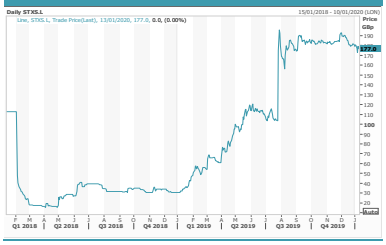
Pharmaceuticals & Biotechnology



Source: Refinitiv

Market data

EPIC/TKR	STX
Price (p)	176.5
12m High (p)	202.0
12m Low (p)	32.0
Shares (m)	117.2
Mkt Cap (£m)	206.8
EV (£m)	197.2
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

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-	Accrufer launch

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SHIELD THERAPEUTICS

Taking on China

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. On 8 January, STX announced a development and commercialisation licence deal in China with Beijing Aosaikang Pharmaceutical Co (ASK Pharm), whose local expertise should support approval and deliver strong licensing income in what is the world's second largest pharmaceuticals market.

- **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.

- **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.

- **Valuation:** Addition of the China deal takes our valuation to £399m/341p. The $11.4m/£8.7m upfront payment extends STX's cash runway into 2021. The next value inflection point will be when STX announces who its US commercial partner(s) is, and the terms of the licensing deal.

- **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.

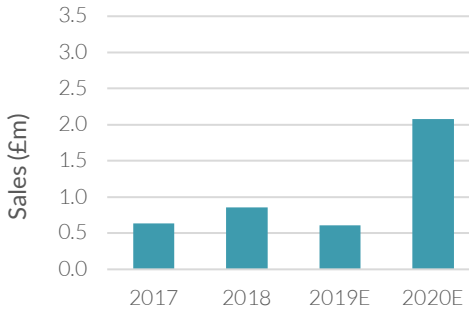
- **Investment summary:** The FDA approval and pending launch of Accrufer reinforces our view that STX is at an exciting juncture. It has delivered on all the goals set at the time of its IPO in 2016. Feraccru/Accrufer has been validated by EU and US regulatory approvals, and the commercial deal in Europe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

Financial summary and valuation

Year-end Dec (£m)	2017	2018	2019E	2020E	2021E
Gross revenues	**0.64**	**11.88**	**2.91**	**9.81**	**3.05**
Sales	0.64	0.86	0.61	2.08	3.05
R&D	-4.71	-4.30	-3.31	-4.64	-3.89
Other income	0.00	11.03	2.30	7.73	0.00
EBITDA	-18.48	-2.47	-5.46	-1.49	-8.72
Underlying EBIT	-18.90	-3.26	-6.25	-2.28	-9.51
Reported EBIT	-20.95	-5.17	-8.16	-4.19	-11.42
Underlying PBT	-18.91	-3.26	-6.24	-2.31	-9.56
Statutory PBT	-20.99	-5.16	-8.15	-4.22	-11.46
Underlying EPS (p)	-15.58	0.09	-4.49	-1.38	-7.66
Statutory EPS (p)	-17.43	-1.55	-6.12	-3.01	-9.28
Net (debt)/cash	13.30	9.63	6.19	6.43	-0.80

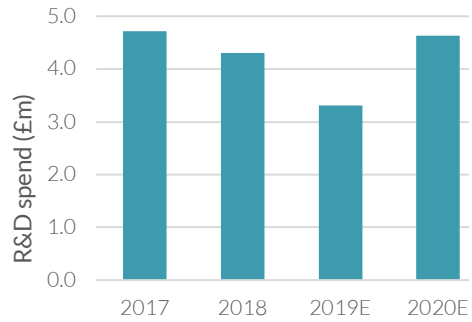
Source: Hardman & Co Life Sciences Research

Sales & gross margin



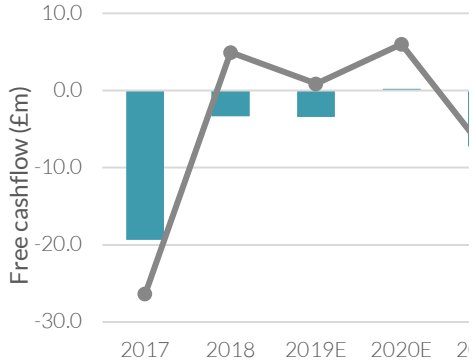
- From 2019E, sales simply reflect the royalties derived from Feraccru/Accrufer
- The drop in 2019E sales reflects the transition from direct selling by STX to royalties from Norgine in 4Q'18
- Accelerated growth expected in 2020 is due to launches in additional European countries and the US
- Out of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

R&D investment



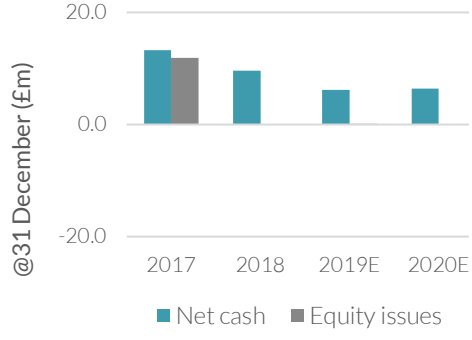
- R&D spend is expected to increase in 2020, with the initiation of the large Feraccru Phase III paediatric study
- Spend in 2017 and 2018 reflected investment in the AEGIS-CKD and AEGIS-H2H studies
- Future R&D investment timing is flexible on available resources, but it could include progression of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

Free cashflow and operating cashflow per share (OCFPS)



- On current forecasts, STX has a cash runway into 2021; a US commercialisation deal is expected within the next six months, which would 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) & capital 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)
- The commercial deal with Norgine greatly enhanced STX's cash position, with the £11.0m upfront payment leaving cash on 31 December 2018 at £9.8m.
- Given the scheduled paediatric study, STX will require more funds in the future, which could come from one, or a combination, of equity, debt or licensing/distribution deals

Source: Company data; Hardman & Co Life Sciences Research

Chinese partnership agreed

Second major deal

Delivering on strategy

Accrufer/Feraccru has been approved for the broad indication of ID in adults in both the US and Europe

STX's success currently depends on successful commercialisation of Feraccru/Accrufer, a safe and effective iron replacement therapy that offers a better tolerated treatment option over existing oral iron products (ferrous salts) and a more convenient and cost-effective option compared with IV iron therapy. The growing IV iron replacement market is currently valued in excess of $1bn in the US alone. Following EU approval of Feraccru in February 2016, STX has made good progress with its clinical strategy, demonstrating in a Phase III trial that oral Feraccru is as effective as IV iron and achieving a broad label FDA approval in 2019.

STX operates a lean business model, partnering with expert organisations for commercialisation (reimbursement, marketing, sales) of Feraccru/Accrufer in key markets. It has been successfully delivering on its commercial strategy since 2016, when it signed its first deal with AOP Orphan Pharmaceuticals ("AOP"), and it commenced licensing activities for China and the US in 2018 and 2019, respectively.

The deal for China, announced 8 January 2020, is excellent validation of this strategy and augurs well for a higher-value US deal later this year. In its own right, the partnership with ASK Pharm, for late-stage development and commercialisation in the very large Chinese market, delivers immediate funds to STX and the promise of future licensing income for, potentially, a greater than 10-year period starting from the first commercial sales.

Feraccru/Accrufer offers an alternative to current iron replacement therapies, which are difficult to tolerate (oral) or inconvenient to use (IV)

STX commercialisation agreement history

Date	Partner	Value	Detail – rights, territories	Duration
2017	AOP	Undisclosed (U/F, M/S, royalties)	Commercial rights out-licensed Central and Eastern Europe, Scandinavia	
Jul-2017	Ewopharma	Undisclosed (U/F, M/S, royalties)	Commercial rights out-licensed Switzerland	
Sep-2018	Norgine	£11m U/F Max €54.5m development & sales M/S Tiered royalties on net sales (25% up to 40%)	Commercial rights out-licensed Europe, Australia, NZ	Until patent expiry in territory
Jan-2020	ASK Pharm	$11m U/F Max $51.4m regulatory & sales M/S Tiered royalties on net sales (10% or 15%)	Development and commercial rights out-licensed China, Hong Kong, Macau, Taiwan ASK Pharm responsible for manufacture	Until patent expiry in territory

U/F Upfront, M/S Milestones
Source: Hardman & Co Life Sciences Research

Deal terms

This deal is important for STX for a number of reasons: i) it progresses management's stated strategy to out-license Feraccru/Accrufer to specialist organisations as part of geographical expansion; 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, and

where there are regulatory mechanisms in place in favour of drugs manufactured within China (e.g. exclusivity periods). STX will retain final say on in-country development strategy to ensure activities are compatible with those in other territories.

Overall, this deal with ASK Pharm follows the usual industry format for licensing agreements:

- **An up-front payment:** $11.4m/£8.7m; with tax in China, we assume $10.2m/£7.7m will be recognised through the P&L account in fiscal 2020.
- **Regulatory milestone:** $11.4m/£8.7m upon approval of Feraccru/Accrufer in China.
- **Sales milestones:** Up to $40.0m/£30.5m payable upon specified cumulative sales targets (undisclosed).
- **Royalties:** 10% or 15% of net sales for the duration of the IP in China, tiered based on specified sales.

ASK Pharm will be responsible for the costs of further clinical and regulatory activities, in addition to manufacturing and distribution in the territory. This is in contrast to the Norgine arrangement, whereby STX retains responsibility for the cost of manufacture and supply. As with the Norgine transaction, this deal specifies a timeframe for the receipt of royalties – either for 10 years from first commercial sales or for the duration of IP, whichever is longer.

Beijing Aosaikang Pharmaceutical Co

ASK Pharm (XSEC:002755, market cap: CYN15bn/$2.2bn) is an integrated pharmaceutical enterprise headquartered in Nanjing, Jiangsu Province, China. Its focus is specialist gastrointestinal and oncology pharmaceuticals and it is one of China's leading proton pump inhibitor drug manufacturers. Its sales operation is very large, with turnover in China of over US$560m in 2018 delivered by ca.1,000 reps. ASK Pharm's therapeutic expertise and strong sales capabilities should be more than sufficient to support Feracru/Accrufer to grow and optimally penetrate the Chinese iron replacement market. Moreover, China is a highly complex market for manufacturers – STX has been wise in choosing a solely Chinese enterprise in terms of the speed to launch.

Route to market

Feraccru/Accrufer sits nicely between existing oral therapies and IV administration

There are a few steps that need to be completed before Feraccru/Accrufer can be launched in China. First, a local registration study, for which the format and design needs to be agreed with The National Medical Products Administration (NMPA; formerly CFDA) will need to be conducted. In its simplest form this could be a PK-type study to demonstrate no differences between an Asian and Caucasian population in utilisation of Feraccru/Accrufer, which would mean that the US/EU Phase III data could be used for registration; in its most complicated form, it would be a full Phase III registration study. Clearly these options will come with different timeframes, risks and costs. Once the required study has been completed, a file will be submitted to the NMPA. We presume that ASK Pharm will seek a broad label for Feraccru/Accrufer as a treatment for ID with and without anaemia, as in Europe and the US.

Data on the treatment pathways specific to China for iron deficiency are limited, but assuming that ASK Pharm/STX will position Feraccru/Accrufer similarly to Europe and the US, it is possible that this study will include IV iron as a control (with Ferinject due to launch 2021), to provide data that will likely better support the reimbursement process following approval.

The Import Drug registration (IDL) process is unpredictable, and at least two partnerships involving commercialisation of foreign iron products in China have been terminated due to roadblocks in registration (see table below).

Iron replacement – China deals

Date	Licensor	Licensee	Type	Value	Notes
2008	Amag	3SBio (China)	Licence and supply agreement, Feraheme in IDA with CKD	$10m U/F Tiered royalty up to 25% on net sales	Terminated in 2014 as approval not obtained within agreed period
2013	Vifor	China Medical System (CMS)	Distribution agreement, Maltofer	Undisclosed	Import drug registration (IDL) process – terminated IDL in 1H'18
2016	Rockwell Medical	Wanbang (subsidiary of Fosun Pharma)	Licence agreement, Rockwell responsible for manufacture, Triferic for dialysis dependent CKD	$4m U/F on start clinical trial Up to $35m M/S (regulatory & sales)	Filed for approval in China

U/F Upfront, M/S Milestones
Source: Hardman & Co Life Sciences Research

Timing of China launch is dependent on a local clinical study…

…successful transfer of the manufacturing technology to ASK Pharm…

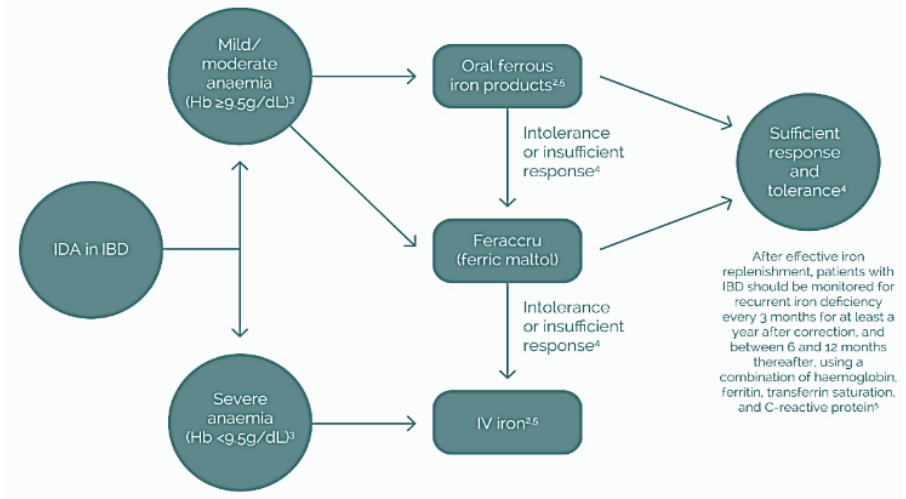
…the unpredictable IDL process…

…and agreements with public and private payers

In terms of market access strategy for primary care and general ID following approval, it will be particularly important to seek inclusion on the National Reimbursement Drug List (NRDL), which provides basic medical coverage to China's population of 1.4 bn, but for which negotiations for new drugs have traditionally been a slow process. Evolution of this system has occurred in recent years, with more frequent updates of the NRDL improving the timelines to reimbursement. In addition, ASK Pharm may seek reimbursement agreements with local governments in individual provinces. ASK Pharm has a local expert and more than 1,000 sales representatives at its disposal, which should make this process more efficient.

In the meantime, contracts will likely be sought with insurers to support private sales prior to a national reimbursement decision. Assuming a registrational trial is needed and initiated by the start of 2021, submission for approval could be achieved by summer 2022, with launch and first sales to take place in 2023.

Feraccru/Accrufer treatment pathway for ID



Source: Shield Therapeutics

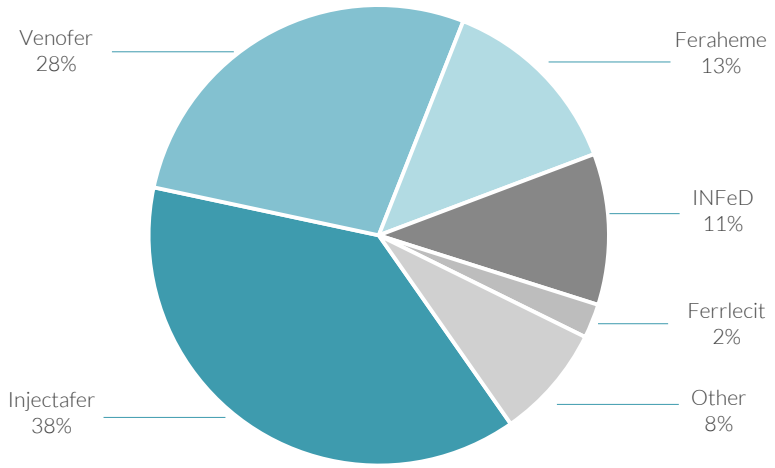
Commercial opportunity

Hardman & 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 for iron replacement therapy – $3.4bn gross/$1.5bn net in 2018 – was provided in our initiation report on STX published on 13 May 2019[1]. Two-thirds of this $3.4bn was derived from the US. In terms of I/V iron replacement therapy, our database of ex-factory sales from the leading players indicates that the US contributed $1.02bn in 2018, a market that is growing by 9% p.a., a figure supported by several corporate documents (AMAG Pharmaceuticals, Daiichi-Sankyo, Vifor Pharmaceuticals). The benefits of Accrufer leave it well placed to take a substantial share of the US market over time.

US IV iron replacement market – 2018



Source: Hardman & Co Life Sciences Research

IQVIA estimates that the total Chinese pharmaceutical market was $137bn in 2018, second only to the US by sales. Ex-factory sales data for iron replacement products in the Chinese markets are lacking, in part because much of the industry has historically been dominated by generic drugs; however, extrapolation of IQVIA figures from 2011 indicate that the 2019 market for iron replacement is in excess of CNY4,000m/$630m. This is likely to be an underestimate given the introduction of new products in the past decade and market expansion driven by increased health spending and the ongoing healthcare reform (including measures in the 12th Five-Year Plan).

As in the US, the greatest competition to Feraccru/Accrufer in China comes from Vifor Pharma, which markets Venofer for IDA, and which is on track to launch Ferinject in 2021 with a focus on patient blood management (PBM). Wanbang Biopharmaceuticals (Fosun) filed an approval submission for oral Triferic (ferric pyrophosphate citrate) in China in 2019, for haemodialysis-dependent CKD, which could therefore also launch in 2021. The extensive educational and promotional activities undertaken by Vifor and its partners also serves to build a market for other products, including Feraccru/Accrufer.

As long as the approval, pricing and reimbursement processes for imported drugs continue to improve, China is set to be the largest market for iron replacement products for chronic conditions such as CKD.

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

Financials & investment case

Valuation update

Total addressable market >300m people

Our sum-of-the-parts valuation of STX has been updated to include the deal with ASK Pharm. The prevalence of potential patients who could benefit from treatment with Feraccru/Accrufer is greater than in the US on the basis of both population size and the greater prevalence of CKD and other chronic disorders[2]. Vifor Pharma estimates the average incidence of IDA in China to be 15%-20%, which suggests that there are 200m-300m people currently suffering from IDA. The total addressable market is clearly very large - we assume that the initial target market will be IDA patients that do not tolerate existing oral therapies. In our view, the greatest sensitivity for Feraccru/Accrufer's value in China is market access, which is complicated by fragmented and evolving systems.

China deal assumptions

- **Milestones:** Assumed to be split into eight payments at cumulative in-market net sales targets between $100m and $14,000m. Not currently modelled.
- **Royalties:** Royalties of 10% are assumed on net in-market sales up to $200m, then 15% on all sales above that.
- **Price:** Discount negotiations are strict in China for public reimbursement of import drugs, net prices achieved are likely to be nearer to those in Europe than the US.
- **Volume:** Total x7 packs per treated patient p.a., as elsewhere.
- **Target market:** Initially approved and positioned for IDA, where there is already a growing market for oral products in chronic diseases such as CKD; future label expansion for general ID likely.
- **Launch:** Estimated in 2023, assuming trial authorisation is achieved by the beginning of 2021 and the IDL registration process is successfully completed by the end of 2022 (this is subject to a number of uncertainties).
- **Peak sales:** Assumed by year 10 after launch, with patent protection until 2033 (also subject to uncertainty).
- **Risk adjustment:** Although Feraccru/Accrufer is approved in Europe and the US, several similarly approved iron replacement products have failed to achieve commercialisation in China due to complex regulatory processes – we therefore apply a 75% risk rate to the DCF.

Feraccru/Accrufer target market China

Penetration rate	Target population captured (m)	Peak in market sales (£m)	Peak in-market sales ($m)
0.1%	0.1	22.3	29.2
0.5%	0.4	111.6	146.2
1%	1.2	223.2	292.4
2.5%	1.8	558.1	731.1
5%	**3.6**	**1,116.2**	**1,462.2**
10%	7.2	2,232.3	2,924.3
20%	14.4	4,464.7	5,848.7

Source: Hardman & Co Life Sciences Research

[2] Li L et al (2015) The prevalence of anemia in central and eastern china: evidence from the china health and nutrition survey. Southeast Asian J Trop Med Public Health 46:2

- **Market penetration:** Greatest uncertainty due to changing landscape – we consider a range from 0.1% to 20% (to account for access, compliance, etc.) of the initial target market in IDA patients; we assume ASK Pharm achieves 5% on Feraccru's target market at peak, or ca.$1.5bn in annual sales.

Sum-of-the-parts

A detailed assessment of valuation was provided in our initiation report[1], which generated a risk-adjusted value for STX of £194m, or 166p per share. Approval in the US added £14m, or 12p per share, to this valuation, which, combined with minor updates, put our last sum-of-the-parts valuation of STX at £221m/189p per share.

The China deal added £162m to our valuation, or 138p per share…

The China deal added £162m/138p per share to Feraccru/Accrufer's royalty stream rNPV, which combined with updated forex and rolling forward the model, resulted in a total rNPV of £393m/335p per share. Addition of the upfront payment from the China deal improved cashflow such that the company will be cash-positive until 2021.

…the next valuation inflection point will be signing the US commercial partner

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

Source: Hardman & Co Life Sciences Research

This valuation is taking a conservative view on the US launch and does not allow for any up-front payments on signing up with the US distribution partner(s), which could be substantial for a de-risked product (i.e. greater than the $11.4m for China). It considers only IDA in Europe, the US and China – successful expansion into the general ID market will increase our valuation further.

News flow

STX prudently waited for Accrufer to be regulatory de-risked before signing a commercial partner in the US…

Together with its advisors, STX has been in discussions with a number of potential commercial partners in the US since the second half of 2019. While it could have done a deal prior to the FDA announcement, it would likely have been on less good terms than can be achieved today, with the product de-risked by the regulator and a broad label awarded. The deal in China strengthens its hand further, as it now has the cash runway that allows a process towards an optimal, rather than a time constrained, deal. It is also possible that STX will sign with more than one partner in the US, depending on geographical coverage.

…which, along with the improved cash position from China, should put it in a strong negotiating position

We believe that the company will try to obtain a similar deal to that signed with Norgine, and unlike the deal in China, whereby STX controls all the manufacturing and supply arrangements. Clearly, STX cannot complete manufacturing of the end product until the US deal is signed, because the packaging will need to be in the partner's branding. This may also apply to the final product, with the capsule embossed with a company logo and/or 'Accrufer' for identification purposes. Perception of whether STX has signed with the 'right' partner(s) for the US market, when announced, will represent the next significant value inflection point, in our view.

Accrufer – next steps	
Date	**Event**
25 Jul 2019	FDA approval
1Q'20	Conclude deal with US distribution partner(s)
2Q'20	Complete manufacturing in partner's brand
Late-2020	Formal US launch

Source: Hardman & Co Life Sciences Research

Financial summary

- Apart from inclusion of $10.2m/£7.7m in licensing income in 2020, there have been no changes to forecasts since publication of the latest financial results. A trading statement for fiscal 2019 is expected by the start of next month.
- Any impact on royalty income from the China deal is outside the forecast period.
- 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.

Financial summary

Year-end Dec (£m)	2017	2018	2019E	2020E	2021E
GBP:EUR	1.14	1.14	1.18	1.18	1.18
GBP:USD	1.29	1.31	1.32	1.32	1.32
Profit & Loss					
Gross revenues	0.64	11.88	2.91	9.81	3.05
Product sales	0.64	0.86	0.61	2.08	3.05
COGS	-0.16	-0.31	-0.39	-1.25	-1.77
Gross profit	0.48	0.55	0.22	0.83	1.28
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	7.73	0.00
EBITDA	-18.48	-2.47	-5.46	-1.49	-8.72
Underlying EBIT	-18.90	-3.26	-6.25	-2.28	-9.51
Net interest	0.00	0.01	0.01	-0.03	-0.04
Underlying PBT	**-18.91**	**-3.26**	**-6.24**	**-2.31**	**-9.56**
Tax payable/credit	1.41	3.36	0.99	0.70	0.58
Underlying net income	-17.50	0.10	-5.25	-1.62	-8.97
Weighted av. shares (m)	112.36	116.43	116.81	117.19	117.19
Underlying EPS (p)	**-15.58**	**0.09**	**-4.49**	**-1.38**	**-7.66**
Fully diluted EPS (p)	-15.58	0.09	-4.49	-1.38	-7.63
Balance sheet (@31 Dec)					
Share capital	1.75	1.75	1.76	1.76	1.76
Reserves	39.46	38.68	31.54	28.02	17.14
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	6.34	6.58	-0.65
Invested capital	**28.31**	**30.80**	**27.11**	**23.35**	**19.70**
Net cash/debt	13.30	9.63	6.19	6.43	-0.80
Cashflow					
Underlying EBIT	-18.90	-3.26	-6.25	-2.28	-9.51
Non-cash items	0.43	1.80	1.80	1.80	1.80
Change in working capital	-0.29	-0.40	0.03	-0.20	-0.13
Tax & interest	1.99	1.86	2.01	0.96	0.65
Operational cashflow	**-17.99**	**-1.85**	**-4.28**	**-0.54**	**-7.70**
Capital expenditure	0.00	0.00	0.00	0.00	0.00
Free cashflow	-19.33	-3.32	-3.46	0.24	-7.23
Acquisitions	-0.24	-0.35	0.00	0.00	0.00
Equity issues	11.88	0.00	0.02	0.00	0.00
Change in net debt	**-7.68**	**-3.67**	**-3.44**	**0.24**	**-7.23**
OCFPS (p)	-14.38	-0.28	-2.10	0.21	-6.17

Source: Hardman & Co Life Sciences Research

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