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Shield Therapeutics

FY19 results

All eyes on a US partnering deal

Pharma & biotech

Shield Therapeutics (STX) has reported FY19 results; total revenue of £0.7m reflects royalties on Feraccru sales from European partner Norgine. 2019 achievements include FDA approval of STX's key asset for the treatment of iron deficiency in patients with any underlying cause – the broadest possible label – in the critical US market. Momentum has continued into 2020 with an out-licensing deal with China-based Beijing Aosaikang Pharmaceutical (ASK Pharm) that covers China, Hong Kong, Macau and Taiwan. The next key inflection point is a US partnering deal, and discussions are ongoing with the aim of closing a transaction at the earliest opportunity in 2020. We expect Accrufer launch later this year once a partner has been found. STX reported a cash balance of £10.4m at 30 April 2020 implying a cash runway to Q121. We value Shield at £381.7m.

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
12/18	11.88	(5.15)	(1.5)	0.0	N/A	N/A
12/19	0.72	(9.07)	(7.5)	0.0	N/A	N/A
12/20e	12.66	1.14	2.0	0.0	48.3	N/A
12/21e	8.99	(4.31)	(3.2)	0.0	N/A	N/A

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

2020 focus on US partnering activity

STX reported FY19 revenues of £0.7m, as Feraccru/Accrufer (oral ferric maltol) is making inroads in Europe, with sales volumes growing ~70%. Further uplift in Europe will be determined by launches in additional countries (France, Italy and Spain expected in 2021) as well as ongoing growth in launched countries (Germany and the UK). Key inflections in 2020 include the US partnering deal, initiation of a paediatric study (a requirement for both Europe and US regulatory bodies) utilising a liquid formulation and the development of a new formulation of PT20 with a view to start the additional pivotal Phase III trial required in 2022.

Financials: Cash runway to Q121

Shield reported an unaudited cash balance of £10.4m at 30 April 2020 (including the $11.4m licence payment received from ASK Pharm), which implies a cash runway into Q121. We expect a US partnering deal by year-end 2020 and the associated upfront licensing payment to strengthen the balance sheet, further reducing the requirement for a capital increase. With ongoing growth in Europe and a US launch on the horizon, we forecast that sustainable profitability is achievable from 2022, with gross margins nearing c 50–60% in the long term. Partnering strategies enhance economic returns and de-risk the investment case.

Valuation: £381.7m or 326p/share

Our revised valuation is £381.7m or 326p/share, vs £369.2m or 315p/share (derived from an rNPV model). Our underlying assumptions for Shield remain unchanged. Our valuation reflects a revised end-2020 net cash forecast of £7.2m due to slight changes in working capital rolling on with the FY19 results. We have updated for FX and rolled forward our model. Our NPV calculation is based on Feraccru achieving peak sales of €130m in Europe, $410m in the US and $126m in China.

22 May 2020

Price	**96.5p**
Market cap	**£113m**
	£0.82/US$; £0.90/€
Unaudited net cash (£m) at 30 April 2020	10.4
Shares in issue	117.2m
Free float	32%
Code	STX
Primary exchange	AIM
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(8.5)	(36.9)	(15.7)
Rel (local)	(14.1)	(21.3)	2.2
52-week high/low		196p	54p

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

Out-licensing US rights to Feraccru	2020
Launches in the US and additional EU states as covered by Norgine	2020/21

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Edison profile page

Worldwide opportunity driven by ID/IDA prevalence

In Europe, Feraccru is being marketed by commercialisation partner Norgine, and the product was launched in Germany and the UK in Q119. It is reimbursed throughout Germany, however we note in the United Kingdom, reimbursement is limited to one-third of formularies in England (where each of the ~200 Clinical Commissioning Groups has its own formulary), with no coverage to date in Scotland, Wales and Northern Ireland (Norgine is in the process of submitting applications). Growth in the UK will be dependent on widening access. Future growth in Europe will depend on launches in other European countries, which are reliant on formulary access and pricing negotiations.

US market within grasp in 2020

In the near term the US market is the most significant opportunity given the broad label awarded (iron deficiency), addressable patient population (eight to nine million US iron deficiency anaemia (IDA) patients, source: STX presentation), and Accrufer's positioning as an alternative to IV iron and thus premium pricing relative to existing oral salts and on a par with IV iron (on an annualised level). On this point it was disappointing that in the AEGIS head to head (H2H) study, the product has not met the primary endpoint on non-inferiority to IV iron, leading to a €2.5m milestone repayment to Norgine from STX. AEGIS-H2H was not required for regulatory approval and it is still likely that the 52-week data (which shows the product was effective and generally well tolerated over the period) will prove valuable for health economics purposes and in pricing and reimbursement discussions. We believe Feraccru/Accrufer's profile as a highly tolerable oral iron product will still enable it to garner market share given treatment discontinuation rates are high (30–60%), with first-line treatment utilising salt-based oral iron products (which have intolerable side effects). We expect use in iron deficiency (ID)/IDA in patients whose iron level does not warrant intravenous iron infusions.

China deal adds to overall value proposition

STX has an exclusive deal for Feraccru/Accrufer with China-based Beijing Aosaikang Pharmaceutical (ASK Pharm) that covers China, Hong Kong, Macau and Taiwan. ASK Pharm will complete any required clinical trials in China and file the marketing authorisation for the treatment of iron deficiency in all territories covered by the deal. China represents a large market in volume terms (>280m IDA population, source ASK Pharm, Vifor). Although at lower pricing than the US and European opportunity, the licensing deal adds to Feraccru's overall value proposition. Under the deal terms with ASK Pharm, Shield received $11.4m as an upfront payment and is eligible for a further $11.4m on approval in China. Shield will receive tiered royalties of 10% or 15% of net sales of Feraccru/Accrufer (throughout the duration of the intellectual property) plus up to $40m in sales-related milestones. ASK Pharma is a speciality pharma company with a focus on gastrointestinal and oncology treatment. Feraccru/Accrufer fits into its therapeutic focus well and will benefit from the 1,000-strong commercial team in China on potential launch. Alocal Phase III clinical study and regulatory approval will likely take two to three years to compete, thus we forecast launch in China in 2023.

Clinical work continues in 2020

STX plan to initiate the required (as per EMA and FDA approvals) paediatric study for Feraccru/Accrufer. The paediatric study requires a liquid formulation (rather than the capsule formulation approved in adults) and the first step is to manufacture a liquid formulation and then prove its equivalence to the capsule in a study (to be conducted towards end 2020). The estimated cost of the paediatric study is £5m over two to three years (this is already reflected in our R&D forecasts).

Additionally, STX's iron-based phosphate binder PT20, which has already completed one of the two required pivotal, Phase III studies, is coming back into focus. Reformulation work is planned for H220 (and will take 15–18 months) to enable the initiation of the second Phase III trial required for regulatory submission. We do not include PT20 in our forecasts or valuation of STX.

Exhibit 1: Financial summary

Year end 31 December £000s	2017	2018	2019	2020e	2021e
PROFIT & LOSS					
Revenue	637	11,881	719	12,659	8,991
Cost of sales	(155)	(311)	(485)	(1,769)	(4,204)
Gross profit	482	11,570	234	10,891	4,787
Gross margin %	76%	97%	33%	86%	53%
SG&A (expenses)	(16,722)	(12,429)	(6,773)	(6,750)	(6,098)
R&D costs	(4,711)	(4,300)	(2,496)	(3,000)	(3,000)
Other income/(expense)	0	0	0	0	0
EBITDA	(18,514)	(2,469)	(6,414)	3,391	(2,213)
Depreciation and amortisation	(2,437)	(2,690)	(2,621)	(2,250)	(2,098)
Reported Operating Income	(20,951)	(5,159)	(9,035)	1,141	(4,311)
Exceptionals and adjustments	(2,571)	0	0	0	0
Adjusted Operating Income	(18,380)	(5,159)	(9,035)	1,141	(4,311)
Finance income/(expense)	(43)	8	(31)	0	0
Reported PBT	(20,994)	(5,151)	(9,066)	1,141	(4,311)
Profit Before Tax (norm)	(18,423)	(5,151)	(9,066)	1,141	(4,311)
Income tax expense	1,406	3,359	266	1,200	600
Reported net income	(19,588)	(1,792)	(8,800)	2,341	(3,711)
Average Number of Shares Outstanding (m)	112.4	116.4	117.0	117.2	117.2
Year-end number of shares, m	112.4	116.4	117.0	117.2	117.2
Basic EPS (p)	(17.43)	(2.00)	(7.52)	2.00	(3.17)
EPS - normalised (p)	(15.2)	(1.5)	(7.5)	2.0	(3.2)
Dividend per share (p)	0.00	0.00	0.00	0.00	0.00
BALANCE SHEET					
Property, plant and equipment	13	155	26	18	13
Goodwill	0	0	0	0	0
Intangible assets	29,961	30,957	29,898	27,906	26,063
Other non-current assets	0	0	0	0	0
Total non-current assets	29,974	31,112	29,924	27,924	26,075
Cash and equivalents	13,299	9,776	4,141	7,235	2,435
Inventories	125	109	948	1,943	2,310
Trade and other receivables	1,572	1,031	356	7,278	13,335
Other current assets	0	1,500	950	950	950
Total current assets	14,996	12,416	6,395	17,406	19,030
Non-current loans and borrowings	0	0	0	0	0
Other non-current liabilities	0	0	0	0	0
Total non-current liabilities	0	0	0	0	0
Trade and other payables	3,501	2,548	3,547	9,717	12,704
Current loans and borrowings	0	0	0	0	0
Other current liabilities	262	403	607	607	607
Total current liabilities	3,763	3,098	4,174	10,324	13,311
Equity attributable to company	41,207	40,430	32,145	34,986	31,774
CASH FLOW STATEMENT					
Reported net income	(19,588)	(1,792)	(8,800)	2,341	(3,711)
Depreciation and amortisation	2,437	2,690	2,621	2,250	2,098
Share based payments	560	1,013	456	500	500
Other adjustments	39	4	33	0	0
Movements in working capital	(186)	(255)	555	(1,747)	(3,438)
Interest paid/received	0	0	0	0	0
Income taxes paid/received	587	(1,500)	1,040	0	0
Cash from operations (CFO)	(16,151)	151	(4,066)	3,344	(4,550)
Capex	(3,408)	(3,345)	(1,384)	(250)	(250)
Acquisitions & disposals net	0	0	0	0	0
Other investing activities	0	50	18	0	0
Cash used in investing activities (CFIA)	(3,408)	(3,295)	(1,366)	(250)	(250)
Net proceeds from issue of shares	11,880	0	0	0	0
Movements in debt	0	0	0	0	0
Other financing activities	0	0	0	0	0
Cash from financing activities (CFF)	11,880	(379)	(203)	0	0
Cash and equivalents at beginning of period	20,978	13,299	9,776	4,141	7,235
Increase/(decrease) in cash and equivalents	(7,679)	(3,523)	(5,635)	3,094	(4,800)
Cash and equivalents at end of period	13,299	9,776	4,141	7,235	2,435
Closing net (debt)/cash	13,299	9,776	4,141	7,235	2,435

Source: Company accounts, Edison Investment Research

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