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# Shield Therapeutics

Interim results

## US partner next major inflection point

Pharma & biotech

**Shield Therapeutics' (STX's) interim results highlight the progress made year to date. Re-analysis of the Feraccru/Accrufer AEGIS-H2H data show it is a credible alternative to IV iron therapy for iron deficiency anaemia (IDA) in the long term. With the product out-licensed in China to partner ASK Pharm, all eyes remain on the announcement of a US commercial partner (expected this year). Royalties received from H120 sales of the product (UK and Germany) by partner Norgine are slowly building, but pricing and reimbursement discussions resuming in Europe could lead to ongoing rollouts in key countries (France, Spain and Italy) in 2021. STX's cash runway extends into Q121, an upfront licensing payment from a US deal would ameliorate the need for further capital. We value Shield at £379.1m.**

| 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 | 10.5 | (0.8) | 0.3 | 0.0 | N/A | N/A |
| 12/21e | 8.9 | (4.4) | (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.

## US partnering and launch expected by year end

The re-analysis of the Feraccru/Accrufer AEGIS-H2H data confirmed Feraccru is a credible alternative to IV iron. This could potentially accelerate US partnering discussions and the resumption of pricing and reimbursement negotiations in key EU markets. Feraccru/Accrufer is making inroads in Europe, with net sales growing ~50% over the previous six months (Germany and UK), further uplift in Europe will be determined by additional launches from late 2021 by partner Norgine. The major focus for STX is establishing a US partner, as the US is a critical market (c 50% of our STX valuation) and management has ordered launch stock ahead of the potential year-end launch, highlighting its confidence there will be a deal in Q420.

## Financials: Cash runway into Q121

Shield reported revenues of £8.9m and a net profit of £3.1m in H120 (H119: net loss £4.2m), benefiting from the $11.4m upfront payment from ASK Pharm. The H120 cash position of £6.5m implies a runway into Q121. A US partnering deal and associated upfront licensing payment would extend the cash reach and enable STX to start the formulation development work on PT20 (phosphate binder). We forecast that sustainable profitability is achievable from 2022 (assuming US launch 2020), with gross margins nearing c 50–60% in the long term. Partnering strategies enhance economic returns and de-risk the investment case.

## Valuation: £379.1m or 324p/share

Our revised valuation is £379.1m or 324p/share, versus £381.7m or 326p/share. We have revised our FY20 forecasts downwards by removing any US sales contribution from Accrufer. We have increased our G&A and reduced our R&D assumptions for FY20. We roll forward our model, update for FX and include end-2020 net cash forecast of £5.5m. Our NPV calculation is based on Feraccru achieving peak sales of €130m in Europe, $410m in the US and $126m in China.

**18 September 2020**

| | |
|---|---|
| **Price** | **139.5p** |
| **Market cap** | **£163m** |
| | £0.77/US$; £0.91/€ |
| Unaudited net cash (£m) at 30 June 2020 | 6.5 |
| Shares in issue | 117.2m |
| Free float | 32% |
| Code | STX |
| Primary exchange | AIM |
| Secondary exchange | N/A |

### Share price performance


| % | 1m | 3m | 12m |
|---|---|---|---|
| Abs | 12.1 | 55.0 | (24.8) |
| Rel (local) | 13.2 | 58.9 | (10.4) |
| 52-week high/low | 193p | | 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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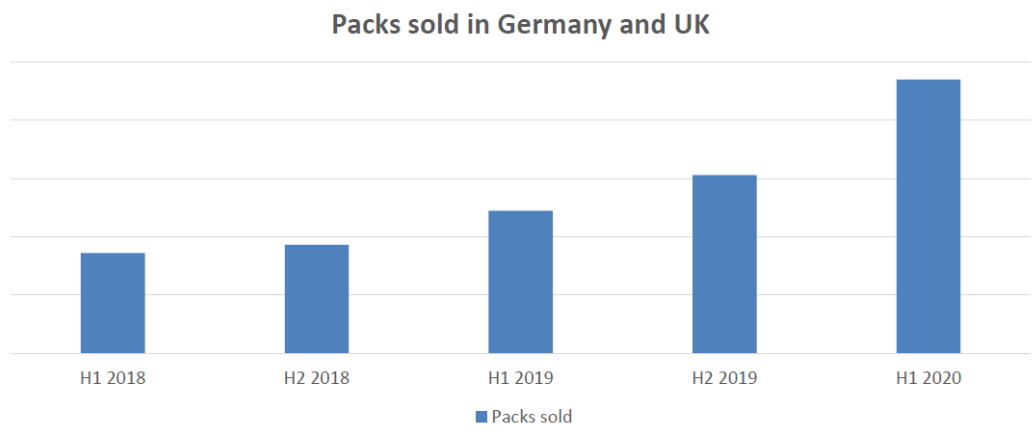
## US 2020 market in focus

The expected announcement in Q4 of a US partnering deal for Feraccru/Accrufer should be a major inflection point for STX. Management is confident that ongoing discussions will bear fruition and launch of the product around year end is a possibility (launch stocks of US packaging Accrufer have been ordered ahead of potential US launch). A partnering deal will aim to optimise financial deal terms and additionally maximise the products potential across a broad range of therapy areas, beyond inflammatory bowel disease (IBD) and chronic kidney disease (CKD) associated anaemia to encompass iron deficiency of any cause as per its US prescribing information. STX is engaged with multiple companies, has several non-binding offers and is now in advanced discussions. Partnering discussions have likely been aided by the recent findings from the re-analysis of the AEGIS-H2H data on Feraccru/Accrufer confirming the product is a competitive oral alternative to IV iron in the longer term.

Feraccru/Accrufer (oral ferric maltol) is making inroads in Europe, with net sales growing ~50% (Germany and UK). Exhibit 1 highlights the slow but steady growth since Norgine launched the products back into the market in H119. Further uplift in Europe will be determined by launches from late 2021 in additional countries, subject to pricing and reimbursement negotiations that had been put on hold while the re-analysis of the AEGIS-H2H data was being carried out. STX note that negotiations will resume as soon as the H2H clinical study report is available (expected October 2020).

**Exhibit 1: Europe commercialisation net packs sold by Norgine**

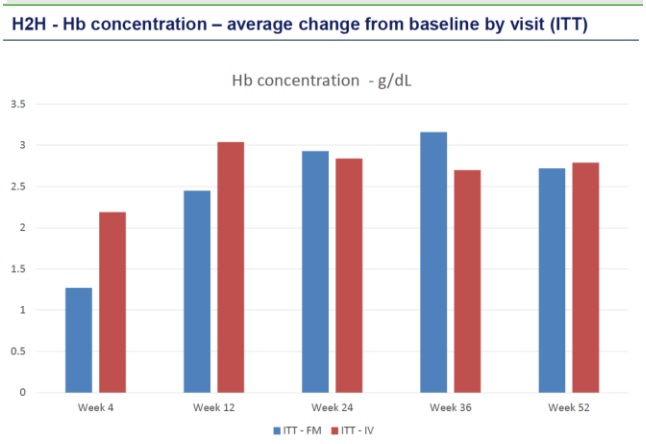



Source: STX corporate presentation

### AEGIS-H2H non-inferiority versus IV iron at 52 weeks confirmed

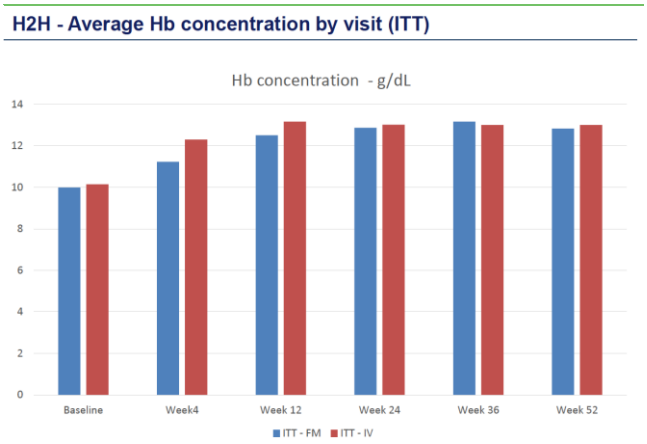
In August STX announced an update that the re-analysis demonstrates that Feraccru/Accrufer is a 'credible alternative' to IV iron therapy for IDA in the long term (Exhibit 2 and 3). We note the product did not meet the primary endpoint of non-inferiority at 12 weeks versus IV iron, although the average increase in Hb levels in Feraccru patients was ~2.5g/dL in the intent to treat population, which is clinically significant (vs ~3g/dL for IV). However, we note that 82% of IV patients required more than one infusion due to iron depletion in this phase and 138 days were taken off work collectively. Importantly, Feraccru did correct anaemia and maintain Hb levels over the long-term phase of the trial (as defined by the 40-week extension phase). We believe this will have positive implications for health economic outcomes, as Feraccru has no administration-related costs or resource use (unlike IV iron, which also has a higher drug cost), reducing the burden on healthcare providers and potentially reducing overall hospitalisation costs.

**Exhibit 2: Average change in patient Hb concentration from baseline**




Source: STX corporate presentation

**Exhibit 3: Average patient Hb concentration by visit**




Source: STX corporate presentation

While we note AEGIS-H2H was not required as a registration study (thus the regulatory status of the product is unaffected), the headline results of long-term Hb correction are comparable to IV iron for chronic conditions of anaemia. We believe this will have positive implications for health economic outcomes, pricing strategies, reimbursement negotiations and partnering activities.

## China deal adds to overall value proposition

In January 2020, an out-licensing deal with China-based Jiangsu Aosaikang Pharmaceutical (ASK Pharm) was announced that covers China, Hong Kong, Macau and Taiwan, which led to an $11.4m upfront payment to STX. Following discussions with the China regulatory authority (CDE), Feraccru/Accrufer could launch in China within three years (subject to assumption of NDA submission H122). The regulator has indicated a Phase III study in IBD will be required (but a pharmacokinetic study, or a Phase III in CKD may not be needed). The IBD study in China patients could start in 2021, once CDE confirm the exact submission requirements. 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; we forecast China launch in 2023. Under the deal terms with ASK Pharm, STX received $11.4m as an upfront payment and is eligible for a further $11.4m on approval in China. 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 sales-related milestones. ASK Pharm 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.

## Clinical work continues in 2020/21

STX has developed a liquid formulation of Feraccru/Accrufer, is necessary to start a paediatric study (a requirement for both Europe and US regulatory bodies). The first phase (a crossover study to confirm the liquid formulation is equivalent to capsules, n=32 healthy adult volunteers) is expected to complete by end 2020. This implies the main paediatric study could start in H121. STX could start developing a new formulation of its iron-based phosphate binder PT20 in H220 (subject to funding which is dependent on a US Feraccru/Accrufer deal), with a view to start the additional pivotal Phase III trial required for regulatory submission in 2022 (PT20 has already completed a pivotal clinical trial).

## Exhibit 4: Financial summary

| December | £000s | 2017 | 2018 | 2019A | 2020E | 2021E |
|---|---|---|---|---|---|---|
| Revenue | | 637 | 11,881 | 719 | 10,496 | 8,905 |
| Cost of sales | | (155) | (311) | (485) | (1,063) | (4,175) |
| Gross profit | | 482 | 11,570 | 234 | 9,434 | 4,730 |
| Gross margin % | | 76% | 97% | 33% | 90% | 53% |
| SG&A (expenses) | | (16,722) | (12,429) | (6,773) | (7,750) | (6,098) |
| R&D costs | | (4,711) | (4,300) | (2,496) | (2,500) | (3,000) |
| Other income/(expense) | | 0 | 0 | 0 | 0 | 0 |
| EBITDA | | (18,514) | (2,469) | (6,414) | 1,434 | (2,270) |
| Depreciation and amortisation | | (2,437) | (2,690) | (2,621) | (2,250) | (2,098) |
| Reported Operating Income | | (20,951) | (5,159) | (9,035) | (816) | (4,369) |
| Exceptionals and adjustments | | (2,571) | 0 | 0 | 0 | 0 |
| Adjusted Operating Income | | (18,380) | (5,159) | (9,035) | (816) | (4,369) |
| Finance income/(expense) | | (43) | 8 | (31) | 0 | 0 |
| Reported PBT | | (20,994) | (5,151) | (9,066) | (816) | (4,369) |
| Profit Before Tax (norm) | | (18,423) | (5,151) | (9,066) | (816) | (4,369) |
| Income tax expense | | 1,406 | 3,359 | 266 | 1,200 | 600 |
| Reported net income | | (19,588) | (1,792) | (8,800) | 384 | (3,769) |
| 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) | | -17.4 | -2.0 | -7.5 | 0.3 | -3.2 |
| EPS - normalised (p) | | -15.2 | -1.5 | -7.5 | 0.3 | -3.2 |
| Dividend per share (p) | | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | | | | | | |
| 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 | 5,546 | 513 |
| Inventories | | 125 | 109 | 948 | 1,168 | 2,294 |
| Trade and other receivables | | 1,572 | 1,031 | 356 | 3,906 | 13,172 |
| Other current assets | | 0 | 1,500 | 950 | 950 | 950 |
| Total current assets | | 14,996 | 12,416 | 6,395 | 11,570 | 16,929 |
| 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 | 5,838 | 12,617 |
| 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 | 6,445 | 13,224 |
| Equity attributable to company | | 41,207 | 40,430 | 32,145 | 33,029 | 29,760 |
| | | | | | | |
| Cashflow statement | | | | | | |
| Reported net income | | (19,588) | (1,792) | (8,800) | 384 | (3,769) |
| 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 | (1,479) | (3,613) |
| 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) | 1,655 | (4,783) |
| 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 | 5,546 |
| Increase/(decrease) in cash and equivalents | | (7,679) | (3,523) | (5,635) | 1,405 | (5,033) |
| Cash and equivalents at end of period | | 13,299 | 9,776 | 4,141 | 5,546 | 513 |
| Closing net (debt)/cash | | 13,299 | 9,776 | 4,141 | 5,546 | 513 |

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