launched, and 12.5% in China. However, sales execution risk remains, as for any company launching products, and we will closely monitor the US sales evolution versus our early years sales ramp-up expectations. The US opportunity is a key value driver and represents ~70% of our valuation. We have lowered our near-term sales trajectory in Europe but maintain our peak sales forecasts. Timely sales growth over the next few quarters is critical to achieving this. All other forecasts are unchanged. We have rolled forward our model and reflect reported net cash at 30 June 2021 of £22.6m.

Exhibit 2: Valuation

Product	Market	Indication	Launch	Peak	Peak sales	NPV (£m)	Probability	rNPV (£m)	rNPV/share (p)
Feraccru/Accrufer	EU5	IDA	2019	2028	€130m	111.3	100%	111.3	51.6
	US	IDA	2021	2027	$256m	438.5	100%	438.5	203.1
	China	IDA	2023	2031	$126m	78.6	75%	58.9	27.3
Net cash at 30 June 2021						22.6	100%	22.6	10.5
Valuation						**651.0**		**631.3**	**292.5**

Source: Edison Investment Research

Financials

STX's revenues remain wholly dependent on the success of Feraccru/Accrufer. STX reported H121 revenues of £0.5m vs £8.9m in H120, as the prior year benefited from the £8.7m ($11.4m) upfront licence payment from ASK Pharm. Royalties received from partner Norgine relating to Feraccru sales in Europe were flat at £0.5m vs H220. We forecast total revenues of £3.9m in FY21 (this includes £2.0m US Accrufer sales, plus £1.4m in royalties from partner Norgine on European Feraccru sales and a £0.5m upfront payment from Korea Pharma). We expect total revenues to increase to £19.3m in FY22 (this includes US sales of £16.4m, plus £2.9m in royalties from Norgine). We note that Accrufer is still in the early phases of launch in the United States and the timing of achieving payor coverage will have a significant impact on our sales trajectory and revenue forecasts.

During H121 SG&A expenses increased to £6.1m (H120: £4.8m) due to pre-launch costs in the United States. R&D expenses increased to £1.6m (H120: £0.7m) predominately due to the paediatric study (Stage 1 completed). This resulted in an operating loss for the period of £7.6m (H120: £2.4m profit). We expect expenditure to increase significantly as the US launch gathers momentum and the final stage of the paediatric study starts, offset by growing sales in the United States and Europe. Based on its financial guidance, we expect STX to move into sustainable profitability on an annualised basis from FY23. STX reported an unaudited cash balance of £22.6m at 30 June 2021 following the share placing in March (£27.7m net). Management expects this is sufficient to take it to the point at which it is cash flow positive, which it expects to reach on a monthly basis within 18 months of US launch. Our forecast cash requirement and break-even assumptions are reliant on STX reaching our revenue forecasts and we note that sales are dependent on gaining timely broad market access.

Exhibit 3: Financial summary

Accounts: IFRS, year-end: 31 December £000s	2017	2018	2019	2020	2021e	2022e
PROFIT & LOSS						
Revenue	637	11,881	719	10,387	3,904	19,308
Cost of sales	(155)	(311)	(485)	(1,354)	(1,067)	(3,396)
Gross profit	482	11,570	234	9,033	2,837	15,912
Gross margin %	76%	97%	33%	87%	73%	82%
SG&A (expenses)	(16,722)	(12,429)	(6,773)	(8,608)	(23,980)	(26,427)
R&D costs	(4,711)	(4,300)	(2,496)	(2,579)	(2,500)	(2,500)
Other income/(expense)	0	0	0	0	0	0
EBITDA	(18,514)	(2,469)	(6,414)	551	(21,588)	(11,098)
Depreciation and amortisation	(2,437)	(2,690)	(2,621)	(2,705)	(2,055)	(1,917)
Reported operating income	(20,951)	(5,159)	(9,035)	(2,154)	(23,642)	(13,015)
Exceptionals and adjustments	(2,571)	0	0	0	0	0
Adjusted operating income	(18,380)	(5,159)	(9,035)	(2,154)	(23,642)	(13,015)
Finance income/(expense)	(43)	8	(31)	268	90	0
Reported profit before tax	(20,994)	(5,151)	(9,066)	(1,886)	(23,552)	(13,015)
Adjusted profit before tax	(18,423)	(5,151)	(9,066)	(1,886)	(23,552)	(13,015)
Income tax expense	1,406	3,359	266	(744)	600	1,952
Reported net income	(19,588)	(1,792)	(8,800)	(2,630)	(22,952)	(11,062)
Average number of shares outstanding (m)	112.4	116.4	117.0	117.2	195.5	215.9
Year-end number of shares, m	116.4	116.4	117.2	117.6	215.9	215.9
Basic EPS (p)	(17.4)	(2.0)	(7.5)	(2.2)	(11.7)	(5.1)
EPS - normalised (p)	(15.1)	(1.5)	(7.5)	(2.2)	(11.7)	(5.1)
Dividend per share (p)	0.0	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET						
Property, plant and equipment	13	155	26	32	22	16
Intangible assets	29,961	30,957	29,898	27,266	25,471	23,811
Other non-current assets	0	0	0	0	0	0
Total non-current assets	29,974	31,112	29,924	27,298	25,493	23,826
Cash and equivalents	13,299	9,776	4,141	2,940	8,483	2,386
Inventories	125	109	948	1,379	586	933
Trade and other receivables	1,572	1,031	356	619	4,676	5,304
Other current assets	0	1,500	950	292	292	292
Total current assets	14,996	12,416	6,395	5,230	14,037	8,915
Non-current loans and borrowings	0	0	0	0	0	0
Other non-current liabilities	0	0	0	0	0	0
Total non-current liabilities	0	0	0	0	0	0
Trade and other payables	3,501	2,548	3,547	1,471	3,224	6,997
Current loans and borrowings	0	0	0	0	0	0
Other current liabilities	262	550	627	781	781	781
Total current liabilities	3,763	3,098	4,174	2,252	4,005	7,778
Equity attributable to company	41,207	40,430	32,145	30,276	35,526	24,963
CASH FLOW STATEMENT						
Reported net income	(19,588)	(1,792)	(8,800)	(2,630)	(22,952)	(11,062)
Depreciation and amortisation	2,437	2,690	2,621	2,705	2,055	1,917
Share based payments	560	1,013	456	771	500	500
Other adjustments	39	3	31	(3)	0	0
Movements in working capital	(186)	(255)	555	(2,630)	(1,511)	2,798
Interest paid/received	0	(8)	31	(268)	0	0
Income taxes paid/received	587	(1,500)	1,040	655	0	0
Cash from operations (CFO)	(16,151)	151	(4,066)	(1,400)	(21,909)	(5,847)
Capex	(3,408)	(3,345)	(1,384)	(23)	(250)	(250)
Acquisitions & disposals net	0	0	0	0	0	0
Other investing activities	0	50	18	3	0	0
Cash used in investing activities (CFIA)	(3,408)	(3,295)	(1,366)	(20)	(250)	(250)
Net proceeds from issue of shares	11,880	0	0	0	27,702	0
Movements in debt	0	0	0	0	0	0
Other financing activities	0	(379)	(203)	(47)	0	0
Cash from financing activities (CFF)	11,880	(379)	(203)	(47)	27,702	0
Cash and equivalents at beginning of period	20,978	13,299	9,776	4,141	2,940	8,483
Increase/(decrease) in cash and equivalents	(7,679)	(3,523)	(5,635)	(1,467)	5,543	(6,097)
Effect of FX on cash and equivalents	0	0	0	266	0	0
Cash and equivalents at end of period	13,299	9,776	4,141	2,940	8,483	2,386
Closing net (debt)/cash	13,299	9,776	4,141	2,940	8,483	2,386

Source: Company accounts, Edison Investment Research

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