HARDMAN&CO.

Pharmaceuticals & Biotechnology

Source: Refinitiv

Market data

EPIC/TKR	**STX**
Price (p)	**133.0**
12m High (p)	202.0
12m Low (p)	54.0
Shares (m)	117.2
Mkt Cap (£m)	155.9
EV (£m)	151.9
Free Float*	33%
Market	AIM

**As defined by AIM Rule 26*

Description

Shield Therapeutics (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

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
2Q'20	Paediatric studies to start
Apr'20	FY'19 results
Mid-2020	Accrufer launch

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SHIELD THERAPEUTICS

2020 – a transitional year

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. STX's strategy is to out-license its products for commercialisation. On 8 January, STX announced a development and commercialisation deal in China with Beijing Aosaikang Pharmaceutical Co (ASK Pharm), further validating this approach. In 2019, the FDA approved this drug for a broad indication, opening up a US market currently worth more than $1bn p.a. A US partnership deal is expected in 2020 and will be transitional for STX.

- **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.

- **Feraccru:** Ferric maltol is a novel oral iron replacement therapy approved in Europe (Feraccru®) and the US (Accrufer®) for treatment of ID. ID results from depletion of iron stores in the liver, and is associated with chronic disorders and poor nutrition. Feraccru is very well tolerated, unlike salt-based oral products.

- **Coming up in 2020:** There are several important value inflection points ahead. Key will be the signing of a US licensing deal, allowing Accrufer to launch in the US. In addition, the initiation of a Phase III study in paediatric patients will progress STX towards expansion of Feraccru's label and target market.

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

- **Investment summary:** The FDA approval and pending launch of Accrufer in the US reinforce our view that STX is at an exciting juncture. Feraccru/Accrufer has been validated by EU and US regulatory approvals, and a good deal with a Chinese partner was finalised at the start of this year. Announcement of a commercialisation partner in the US represents the next valuation inflection point, and is expected in the first half of 2020.

Financial summary and valuation

Year-end Dec (£m)	2017	2018	2019E	2020E	2021E
Gross revenues	**0.64**	**11.88**	**2.92**	**11.07**	**3.14**
Sales	0.64	0.86	0.62	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	-5.46	-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**	**3.94**	**5.32**	**-1.95**

Source: Hardman & Co Life Sciences Research

Commercialisation under way

Introducing Shield Therapeutics…

As a growth-phase pharmaceutical company, STX is a relatively de-risked proposition, both clinically and commercially. Feraccru/Accrufer (Feraccru) is a straightforward iron replacement product with a very large potential market. It has been approved for treatment of adult patients in the US and Europe, and STX has signed good deals with commercialisation partners in Europe and in China. The large potential market is driven by the ubiquity of ID worldwide and, as a supplement for chronic conditions, its repeated use. Feraccru's incorporation into NHS Trust policies, and the recent clinical data showing comparable efficacy with the market-leading intravenous (IV) iron replacement, act as good validation of Feraccru's potential.

…Accrufer/Feraccru approved in the US and Europe…

…and validated by commercial partners

STX has a semi-virtual business model, which allows an asset-light structure (and the associated flexibility and scalability). It is currently in the midst of delivering on its strategy to out-license its products for global commercialisation. For full financial analysis and valuation details, see our research reports at www.hardmanandco.com/research/corporate-research.

Simple product, large market

Oral iron replacements are low-risk…

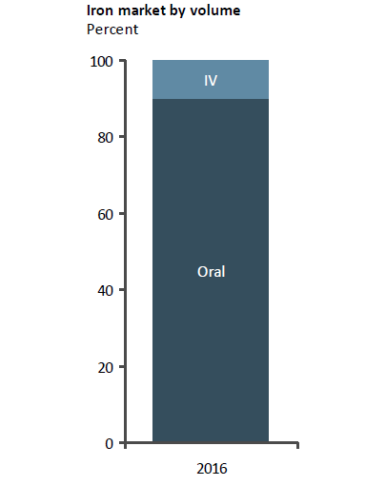
Iron is ubiquitous in the body and best known for its role in the synthesis of haemoglobin (Hb), which transports oxygen in red blood cells. It is stored in the liver and bone marrow, among other sites, and is released and sequestered among compartments in a highly dynamic process. When the body's requirement for iron exceeds its intake from food, iron stores are depleted, which can lead to ID. This ultimately affects the production of haemoglobin, resulting in fatigue and lethargy – the classic symptoms of anaemia. Symptoms of general ID are not specific and may develop slowly, so that they are not readily recognised. Ferric maltol was originally approved for use in adult inflammatory bowel disease (IBD) patients with iron deficiency anaemia (IDA) in Europe, but it is now indicated for all adult patients with ID, with or without anaemia, in both Europe and the US.

…and play a vital role in healthy body functioning

Simple product

Feraccru answers the tolerability issues of existing salt-based oral therapies on the basis of its chemical structure. Although not the focus of this short report, ferric maltol is a complex of Fe^{3+} and maltol molecules that remains soluble in the GI tract, only dissociating into maltol and iron when it is taken up by the cells lining the gut. In contrast, salt-based oral iron supplements require iron to dissociate from the carrier salt for uptake, which can form insoluble products that collect to irritate the gut's lining. Moreover, since Fe^{3+} is a form that is accessible to the body's iron transport mechanism, its uptake is naturally regulated according to the body's needs, with any unabsorbed Feraccru excreted. Feraccru's capsule formulation makes it straightforward to administer, transport and store.

Iron supplement market



Source: Shield Therapeutics

Market potential

ID has a global prevalence of 4%-12% in adults, and IDA affects around half of adult male and postmenopausal female ID patients. The WHO rates ID as the most common and widespread nutritional disorder in the world, and prevalence is expected to grow as aging populations drive an increase in chronic disorders. ID(A) is treated through iron replacement therapy, using either oral products or IV administration. Although restoring iron levels more rapidly, IV iron is inconvenient, expensive and must be administered in hospital due to the risk of life-threatening hypersensitivity reactions. Cheap salt-based oral therapies, on the other hand, are accessible – making up ca.90% of the iron market by volume – but their limitations include poor gut tolerability and slower efficacy due to less efficient absorption.

Harman & Co estimates the US IV iron replacement market at $1.02bn in 2018…

…and growth of 9%

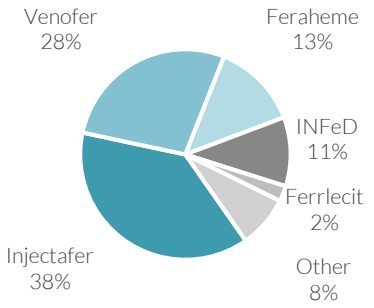
A full assessment of the global commercial opportunity – $3.4bn gross/$1.5bn in 2018 – was provided in our initiation report on STX, published on 13 May 2019[1]. Of this, about two-thirds is derived from the US. Our database of ex-factory sales from the leading players indicates that the US market for IV iron replacement products was valued at $1.02bn in 2018, a figure supported by several corporate documents (AMAG Pharmaceuticals, Daiici-Sankyo, Vifor Pharmaceuticals), and growth of 9%. The benefits of Accrufer leave it well placed to take a substantial share of the US market over time.

De-risked and validated

Safe and effective in clinical studies

Feraccru has been shown to be safe and effective in five completed clinical trials. The most recent was a successful 'non-inferiority' study in which Feraccru was compared head-to-head with the market-leading IV iron replacement, Ferinject (Injectafer ex-US) and was shown to be as clinically effective.

US IV iron replacement market – 2018



Source: Hardman & Co Life Sciences Research

Third-party validation

STX's out-licensing strategy for commercialisation is proving successful, with three commercialisation partners signed in Europe and a recent deal in China. These partnerships provide meaningful third-party validation of the technology and its potential. STX's biggest partner in Europe, agreed September 2018, is the speciality pharmaceuticals company Norgine. Norgine has an exclusive commercial licence to Feraccru in certain Europe territories, Australia and New Zealand, with STX retaining its IP and responsibility for manufacture, supply and development. STX received an £11m upfront on signing, and has the potential to receive a total €54.5m in development and sales milestones, in addition to tiered sales royalties of 25%-40%.

Investment summary

We discuss the impact on valuation of the most recent deal, agreed January 2020, with Beijing Aosaikang Pharmaceutical Co (ASK Pharm) in our note, *Taking on China*[2]. This deal is important for a number of reasons: i) it progresses the out-licensing strategy to the world's second-largest pharmaceuticals market; ii) it provides much-needed cash for 2020 while a US deal is being finalised; iii) it reduces STX's clinical and regulatory risk in China where ferric maltol is not approved; and iv) it removes STX's responsibility to finance development, and control manufacturing and supply in China, where it does not have expertise. Addition of the China deal took our valuation of STX to £399m/341p, and the $11.4m/£8.7m upfront payment from ASK Pharm extends STX's cash runway into 2021.

Summary valuation – unchanged

Shield Therapeutics	£m
Feraccru royalty stream – risk-adjusted	393
PT20 royalty stream – risk-adjusted	0.1
Net cash/(debt) (2020E)	6.4
Market capitalisation	**399.2**
Shares in issue (m)	117.2
Valuation/share (p)	**341**

Source: Hardman & Co Life Sciences Research

The next value inflection point will be when STX announces a US commercial partner(s) along with the terms of the deal.

[1] https://www.hardmanandco.com/wp-content/uploads/2019/05/Shield-Therapeutics-STX-Hardman-Initiation-note-13-May-19.pdf
[2] https://www.hardmanandco.com/research/corporate-research/taking-on-china/

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**	***2.92**	**11.07**	**3.14**
Product sales	0.64	0.86	0.62	2.15	3.14
COGS	-0.16	-0.31	-0.40	-1.29	-1.82
Gross profit	0.48	0.55	0.22	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	-5.46	-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
Underlying PBT	**-18.91**	**-3.26**	**-6.24**	**-1.10**	**-9.52**
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
Underlying EPS (p)	**-15.58**	**0.09**	**-4.49**	**-0.34**	**-7.62**
Fully diluted EPS (p)	-15.58	0.09	-4.48	-0.34	-7.60
Balance sheet (@ 31 Dec)					
Share capital	1.75	1.75	1.76	1.76	1.76
Reserves	39.46	38.68	31.52	29.22	18.38
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	*4.08	5.47	-1.80
Invested capital	28.31	30.80	29.34	25.65	22.08
Net cash/debt	13.30	9.63	3.94	5.32	-1.95
Cashflow					
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
Operational cashflow	**-17.99**	**-1.85**	**-4.97**	**0.61**	**-7.74**
Capital expenditure	0.00	0.00	0.00	0.00	0.00
Free cashflow	-19.33	-3.32	-5.69	1.38	-7.27
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**	**-5.69**	**1.38**	**-7.27**
OCFPS (p)	-14.38	-0.28	-3.13	1.18	-6.20

**Reported in trading update released 27 January 2020*

Source: Hardman & Co Research

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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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