EDISON

Shield Therapeutics

Accrufer coming to America

US commercialisation strategy

Pharma & biotech

Shield Therapeutics (STX) has placed c 83m shares at a deep discount (30.0p/share) to the market price, resulting in a gross raise of £25m. The funds will be utilised to support the US launch and commercialisation of Accrufer (iron deficiency), and thus clarify the strategy in this territory for its key asset. STX will now focus on establishing its US-based operations ahead of imminent launch of the product (launch stocks are ready to be shipped). Our higher valuation reflects the retention of full economics vs our prior out-licensing assumption, and we now forecast STX launch in the US in Q221 vs 2022 previously. Following the raise, the main risk relates to sales execution. However, we see significant upside given that the current share price fully discounts the US opportunity. We value STX at £471.4m.

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
12/18	11.9	(5.2)	(1.5)	0.0	N/A	N/A
12/19	0.7	(9.1)	(7.5)	0.0	N/A	N/A
12/20e	9.4	(3.1)	(1.6)	0.0	N/A	N/A
12/21e	6.6	(22.4)	(11.2)	0.0	N/A	N/A

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

US commercialisation key to unlocking value

Accrufer received FDA approval in 2019 for the broadest possible label to encompass iron deficiency of any cause, as per its US prescribing information. Timely launch (and subsequent market access coverage) is critical in our view, as the product could offer an improved value proposition to patients and payors versus existing oral treatments or the alternative, an iv treatment in the hospital setting. Key to success is hiring the right personnel, and STX has identified four US-based individuals (including chief commercial officer, Brian Groch) with the relevant sales, medical liaison, supply chain and market access experience.

Break-even in 2023, sustainable profitability thereafter

Management expects initial SG&A costs of $25–30m per year (2021/22), increasing to $40–45m in year three, to establish and expand its US operations to include 30–60 sales reps who would target the top 30% of oral iron prescribers (~11,000 physicians). With the costs outlined, STX expects to reach break-even on a monthly basis within 15–18 months after US launch. Profitability in FY23 is achievable on the basis of our current forecast revenue streams ex-US (royalties of £16.1m and milestones of £9.5m) plus a minimum US sales contribution of c $25m.

Valuation: £471.4m or 218p/share

Our revised valuation is £471.4m or 218p/share vs £298.5m or 254p/share. We now reflect STX-led US commercialisation (vs partnering), remove the £10m upfront payment related to partnering activities and include significant SG&A costs. Our revised US peak sales forecast of $256m in 2027 (vs $410m in 2029) reflects a shorter treatment duration. Peak sales in the EU and China are unchanged. Our valuation includes unaudited net cash at 31 January 2021 of £2.3m. The post-period raise and open offer has extended the cash runway to forecast break-even in FY23.

5 March 2021

Price	**39p**
Market cap	**£46m**
	£0.72/US$; £0.87/€
Unaudited net cash (£m) at 31 January 2021	2.3
Shares in issue (assuming all open offer shares are taken up)	215.8m
Free float	60%
Code	STX
Primary exchange	AIM
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(25.3)	(63.5)	(69.6)
Rel (local)	(26.9)	(64.4)	(69.6)
52-week high/low		139p	36p

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. Feraccru is marketed through partners Norgine, AOP Orphan and Ewopharma.

Next events

Potential US launch	2021
Launches in additional EU states as covered by Norgine	2021
Start of Phase III paediatric study	Mid-2021

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Valuation

Our revised STX valuation of £471.4m or 218p/share (vs £298.5m or 254p/share previously) is based on a risk-adjusted net present value (NPV) model of Feraccru/Accrufer (Exhibit 1) for treatment of iron deficiency anaemia (IDA) in Europe (as covered by Norgine), the US (STX-led commercialisation) and China (as covered by ASK Pharm). Our significantly higher valuation reflects the substantial economics that STX could generate if its US self-commercialisation strategy is successful based on the guidance management has outlined, vs prior partnering assumptions of 20% royalties on sales plus a £10m upfront payment. We bring forward US launch by one year to 2021 (management expects the first sales in Q221) and remove our forecast £10m upfront payment predicated on a partnering deal in late 2021. Adding unaudited net cash at 31 January 2021 of £2.3m and using a discount rate of 10% for Europe, where the product is launched, and 12.5% for the US and China, we reach our risk-adjusted NPV of 218p/share. We have rolled forward our model and updated FX to reflect current spot rates. All other forecasts are unchanged. 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.

Exhibit 1: Valuation

Product	Market	Indication	Launch	Peak	Peak sales	NPV (£m)	Probability	rNPV (£m)	rNPV/share (p)
Feraccru/Accrufer	EU5	IDA	2019	2028	€130m	112.4	100%	112.4	52.1
	US	IDA	2021	2027	$256m	340.5	90%	306.4	142.0
	China	IDA	2023	2031	$126m	74.5	75%	50.3	23.3
Net cash at 31 January 2021 (unaudited)						2.3	100%	2.3	1.1
Valuation						**529.6**		**471.4**	**218.4**

Source: Edison Investment Research

US assumptions: for the US, we assign a probability of success of 90%, in line with our treatment of assets at the approved stage of development. Our revised peak sales forecast is $256m in 2027 vs $410m in 2029. We have increased our net price per pack to $250 (previously $225) and reduced the duration of treatment to four months (previously six months) to reflect recent management commentary. We note that company-sponsored payor research has indicated that Accrufer could have non-preferred formulary status at tested price points to ensure good patient access. Our peak penetration rate expected for the US market is largely unchanged at 10%. We assume a 90% gross margin; COGS comprise the cost of manufacturing Accrufer (c 5% of sales) and a pay-away to Vitra Pharmaceuticals for royalties on sales (5%). We forecast initial SG&A of $25m (£18m) in 2021 to rise to $60m (£43m) in 2025.

Europe assumptions: from the European market (as covered by Norgine), revenues to STX comprise a tiered royalty (25–40%) on sales, development milestones (€4.5m) and sales-related milestones (up to €50m). COGS comprise the cost of manufacturing Feraccru (c 10% of sales) and a pay-away to Vitra Pharmaceuticals for royalties on Norgine sales (5%). STX will receive reimbursement for manufacture and supply, and this amount will be netted against the royalty received during each period. We model both US and European sales to composition of matter patent expiry in 2035.

China assumptions: for China, we assign a probability of success of 75%, in line with our treatment of assets at Phase III stage of development. Under the deal terms with ASK Pharm, STX is eligible for a further $11.4m milestone on approval in China, which we forecast in 2023. STX will receive tiered royalties of 10% or 15% on net sales of Feraccru/Accrufer (throughout the duration of the intellectual property) plus up to $40m in cumulative sales-related milestones. Vitra Pharmaceuticals has elected to receive 10% of the upfront and sales-related milestones instead of royalties on future sales.

STX shares are currently trading at 38.5p (at close on 4 March 2021), which is below the value ascribed to the European opportunity solely according to our valuation and therefore assumes no value is generated from selling Accrufer in any territories outside the EU. Clearly, there is a large discrepancy between our valuation and the share price, which reflects the market's perceived execution risk for an STX-led US commercialisation strategy. Over time, as the company demonstrates its ability to generate and ramp up Accrufer sales in the US in a timely manner, we would expect the valuation differential to close. We highlight that while an STX-led launch could provide greater long-term value to shareholders, significant commercial risks remain, including the group's ability to recruit, train and retain adequate numbers of effective sales and marketing personnel as well as obtaining market access. We note that discussions are underway with several companies that could co-promote or sub-license Accrufer in specific territories or therapy areas that could complement and support an STX-led launch.

Financials

STX's revenues remain wholly dependent on the success of Feraccru/Accrufer. For FY21, we now forecast total revenues of £6.6m (this includes £2.0m US Accrufer sales plus £3.8m in royalties and £0.9m sales milestone from partner Norgine on European Feraccru sales). We expect total revenues to increase to £27.1m in FY22 (including US sales of £16.4m, plus £9.8m in royalties and a £0.9m sales milestone from Norgine). We forecast an operating loss of £22.4m and £8.5m in FY21 and FY22 respectively.

Based on its financial guidance (see below), we expect STX to move into sustainable profitability on an annualised basis from FY23. Specifically, we forecast operating profit of £37.0m in FY23 based on total revenues of £84.8m (we forecast US sales of £55.6m, European royalty contributions plus an £8.2m forecast China approval milestone payment from partner ASK Pharm). We expect rapid margin expansion and forecast operating margins could reach some 52% by 2024, given 90% gross margins and that the main operating costs for the business will likely relate to US SG&A. We expect R&D expenses of £2.5m in 2021 and 2022 to reduce significantly thereafter as the paediatric study wraps up. Currently, we do not include any potential R&D costs for a once-a-day formulation or any other post-marketing clinical trials.

Following the £8.7m ($11.4m) upfront licence payment in 2020, STX has £2.3m (unaudited) in cash as of 31 January 2021 and no debt. Post period, the recent raise (£25m gross from an equity placing, plus a further £4.2m gross expected to be raised through an open offer to existing shareholders) would extend the cash runway to our forecast maiden profitability in FY23. We include the expected proceeds from these raises in our financial forecasts given management's confidence in their successful completion. The funds raised will be utilised to support the launch of Accrufer and establish the US commercial operations, and should fully satisfy the $30–40m (c £21–29m) cash outlay which STX estimates is necessary to reach the point at which it generates cash. Our forecast cash requirement and break-even assumptions are reliant on STX reaching our 2022 total revenue forecast of £27.1m.

STX has issued the following financial guidance:

'Shield believes that around $30 million to $40 million (c £21 million to £29 million) should provide the finance necessary to reach the breakeven point.'

'Shield's launch plan for the US expects annual SG&A costs in the US to be around $40 million to $45 million by year three.'

'Based on the Group's cash flow forecasts, including the costs of the US launch of Accrufer and the paediatric study, the Group could start to breakeven on a monthly basis within 15-18 months after launch provided sales and costs are within the range anticipated by the Directors.'

Exhibit 2: Financial summary

Accounts: IFRS, year-end: 31 December	£000s	2017	2018	2019	2020e	2021e	2022e
PROFIT & LOSS							
Revenue		637	11,881	719	9,412	6,637	27,062
Cost of sales		(155)	(311)	(485)	(429)	(2,513)	(6,556)
Gross profit		482	11,570	234	8,983	4,125	20,506
Gross margin %		76%	97%	33%	95%	62%	76%
SG&A (expenses)		(16,722)	(12,429)	(6,773)	(9,550)	(24,048)	(26,499)
R&D costs		(4,711)	(4,300)	(2,496)	(2,500)	(2,500)	(2,500)
Other income/(expense)		0	0	0	0	0	0
EBITDA		(18,514)	(2,469)	(6,414)	(817)	(20,325)	(6,534)
Depreciation and amortisation		(2,437)	(2,690)	(2,621)	(2,250)	(2,098)	(1,959)
Reported operating income		(20,951)	(5,159)	(9,035)	(3,067)	(22,424)	(8,492)
Exceptionals and adjustments		(2,571)	0	0	0	0	0
Adjusted operating income		(18,380)	(5,159)	(9,035)	(3,067)	(22,424)	(8,492)
Finance income/(expense)		(43)	8	(31)	0	0	0
Reported profit before tax		(20,994)	(5,151)	(9,066)	(3,067)	(22,424)	(8,492)
Adjusted profit before tax		(18,423)	(5,151)	(9,066)	(3,067)	(22,424)	(8,492)
Income tax expense		1,406	3,359	266	1,200	600	1,274
Reported net income		(19,588)	(1,792)	(8,800)	(1,867)	(21,824)	(7,218)
Average number of shares outstanding (m)		112.4	116.4	117.0	117.6	195.5	215.8
Year-end number of shares, m		116.4	116.4	117.2	117.6	215.8	215.8
Basic EPS (p)		(17.4)	(2.0)	(7.5)	(1.6)	(11.2)	(3.3)
EPS - normalised (p)		(15.1)	(1.5)	(7.5)	(1.6)	(11.2)	(3.3)
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	18	13	9
Intangible assets		29,961	30,957	29,898	27,906	26,063	24,358
Other non-current assets		0	0	0	0	0	0
Total non-current assets		29,974	31,112	29,924	27,924	26,075	24,367
Cash and equivalents		13,299	9,776	4,141	2,894	7,347	2,950
Inventories		125	109	948	472	1,381	1,801
Trade and other receivables		1,572	1,031	356	1,523	9,511	14,393
Other current assets		0	1,500	950	950	950	950
Total current assets		14,996	12,416	6,395	5,839	19,189	20,094
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	2,358	7,593	13,508
Current loans and borrowings		0	0	0	0	0	0
Other current liabilities		262	550	627	627	607	607
Total current liabilities		3,763	3,098	4,174	2,985	8,200	14,115
Equity attributable to company		41,207	40,430	32,145	30,778	37,064	30,346
CASH FLOW STATEMENT							
Reported net income		(19,588)	(1,792)	(8,800)	(1,867)	(21,824)	(7,218)
Depreciation and amortisation		2,437	2,690	2,621	2,250	2,098	1,959
Share based payments		560	1,013	456	500	500	500
Other adjustments		39	3	31	0	0	0
Movements in working capital		(186)	(255)	555	(1,880)	(3,662)	612
Interest paid / received		0	(8)	31	0	0	0
Income taxes paid / received		587	(1,500)	1,040	0	0	0
Cash from operations (CFO)		(16,151)	151	(4,066)	(997)	(22,887)	(4,147)
Capex		(3,408)	(3,345)	(1,384)	(250)	(250)	(250)
Acquisitions & disposals net		0	0	0	0	0	0
Other investing activities		0	50	18	0	0	0
Cash used in investing activities (CFIA)		(3,408)	(3,295)	(1,366)	(250)	(250)	(250)
Net proceeds from issue of shares		11,880	0	0	0	27,590	0
Movements in debt		0	0	0	0	0	0
Other financing activities		0	(379)	(203)	0	0	0
Cash from financing activities (CFF)		11,880	(379)	(203)	0	27,590	0
Cash and equivalents at beginning of period		20,978	13,299	9,776	4,141	2,894	7,347
Increase/(decrease) in cash and equivalents		(7,679)	(3,523)	(5,635)	(1,247)	4,453	(4,397)
Cash and equivalents at end of period		13,299	9,776	4,141	2,894	7,347	2,950
Closing net (debt)/cash		13,299	9,776	4,141	2,894	7,347	2,950

Source: Company accounts, Edison Investment Research

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