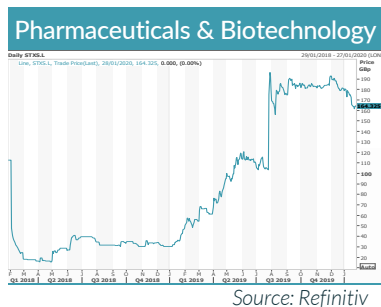




28 January 2020



# SHIELD THERAPEUTICS

## Good demand for Feraccru in Europe

Shield Therapeutics (STX) is a commercial-stage company delivering specialty products that address patients' unmet medical needs, with an initial focus on treating iron deficiency (ID) with ferric maltol. Recent news that the FDA had approved this drug for a broad indication opened up a market in the US currently worth over \$1bn p.a. – a US partnership deal is expected in 2020. A 2019 trading update showed STX's performance to be in line with expectations, with £0.6m in sales-related revenue from Norgine's sales of Feraccru in Europe and £2.3m in milestones. STX's cash runway extends into 2021, in the absence of a US deal.

### Market data

EPIC/TKR	STX
Price (p)	163.0
12m High (p)	202.0
12m Low (p)	41.0
Shares (m)	117.2
Mkt Cap (£m)	191.0
EV (£m)	187.1
Free Float*	33%
Market	AIM

\*As defined by AIM Rule 26

### Description

STX is a commercial-stage pharmaceutical company delivering innovative specialty pharmaceuticals that address patients' unmet medical needs, with an initial focus on anaemia associated with renal and gastrointestinal disorders.

### Company information

CEO	Carl Sterritt
CFO (Interim)	Tim Watts
Chairman	James Karis

+44 207 186 8500

[www.shieldtherapeutics.com](http://www.shieldtherapeutics.com)

### Key shareholders

Directors	9.0%
W. Health	47.8%
MaRu AG	10.7%
R. Griffiths	5.0%
C. Schweiger	4.8%
USS	4.4%

### Diary

1H'20	US Accrufer deal
1Q'20	Paediatric study to start
Apr'20	FY'19 results
Mid-2020	Accrufer launch

### Analysts

Martin Hall	020 7194 7632	<a href="mailto:mh@hardmanandco.com">mh@hardmanandco.com</a>
Dorothea Hill	020 7194 7626	<a href="mailto:dmh@hardmanandco.com">dmh@hardmanandco.com</a>
Grégoire Pavé	020 7194 7628	<a href="mailto:gp@hardmanandco.com">gp@hardmanandco.com</a>

► **Strategy:** STX's strategy is to out-license the commercial rights to its products to partners with marketing and distribution expertise in target markets. These deals allow STX to retain its intellectual property (IP) and to keep investing in its R&D pipeline, while benefiting from immediate and long-term value.

► **Trading update:** Partner sales of Feraccru in European markets were in line with expectations, giving gross revenues of £2.9m. 2H'19 sales volumes were 28% higher than in 1H. The gross cash position, at £4.1m, was lower than forecast, due to a combination of working capital, lower tax rebates and capitalised R&D.

► **China deal:** The novel iron replacement therapy, Feraccru/Accrufer, has been exclusively licensed to ASK Pharm for development and commercialisation in China. This paves the way to a large and growing market for iron replacement products and strengthens STX's hand in ongoing negotiations with potential US partners.

► **Risks:** All drug companies carry development risk. However, the clinical risk with STX is limited because of Feraccru/Accrufer's clinical profile and existing marketing approvals. The main risk is achieving an appropriate partnering deal in the US and executing on commercialisation strategy to capture market share.

► **Investment summary:** The FDA approval and pending launch of Accrufer reinforce our view that STX is at an exciting juncture. It has delivered on all the goals set at the time of its IPO in 2016. Feraccru/Accrufer has been validated by EU and US regulatory approvals, and the commercial deal in Europe looks set to be repeated in the US. Announcement of its commercial partner, together with the terms of any deal, represents the next valuation inflection point.

### Financial summary and valuation

Year-end Dec (£m)	2017	2018	2019E	2020E	2021E
<b>Gross revenues</b>	<b>0.64</b>	<b>11.88</b>	<b>2.93</b>	<b>11.07</b>	<b>3.14</b>
Sales	0.64	0.86	0.63	2.15	3.14
R&D	-4.71	-4.30	-3.31	-4.64	-3.89
Other income	0.00	11.03	2.30	8.92	0.00
EBITDA	-18.48	-2.47	-5.45	-0.28	-8.68
Underlying EBIT	-18.90	-3.26	-6.25	-1.07	-9.47
Reported EBIT	-20.95	-5.17	-8.15	-2.97	-11.38
Underlying PBT	-18.91	-3.26	-6.24	-1.10	-9.52
Statutory PBT	-20.99	-5.16	-8.14	-3.00	-11.42
Underlying EPS (p)	-15.58	0.09	-4.49	-0.34	-7.62
Statutory EPS (p)	-17.43	-1.55	-6.12	-1.97	-9.25
Net (debt)/cash	13.30	9.63	3.96	5.35	-1.92

Source: Hardman & Co Life Sciences Research

## FY'19 trading update

Good FY'19 performance...

STX has issued a trading statement to update the market on its positive operating performance during 2019. The company focused on three aspects – double-digit growth in Feraccru sales volumes delivered by Norgine, positive non-inferiority study data, and FDA approval with a broad label in the US.

### Operating performance

...supporting a transitional year in 2020...

- ▶ **European sales:** Feraccru is currently reimbursed in the UK and Germany, where sales volumes (Feraccru packs) grew 67% in 2019. The final two months of the year benefited from the use of AEGIS-H2H data in Norgine's promotional activities, but, over the year, sales were limited to these two countries, while pricing and reimbursement submissions continue in other territories.
- ▶ **AEGIS-H2H study:** Detailed results were presented in October and showed that Feraccru/Accrufer was non-inferior to Ferinject (intravenous iron) in terms of response rate, providing an alternative option for treatment of iron deficiency anaemia (IDA). The key findings are explained in *More choice for clinicians and patients*.<sup>1</sup>
- ▶ **FDA approval:** A significant milestone was reached in July, with FDA approval of Feraccru/Accrufer for general ID – this broad label is excellent validation of the product's clinical profile, and paves the way to a transitional 2020.
- ▶ **China deal – post-period:** A licence agreement was signed with Beijing Aosaikang Pharmaceutical Co. Ltd for manufacture, development and commercialisation of Accrufer/Ferinject in China and related territories.

...with a US deal expected in 1H'20

2020 will be the transitional year for STX, as it delivers on its commercialisation strategy. Most of the news flow will be regarding a partnership(s) deal for commercialisation of Accrufer in the US, and on Norgine's progress with pricing and reimbursement applications for Feraccru in additional European countries.

### Financial performance

- ▶ **Sales:** STX reported that Norgine had seen a solid increase (67%) in sales volumes in 2019, including 28% half-on-half growth, resulting in sales-related income of £0.6m for STX. On an underlying basis, the "apparent" 19% decrease in sales from £0.86m in 2018 simply reflects the transition from direct selling by STX to sales-related revenues from Norgine in 4Q'18.
- ▶ **Other income:** Milestone payments of £2.3m were also received from Norgine and EWO pharma in 2019, taking gross revenues for the period to £2.9m, as forecast.
- ▶ **Gross cash:** The gross cash balance at 31 December 2019 was £4.1m, £2.2m below forecasts – until the full set of numbers is released, the assumption is that this was due to a combination of working capital, tax rebates and capitalised R&D.

Actual vs. forecasts – summary					
Full-year results (£m)	FY'19 actual	FY'20 actual	Change	FY'20 forecast	Difference Δ
Gross income	11.9	2.9	-75%	2.9	0.0
Gross cash	9.8	4.1	-58%	6.3	-2.2

Source: Hardman & Co Life Sciences Research

<sup>1</sup> <https://www.hardmanandco.com/research/corporate-research/more-choice-for-clinicians-and-patients/>

## Financial summary

- ▶ **Sales forecasts:** Given our conservative approach to the timing of the US launch of Accrufer, there is scope to increase forecasts when the distribution partner is announced, together with the terms of any deal.
- ▶ **Gross cash:** Cashflow forecasts have been updated on reported FY'19 gross cash of £4.1m and for full receipt of the \$11.4m/£8.9m upfront from the China deal.
- ▶ **Cashflow:** For 2019, there is a slight working capital requirement, a smaller-than-anticipated R&D tax rebate, and R&D capitalisation similar to 2018.
- ▶ **Cash runway:** These changes had a minor knock-on effect on future forecasts, but STX remains cash-positive until 2021 in the absence of licensing income.

Financial summary					
Year-end Dec (£m)	2017	2018	2019E	2020E	2021E
GBP:EUR	1.14	1.14	1.14	1.14	1.14
GBP:USD	1.29	1.31	1.28	1.28	1.28
<b>Profit &amp; Loss</b>					
Gross revenues	0.64	11.88	2.93	11.07	3.14
Product sales	0.64	0.86	0.63	2.15	3.14
COGS	-0.16	-0.31	-0.40	-1.29	-1.82
Gross profit	0.48	0.55	0.23	0.86	1.32
Gross margin	75.7%	63.7%	84.0%	85.0%	85.5%
SG&A (underlying)	-14.12	-9.52	-4.45	-5.20	-5.89
Share-based payments	-0.56	-1.01	-1.01	-1.01	-1.01
R&D	-4.71	-4.30	-3.31	-4.64	-3.89
Other income	0.00	11.03	2.30	8.92	0.00
EBITDA	-18.48	-2.47	-5.45	-0.28	-8.68
Underlying EBIT	-18.90	-3.26	-6.25	-1.07	-9.47
Net interest	0.00	0.01	0.01	-0.03	-0.04
<b>Underlying PBT</b>	<b>-18.91</b>	<b>-3.26</b>	<b>-6.24</b>	<b>-1.10</b>	<b>-9.52</b>
Tax payable/credit	1.41	3.36	0.99	0.70	0.58
Underlying net income	-17.50	0.10	-5.24	-0.40	-8.93
Weighted avg. shares (m)	112.36	116.43	116.81	117.19	117.19
<b>Underlying EPS (p)</b>	<b>-15.58</b>	<b>0.09</b>	<b>-4.49</b>	<b>-0.34</b>	<b>-7.62</b>
Fully diluted EPS (p)	-15.58	0.09	-4.48	-0.34	-7.60
<b>Balance sheet (@ 31 Dec)</b>					
Share capital	1.75	1.75	1.76	1.76	1.76
Reserves	39.46	38.68	31.55	29.24	18.40
Provisions	0.26	0.00	0.00	0.00	0.00
Debt	0.00	0.00	0.00	0.00	0.00
less: Cash	13.30	9.78	4.11	5.49	-1.77
<b>Invested capital</b>	<b>28.31</b>	<b>30.80</b>	<b>29.34</b>	<b>25.65</b>	<b>22.08</b>
Net cash/debt	13.30	9.63	3.96	5.35	-1.92
<b>Cashflow</b>					
Underlying EBIT	-18.90	-3.26	-6.25	-1.07	-9.47
Non-cash items	0.43	1.80	1.80	1.80	1.80
Change in working capital	-0.29	-0.40	-0.67	-0.27	-0.21
Tax & interest	1.99	1.86	1.51	0.96	0.65
<b>Operational cashflow</b>	<b>-17.99</b>	<b>-1.85</b>	<b>-4.97</b>	<b>0.61</b>	<b>-7.74</b>
Capital expenditure	0.00	0.00	0.00	0.00	0.00
Free cashflow	-19.33	-3.32	-5.69	1.39	-7.27
Acquisitions	-0.24	-0.35	0.00	0.00	0.00
Equity issues	11.88	0.00	0.02	0.00	0.00
<b>Change in net debt</b>	<b>-7.68</b>	<b>-3.67</b>	<b>-5.67</b>	<b>1.39</b>	<b>-7.27</b>
OCFPS (p)	-14.38	-0.28	-3.13	1.18	-6.20

Source: Hardman & Co Life Sciences Research

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[research@hardmanandco.com](mailto:research@hardmanandco.com)

35 New Broad Street  
London  
EC2M 1NH

+44(0)20 7194 7622

[www.hardmanandco.com](http://www.hardmanandco.com)