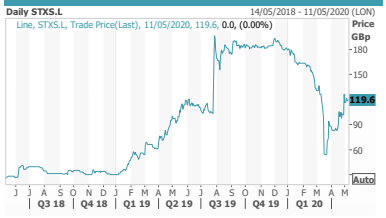
Pharmaceuticals & Biotechnology



Source: Refinitiv

Market data	
EPIC/TKR	**STX**
Price (p)	**118.0**
12m High (p)	197.0
12m Low (p)	55.5
Shares (m)	117.2
Mkt Cap (£m)	138.3
EV (£m)	127.0
Free Float*	33%
Market	AIM

**As defined by AIM Rule 26*

Description

STX is a de-risked pharmaceutical company with a lead product, Feraccru/Accrufer, approved in Europe and the US for the treatment of iron deficiency in adults.

Company information	
CEO	Tim Watts
CFO	-
Chairman	James Karis
	+44 207 186 8500
	www.shieldtherapeutics.com

Key shareholders	
Directors	0.2%
W. Health	47.8%
MaRu AG	10.7%
C.Sterritt	8.8%
Universities SS	4.3%
Jupiter AM	3.7%

Diary	
May'20	2019 results
Jun'20	AGM
23 June	Patent case
Mid-2020	US licensing deal

Analyst	
Martin Hall	020 7194 7622
	mh@hardmanandco.com

SHIELD THERAPEUTICS

Reassuring trading update

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. Feraccru/Accrufer has achieved regulatory approvals for both Europe and the US. The company has faced some unexpected challenges recently, but has not been overly affected by COVID-19. Having negotiated a good deal for the Chinese market, STX is seeing significant interest with respect to a US commercial partner, bringing the opportunity to launch into a >$1bn market. The cash runway for STX extends into 1Q'21.

- **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:** To date, STX has not been affected materially by COVID-19. Its suppliers are all continuing to manufacture, and distribution of drugs is unaffected. Partner, Norgine, has seen sales growth in 1Q'20 and Feraccru represents an alternative for patients who cannot get to hospital for IV iron.

- **US licensing deal:** Although stepping down, the founder and former CEO has agreed to support the licensing process in the US so that the current positive momentum is not lost. We understand that there is a strong shortlist of potential partners.

- **Risks:** All drug companies carry development risk, but STX's has been limited by regulatory approvals in the EU and the US. There is some risk in Europe from a Teva patent challenge due to be heard in June. The main risk is achieving an appropriate US partnering deal and executing on commercialisation strategy.

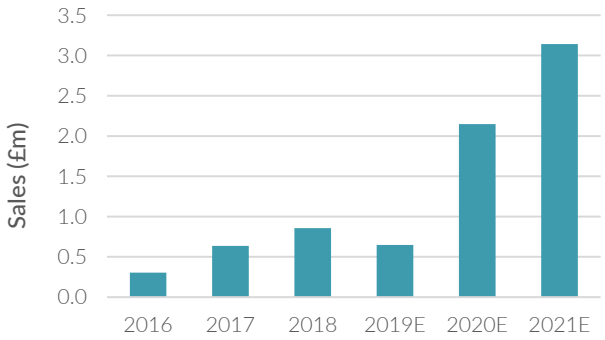
- **Investment summary:** The shares have started to recover from some unexpected news from the company. A good trading update, a period of stabilisation, and any announcement of a US licensing deal are likely to accelerate this recovery. Feraccru provides a good option to physicians seeking alternative therapies for iron-deficient patients reluctant to attend hospitals/ clinics for intravenous (IV) iron therapy due to the risk of contracting COVID-19.

Financial summary and valuation

Year-end Dec (£m)	2017	2018	2019E	2020E	2021E
Gross revenues	**0.64**	**11.88**	**0.65**	**8.80**	**3.14**
Sales	0.64	0.86	0.65	2.15	3.14
R&D	-4.71	-4.30	-3.31	-2.98	-3.50
Other income	0.00	11.03	0.00	6.65	0.00
EBITDA	-18.48	-2.47	-7.75	-0.89	-8.29
Underlying EBIT	-18.90	-3.26	-8.54	-1.68	-9.08
Reported EBIT	-20.95	-5.17	-10.44	-3.59	-10.99
Underlying PBT	-18.91	-3.26	-8.53	-1.73	-9.12
Statutory PBT	-20.99	-5.16	-10.43	-3.63	-11.03
Underlying EPS (p)	-15.58	0.09	-6.45	-1.09	-7.34
Statutory EPS (p)	-17.43	-1.55	-8.08	-2.72	-8.96
Net (debt)/cash	13.30	9.63	1.65	2.41	-4.71

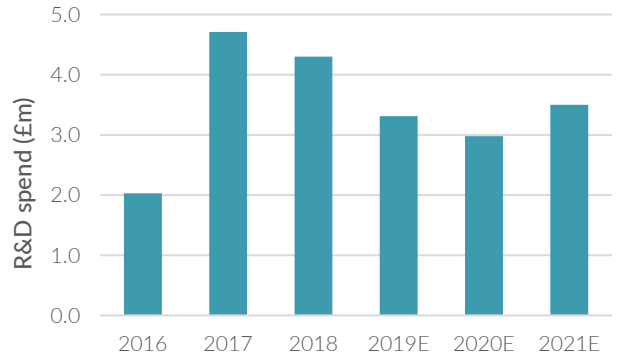
Source: Hardman & Co Life Sciences Research

Product sales



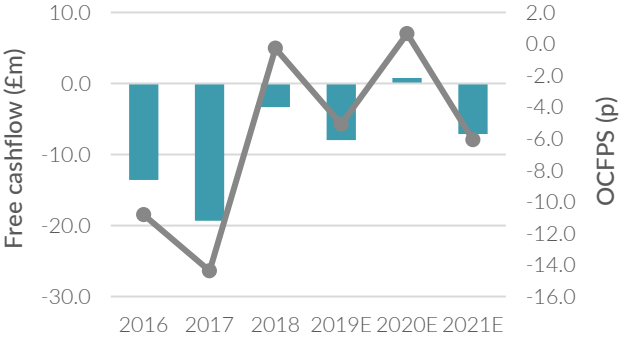
- From 2019, sales simply reflect the royalties derived from Feraccru/Accrufer.
- The drop in 2019 sales reflects the transition from direct selling by STX to royalties from Norgine in 4Q'18.
- Accelerated growth expected in 2020 is due to launches planned in additional European countries and the US.
- Out of the royalty stream, STX has to bear the manufacturing costs of Feraccru for supply to Norgine.

R&D investment



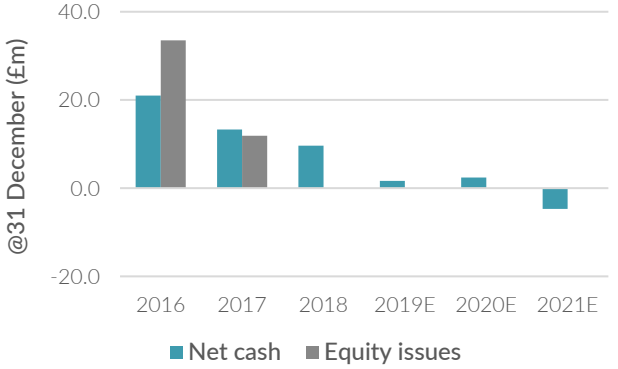
- Delays to the initiation of the paediatric Phase III study has altered the phasing of R&D spend between 2020 and 2021.
- Spend in 2017 and 2018 reflected investment in the AEGIS-CKD and AEGIS-H2H studies.
- Future R&D investment timing is flexible on available resources, but it could include progression of the phosphate assets or development towards a once-a-day dose of Feraccru.

Free cashflow and OFCFPS



- On current forecasts, STX has a cash runway into 2021; a US commercialisation deal is expected within the next two months, which could significantly alter this situation.
- STX is forecast to achieve stable positive cashflows once substantial royalties are received from Feraccru/Accrufer sales across both Europe and the US.

Net cash/(debt) and equity issues



- At IPO in 2016, STX raised £32.5m gross (£30.1m net), which was boosted in 2017 by a Placing of new Ordinary shares to raise £12.5m gross (£11.9m net).
- Commercial deals with Norgine and ASK Pharm have greatly boosted STX's cash position in the past two years.
- In the unlikely absence of any upfront payment with the US licensing deal, STX would require an injection of new capital.

Source: Company data; Hardman & Co Life Sciences Research

2020 trading update

2020 was always expected to be a busy year for STX and this was without the additional challenges caused by COVID-19. To date, the company has made five important announcements and, while some of these had been expected, others were not. The aim of this document is to update the market on these announcements and to highlight what can be expected in the next six months.

STX announcements in 2020	
Announcement	**Event**
8 January	Licensing agreement for Feraccru/Accrufer in China
27 January	Trading update regarding fiscal 2019 results
17 March	Re-assessment of AEGIS-H2H study results
22 April	Board changes
01 May	Business and trading update

Source: Hardman & Co Life Sciences Research

China licensing deal

The market should give more credit to the deal with ASK Pharm for China

The year started well with the early announcement that the company had identified and signed a late-stage development and commercialisation deal with Beijing Aosaikang Pharmaceutical Co (ASK Pharm) in China, the world's second-largest pharmaceuticals market. This licensing deal will provide local expertise, support regulatory approval, and deliver long-term licensing income. In addition, conclusion of the deal triggered the payment of an upfront payment of $11.4m/£8.7m, less any local tax, extending STX's cash runway. Full details of this deal can be found in our report, *Taking on China*, published on 14 January[1].

Fiscal 2019 performance

2019 results due at end of this month

This was followed shortly afterwards by a positive trading statement with respect to operating performance in 2019, particularly the double-digit growth in Feraccru sales volumes delivered by STX's European commercial partner, Norgine[2]. Given subsequent events at the company and the disruption caused by COVID-19, which caused the Financial Conduct Authority (FCA) to ask firms to delay publishing their preliminary financial results to allow time for accurate reporting in light of the coronavirus outbreak. STX is now expected to release its preliminary results in LATE-May 2020.

Re-assessment of AEGIS-H2H results

The unexpected head-to-head announcement was a disappointment…

The market was surprised when the company announced, in March, that it needed to clarify the results published in 2019 from its head-to-head study of Feraccru against intravenous (IV) Ferinject. This study was designed primarily to generate data that could be used in health economic analyses, pricing and reimbursement applications as well as for marketing purposes.

…with the outcome of the board review eagerly awaited

Whereas the company had originally thought that the study had reached its primary end-point, which required achievement of non-inferiority at 12 weeks in both the "intention to treat" (ITT) and "per protocol" (PP) populations, on re-examination of the data by Norgine during reimbursement discussions, it came to light that non-inferiority was not demonstrated in the ITT population and hence the overall study failed to meet its primary end-point. The board has commissioned a review into the analysis of the results and will further update the market once this review has been completed.

[1] www.hardmanandco.com/research/corporate-research/taking-on-china/
[2] www.hardmanandco.com/research/corporate-research/good-demand-for-feraccru-in-europe/

STX is continuing to discuss with Norgine regarding the best approach for using the positive long-term data from the AEGIS-H2H study; for example, for health economics purposes including pricing and reimbursement negotiations.

STX has had to repay the milestone

Under the terms of the agreement with Norgine, a €2.5m milestone was paid to STX for hitting the primary end-point in the study, which will now be returned. Our forecasts for 2019 (P&L) and 2020 (cashflow) have been adjusted accordingly to reflect this repayment.

Board changes

Departure of the founder and former CEO was a surprise…

Although not directly related, this news was followed shortly thereafter by the surprise announcement that Carl Sterritt, founder and CEO, had decided to step down following discussions with major shareholders. Experienced interim CFO, Tim Watts, has stepped up to become CEO and was appointed to the board on 27 April.

…but he will continue to support the conclusion of a US deal

Although Carl will no longer be involved in the running of the company, he has been instrumental in the ongoing discussions with potential commercial partners for Accrufer in the US and will continue to assist Tim Watts through to the conclusion of a deal so that the current positive momentum with this project is not lost.

Consequences of COVID-19

STX operates largely as a virtual company, outsourcing most of its activities. Since the onset of lockdown, its small number of HQ and administrative staff have been working remotely and have been in regular contact both internally and with external partners via the likes of '*Microsoft Teams*'. Contract manufacturing partners have been able to continue the production of Feraccru without disruption, such that the company has sufficient quantities of drug manufactured, covering several months of projected sales activity, in warehousing and ready for distribution.

COVID-19 might provide an unanticipated opportunity

Given that many patients are less willing to attend hospitals/clinics to reduce the risk of being infected with COVID-19, gastroenterologists will be looking for alternatives to the administration of IV iron for the treatment of patients with inflammatory bowel disease and Crohn's disease, both closely associated with iron deficiency. Feraccru is very well positioned to fulfil that role as it can be taken orally at home.

Upcoming news flow from STX

Announcement	Event
Late May	2019 results and issue of annual report
June	AGM
23 June	Defence of challenge to European Patent
2Q-3Q	US commercial deal for Accrufer
17 March	Interim 2002 results
3Q-4Q	Paediatric clinical study

Source: Hardman & Co Life Sciences Research

Manufacturing of Feraccru/Accrufer

STX is already preparing for the US launch

Ferric maltol, the active pharmaceutical ingredient of Feraccru, is manufactured in the UK, which is then shipped to a French company for contract manufacturing of the finished product. STX has made a purchase order for 12.5 metric tonnes of ferric maltol, which is expected to be sufficient to satisfy demand throughout 2021. The French partner continues to make finished product ready for use in Europe through Norgine and AOP, and has been commissioned to prepare for manufacturing of packs for the US market as soon as the commercial partner is finalised.

Results and AGM

2019 results at end of May…

…and AGM in June

Publication of 2019 results and issue of the annual report are expected in late May, followed by the AGM in June. The company has announced already that gross income for 2019 will be adjusted downwards by the €2.5m milestone repayment to Norgine, from £2.9m (January trading statement) to £0.7m. First quarter sales of Feraccru in Germany and the UK continued to grow, but this only covers the period prior to the global lockdown.

European patent opposition

Opposition to European patent to be heard in June

In 2017, the European Patent Office (EPO) granted the company's application for a patent (EP3160951) covering the crystalline forms of ferric maltol. This was followed, in 2018, by an opposition raised by Teva Pharmaceutical Industries Ltd (Teva). Teva's opposition to this composition of matter patent has been scheduled to be heard on 23 June 2020. STX will vigorously defend itself against this patent opposition.

Key dates for patent application EP3160951

Date	Event
28 Oct 2014	Original publication as GB201419174
23 Oct 2015	Patent filed with EPO
06 Dec 2017	EP3160951 published/issued after examination
5 Sep 2018	Teva raises opposition
10 Sep 2018	Opposition admissible
23 Jun 2020	Date of oral proceedings

Source: European Patent Office

Paediatric development programme

COVID-19 has caused a delay to the start of the paediatric trial…

STX had been planning a significant R&D investment into a paediatric version of Feraccru/Accrufer using a liquid formulation and was scheduled to start recruitment of patients into a Phase III trial during 1Q'20. However, a number of companies have indicated that the attendance of patients at clinics and, therefore, the ability to recruit patients into clinical trials, has become more difficult during the COVID-19 lockdown. This has been reinforced by regulatory guidance on the conduct of clinical studies during the COVID-19 emergency. Consequently, STX will continue with its liquid formulation work, but has decided to delay the start of its paediatric trial until 3Q/4Q 2020. This will result in different phasing of R&D spend between 2020 and 2021, thereby extending the company's cash runway.

Cash runway

…but the cash runway now extends to 1Q'20

In its recent trading statement, STX announced that it had gross cash of £11.3m (and no debt) at 31 March 2020. Based on current forecasts, which now include the delayed paediatric development programme, the cash runway is expected to last into the first quarter of 2021.

However, we believe that the company is in advanced discussions with a number of potential US commercial partners and that the conclusion of a deal is not too far away. It is reasonable to expect that any deal will include an upfront payment to reflect the investment that STX has made to date in de-risking Accrufer for the eventual partner. This would extend the cash runway and be positive for the share price.

Forecast summary

- **Sales:** No change has been made to our product sales forecasts, but return of the €2.5m milestone to Norgine has been eliminated from 2019 gross revenues.
- **COVID-19:** Currently, no changes have been made to forecasts as a consequence of COVID-19.
- **Gross cash:** The gross cash position on 31 March 2020 was £11.3m, which included the upfront payment of $11.4m/£8.9m from ASK Pharm as part of the licensing agreement for China.
- **Cash runway:** Removal of the Norgine milestone repayment had a small effect on future cash forecasts, but STX remains cash-positive into 1Q'21, even in the absence of licensing income from a potential US commercialisation deal.

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
Profit & Loss					
Gross revenues	0.64	11.88	0.65	8.80	3.14
Product sales	0.64	0.86	0.65	2.15	3.14
COGS	-0.16	-0.31	-0.41	-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	-2.98	-3.50
Other income	0.00	11.03	0.00	6.65	0.00
EBITDA	-18.48	-2.47	-7.75	-0.89	-8.29
Underlying EBIT	-18.90	-3.26	-8.54	-1.68	-9.08
Net interest	0.00	0.01	0.01	-0.04	-0.04
Underlying PBT	**-18.91**	**-3.26**	**-8.53**	**-1.73**	**-9.12**
Tax payable/credit	1.41	3.36	0.99	0.45	0.53
Underlying net income	-17.50	0.10	-7.54	-1.28	-8.60
Weighted avg. shares (m)	112.36	116.43	116.81	117.19	117.19
Underlying EPS (p)	**-15.58**	**0.09**	**-6.45**	**-1.09**	**-7.34**
Fully diluted EPS (p)	-15.58	0.09	-6.44	-1.09	-7.31
Balance sheet (@ 31 Dec)					
Share capital	1.75	1.75	1.76	1.76	1.76
Reserves	39.46	38.68	29.23	26.05	15.55
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	1.79	2.56	-4.56
Invested capital	**28.31**	**30.80**	**29.34**	**25.39**	**22.01**
Net cash/debt	13.30	9.63	1.65	2.41	-4.71
Cashflow					
Underlying EBIT	-18.90	-3.26	-8.54	-1.68	-9.08
Non-cash items	0.43	1.80	1.80	1.80	1.80
Change in working capital	-0.29	-0.40	-0.67	-0.26	-0.20
Tax & interest	1.99	1.86	1.51	0.95	0.40
Operational cashflow	**-17.99**	**-1.85**	**-7.27**	**0.00**	**-7.34**
Capital expenditure	0.00	0.00	0.00	0.00	0.00
Free cashflow	-19.33	-3.32	-7.98	0.77	-7.12
Acquisitions	-0.24	-0.35	0.00	0.00	0.00
Equity issues	11.88	0.00	0.00	0.00	0.00
Change in net debt	**-7.68**	**-3.67**	**-7.98**	**0.77**	**-7.12**
OCFPS (p)	-14.38	-0.28	-5.09	0.66	-6.08

Source: Hardman & Co Life Sciences Research

Company matters

Registration

Incorporated in the UK with company registration number 09761509

Registered office:

Northern Design Centre
Baltic Business Quarter
Gateshead Quays
Newcastle
NE8 3DF

+44 (0) 191 511 8500

www.shieldtherapeutics.com

London office:

16 Upper Woburn Place
Euston
London
WC1H 0AF

+44 (0) 20 7186 8500

Board of Directors

Board of Directors

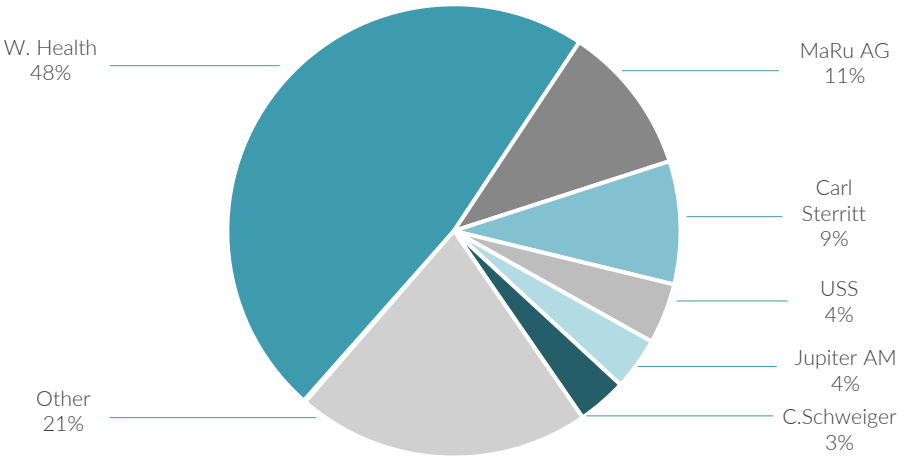
Position	Name	Nominations	Remuneration	Audit
Chairman	James Karis	M	M	
Chief Executive Officer	Tim Watts			
Chief Financial Officer	-			
Non-executive director	Hans Peter Hasler	C		M
Non-executive director	Rolf Hoffmann	M	C	
Non-executive director	Peter Llewellyn-Davies	M		C

M = member; C = chair
Source: Company reports

Share capital

On 8 May 2020, there were 117,188,657 Ordinary shares in issue. In addition, there are 3.94m options outstanding.

Share register



Source: Hardman & Co Life Sciences Research

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The fact that Hardman & Co is commissioned to write the research is disclosed in the disclaimer, and the research is widely available.

The full detail is on page 26 of the full directive, which can be accessed here: http://ec.europa.eu/finance/docs/level-2-measures/mifid-delegated-regulation-2016-2031.pdf

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research@hardmanandco.com

35 New Broad Street
London
EC2M 1NH

+44(0)20 7194 7622

www.hardmanandco.com