EDISON

Shield Therapeutics

Beefing up for the US opportunity

US commercialisation strategy

Pharma & biotech

Shield Therapeutics' (STX's) shares fell sharply in December 2020 on the announcement that a US partnering deal would not be completed in 2020 and that the company is considering launching Accrufer itself in the US. We believe the market reaction has been overdone and the current share price fully discounts any value from the US and China opportunities. Until STX provides further clarity, we have continued to evaluate it based on a US partnering deal. Our modelling suggests an STX-led US launch could more than double longer-term shareholder value, but this is accompanied by increased near-term financial and investment risk, as STX will need to raise funds to establish a small but focused US marketing organisation. We value STX at £298.5m.

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	9.4	(3.1)	(1.6)	0.0	N/A	N/A
12/21e	4.8	(6.4)	(4.9)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

US commercialisation key to unlocking value

Feraccru/Accrufer received FDA approval in 2019 for the broadest possible label to encompass iron deficiency of any cause as per its US prescribing information. The product could offer an improved value proposition to patients and payors versus existing oral treatments or the alternative, an IV treatment in the hospital setting. The US iron market is a huge market at ~10 million patients per annum and represents the largest value proposition for the asset, hence timely launch is critical.

Break-even potential in 2023 under STX-led scenario

For an STX-led US launch, management has illustrated it would require $25–30m per year in 2021/22 to cover the cost of building out US operations including an experienced US-based management team. In this scenario, breakeven is possible in 2023, which given the product's profile is achievable but is contingent on launch by mid-2021. Further access to funding will be key for this option, either through debt facilities and/or an equity raise. We note the current share price reflects the market's perceived execution risk, but by our analysis it is fully discounting both the US and China opportunities, as well as a portion of the European partnership.

Valuation: £298.5m or 254p/share

Our revised valuation is £298.5m or 254p/share, vs £379.1m or 324p/share previously. This reflects a US partnering deal but with more cautious assumptions; we delay launch to 2022 and reduce the upfront payment to £10m. We have also lowered EU sales trajectory in 2021/22 reflecting the need for further launches. We include unaudited net cash at 31 December 2020 of £2.9m, which gives a cash runway to Q221 and could be extended until end 2021 through two loan facilities agreements totalling c £4.4m. Our NPV calculation is based on Feraccru/Accrufer achieving peak sales of €130m in Europe, $410m in the US and $126m in China, through partners.

1 February 2021

Price	**54.5p**
Market cap	**£64m**
	£0.73/US$; £0.89/€
Unaudited net cash (£m) at 31 December 2020	2.9
Shares in issue	117.6m
Free float	41%
Code	STX
Primary exchange	AIM
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(10.7)	(57.8)	(66.7)
Rel (local)	(8.0)	(63.4)	(62.0)
52-week high/low		163.5p	48.5p

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

Potential US launch	2021
Launches in additional EU states as covered by Norgine	2021

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2020 share price underperformance overdone

STX's announcement in December 2020, that its revised strategy is two-pronged and it will continue discussions with potential partners while exploring the benefits of marketing Accrufer (oral ferric maltol) itself in the US, has set the shares back, as expectations had been for a partnering deal by end 2020. Management is evaluating the greater pathway to value: launch the product itself and retain the full economic value or a suboptimal licence deal, which could delay launch of the asset beyond 2021. According to our analysis, the current valuation of the company fully discounts not only the US opportunity, but the potential in China and partially discounts value from the European partnership.

At the December investor update, STX outlined in detail the procedure undertaken to find a suitable partner, the hurdles met at the last stages, the lessons learnt along the way and thus the rationale to consider STX-led commercialisation as an option. A refined, detailed and timely strategy is now required to mitigate shareholder concerns on the US commercialisation strategy. STX is concurrently exploring the logistics and implied economics of self-marketing Accrufer (the brand name in the US) while exploring licensing options (although discussions are at an early stage); a decision either way is expected by the end of Q121. Both approaches have merits: one de-risks the investment case but at lower potential rewards, the other involves greater financial and investment risk, but with potential to more than double longer-term shareholder value. The difference in overall returns between the two strategies is the market's perception of the execution risk, which is impossible to quantify. In the worst case, STX would be unable to agree/execute on a US market launch.

Feraccru/Accrufer received FDA approval in 2019

The product, which has the brand names Feraccru in Europe and Accrufer in the US, received FDA approval in 2019 with the broadest possible label of the treatment of iron deficiency (in adults) with or without anaemia (not restricted to any specific cause). The US iron market dynamics are such that 10m patients are suffering from iron deficiency anaemia resulting in ~10m oral prescriptions per annum and ~2.3m doses of IV iron per annum, with some patients receiving more than one treatment. Treatment options are limited to oral ferrous salts hampered by troublesome side effects associated with low compliance rates and intravenously administered iron (eg Vifor's Ferinject), which is efficacious but requires infusions in the hospital setting and is associated with albeit small risk of fatal anaphylaxis reactions. An intermediary product is required to fill a huge gap in the market; Feraccru/Accrufer is an improved oral iron formulation that is tolerable and efficacious, that could supplant available oral therapies and mitigate the need for IV iron in some patients. Furthermore, the COVID-19 pandemic and limitations on hospital visits plus the potential approval of AstraZeneca/FibroGen's roxadustat (oral hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor for patients with anaemia of chronic kidney disease (CKD)) could increase the demand for oral iron treatments in 2021.

Partnering de-risks the investment case but at the cost of lower returns

A US partnering deal would have led to a cash injection via an upfront payment and additionally fulfilled the markets expectations of deal timing as previously communicated by management. Partners come in all sizes; a large-cap pharmaceutical tie up was unlikely as these companies tend to chase high value and highly innovative therapies. Our forecasts assume 20% royalty on US sales and a £10m ($14m at current FX) upfront payment (previous assumption £15m) and we push out the payment to 2021 and launch to 2022. While we make this adjustment and retain our

partnering forecast, there remains significant uncertainty as to the parameters of a deal that is considered acceptable and value accretive to STX, as well as what is currently on offer in the ongoing partnering discussions. To break-even in 2022, we forecast a potential partner would need to generate US Accrufer sales of $35.0m leading to £5.1m in royalties to STX, plus £10.9m revenue generated from European sales through partner Norgine to reach our forecast operating profit.

STX-led US commercialisation higher risk and higher reward

The main merit to self-commercialisation is the potential for significantly higher longer-term shareholder returns as STX retains the full economics of the asset. Through its 18-month partnering search and exposure to in depth data shared by potential partners, STX gained a fuller insight into all aspects of the US iron market dynamics. STX was approached by a range of smaller companies looking to build a salesforce around Accrufer to establish themselves in the US market ahead of their own product launches, prompting STX to consider the potential benefits of self-commercialisation. STX management believes that through an investment of $25m in in 2021 rising to $45m per year at peak, it could build a US commercial operation co-ordinated by an experienced US operational management team. This would increase the investment risk as STX would need to raise sufficient funds (through costly debt or equity raise at a depressed valuation or a mix) to ensure funding of the US commercial operations. Key to success would be hiring the right personnel, and through its discussions STX has identified four US-based individuals with the relevant sales, medical liaison, supply chain and market access experience to build the foundations it would require. STX estimates a total cash outlay of $30–40m is required to reach break-even, which includes potential US launch costs, expenses related to non-US operations and funding for the planned paediatric study. STX is currently evaluating various financing alternatives in the event of an STX-led launch.

Norgine marketing efforts key to EU5 sales, ASK Pharm to launch in China

In September 2018 STX announced a partnering deal with Netherlands-based Norgine, to market Feraccru in Europe. The US and Europe markets can be differentiated on many grounds and there are many examples of biotech companies that choose a self-commercialisation option for the US and opted for out-licensing or co-marketing strategies in Europe and the rest of the world (RoW) (with individual country reimbursement procedures leading to differing value propositions). Feraccru received regulatory approval from the European Medicines Agency (EMA) initially for the treatment of iron deficiency anaemia (IDA) in inflammatory bowel disease (IBD) patients (in February 2016) and then, more broadly, for the treatment of iron deficiency (ID) in general (in February 2018). Feraccru has been positioned (and is being marketed in Europe) as a second-line (2L) treatment option (twice daily for a minimum of 12 weeks) to treat ID in patients who are intolerant of first-line (1L) salt-based oral irons, and require treatment with intravenous (IV) iron therapy to restore both blood haemoglobin (Hb) levels and iron stores. In January 2019, Norgine re-launched selling and marketing activities in the UK and Germany (80 sales reps); further launches (eg Spain, France, Italy) will be dependent on reimbursement decisions (expected in 2021) following the publication of the AEGIS-H2H data. We have lowered our sales trajectory in 2021 and 2022 accordingly but maintain our peak sales forecast. In China, STX has out licenced the product to ASK Pharm, an IND was recently submitted, we expect an additional Phase III study to start in 2021, and launch is estimated in 2023. We expect further, albeit smaller deals in RoW, which demonstrates the value placed on a tolerable, efficacious oral iron pill. STX is aiming to complete one additional licensing transaction in 2021.

Financials: Cash runway extended to the end of 2021

STX reported an unaudited cash position of £2.9m at 31 December 2020, implying a cash runway to Q221. This has been extended until the end of 2021 through two loan facilities agreements totalling c £4.4m, with major shareholder AOP Orphan (which owns 10.7% of STX) and board member Dr Christian Schweiger (who owns 3.5% of STX). Our financial forecasts include £10m of illustrative debt in 2021, highlighting the requirement for additional funds. This could be provided by an upfront payment by a potential partner; however, we do not forecast this in our current financial forecasts. We forecast break-even by the end of 2022 and that sustainable profitability is achievable from 2023. We expect break-even to be delayed by a year under the STX-led launch scenario. This note explores the dynamics and merits of both scenarios using a six-year DCF analysis.

Scenario 1: Six-year DCF assuming out-licensing deal in the US

An out-licensing deal in 2020 would significantly de-risked the investment case and provided near-term funding to the business. However, this would have been predicated on appropriate deal terms and the 'right' fit of partner for this particular asset. As highlighted in prior notes, a partnering deal would need to aim to optimise financial deal terms and additionally maximise the product's potential across a broad range of therapy areas, beyond IBD and CKD associated anaemia to encompass iron deficiency of any cause as per its US prescribing information. One of the issues with partnering is sufficient buy in and commitment to the product in the long term. Our revised model now assumes a £10m ($14m) upfront payment (vs £15m previously) and we maintain our assumption of 20% royalties on sales. STX management needs to ensure that deal terms do not lead to value dilution. A potential partner would need to recognise Accrufer's broad prescribing label. We note that many smaller companies do however focus on specialising in indications and a large-cap pharma company is unlikely to take interest in an improved formulation product in this pricing range regardless of the product's proven improved profile. STX also alluded in its January trading update that discussions are underway with several companies that could co-promote or sub-license Accrufer in specific therapy areas that could complement a STX-led launch.

During the 16 December 2020 investor presentation, management outlined that for many reasons a deal in the US failed to materialise by year end. Although multiple term sheets were discussed in depth, these were not pursued and management cited 'Financial terms not sufficiently attractive especially smaller companies unable to offer large enough upfront payment to create 'skin in the game' and 'Concerns that counter parties would not deliver Accrufer sales across the broad range of therapy areas where iron deficiency is common'. Furthermore, two very late-stage transactions failed due to unforeseen changes on the potential partner's side.

We have performed a six-year DCF analysis (2021–26) to compare the prospects of a potential partnering strategy to an STX-led launch. STX has indicated it is engaged in discussions with a number of potential partners, and as such that under a partnering scenario a launch is unlikely before late 2021/early 2022. On this basis, for STX to break-even in 2022 we assume total revenues of £16.0m, consisting of £10.9m revenues generated from Feraccru sales in Europe through partner Norgine, US royalties of £5.1m based on a partner generating net Accrufer sales of $35.0m. We include a £10m upfront payment from a potential partner in 2021 in our DCF analysis.

STX has a low operating cost base (it is largely a virtual company with 15 employees), and aside from the paediatric study, minimal R&D costs and zero selling and marketing costs. By 2026 we would expect a steady stream of revenue from the US and European partnering (plus early sales contributions from China) to grow operating profit from £1.6m in 2022 to £53.2m in 2026 (Exhibit 1).

Exhibit 1: Potential financials for US out-licensing deal used in DCF analysis

	2020e	2021e	2022e	2023e	2024e	2025e	2026e
Indicative financials (£m)							
Sales by STX	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Royalties on partner sales	0.709	3.876	15.141	28.567	50.268	69.348	90.607
Milestone payments	8.719	10.887	0.887	9.676	0.732	1.098	2.218
Total revenue	**9.428**	**14.764**	**16.028**	**38.242**	**51.000**	**70.446**	**92.826**
Cost of sales*	(0.432)	(2.332)	(7.013)	(11.773)	(21.073)	(28.253)	(34.664)
Total operating expenses	**(12.050)**	**(8.598)**	**(7.459)**	**(5.830)**	**(5.210)**	**(5.101)**	**(5.000)**
R&D expenses	(2.500)	(2.500)	(2.500)	(1.000)	(1.000)	(1.000)	(1.000)
Selling expenses	0.000	0.000	0.000	0.000	0.000	0.000	0.000
G&A expenses	(7.300)	(4.000)	(3.000)	(3.000)	(2.500)	(2.500)	(2.500)
Depreciation and amortisation	(2.250)	(2.098)	(1.959)	(1.830)	(1.710)	(1.601)	(1.500)
Operating income (reported)	**(3.054)**	**3.833**	**1.556**	**20.640**	**24.716**	**37.092**	**53.162**
Operating margin %	N/A	26.0%	9.7%	54.0%	48.5%	52.7%	57.3%

Source: Edison Investment Research. Note: *Cost of sales includes pay-away to Vitra Pharmaceuticals.

Scenario 2: Six-year DCF assuming STX-led US launch

At the December 2020 investor presentation STX management commented 'A number of potential counterparties were proposing to use Accrufer as their first product, to build a commercial presence ahead of either bringing their own Phase III product to market or licensing in further products.' This 'helped us to understand that there is no reason in principle why Shield should not also contemplate launching Accrufer'. STX management provided some granularity to the economics and financial considerations of a solo US marketing strategy. We discuss these in detail below.

Planning for a successful STX US launch

Through its discussions with potential partners in the US, STX has recruited, on an initial fixed-term consultancy contract, a team of four experienced US-based commercial managers (with expertise in market access, marketing, medical affairs and operations/supply chain) to lead the US launch. All four individuals garnered in depth knowledge of Accrufer while working for potential partners with which previous negotiations failed. Should STX decide to launch in the US, all four would become STX US employees and lead the build out of the operations ahead of Accrufer launch, which could occur as early as mid-2021. The detailed planning for an STX-led launch covers all aspects of launch including supply chain and operations, market research and marketing, market access and salesforce recruitment. Initially an outsourced contract sales organisation would make sense to achieve timely launch, with eventual recruitment of an in-house team of sales reps and staff to focus on market access (hospital formularies, government pricing and managed services, insurance pricing and reimbursement, co-pay/patient assistance strategy).

STX believe 30–60 sales reps would be required to target the top 30% of iron prescribers (~15,000 physicians) who in aggregate write at least 70% of all iron prescriptions in the US. Management has indicated that initial SG&A costs would be c $25–30m in 2021, increasing to £45m per annum in year five to build out the US marketing infrastructure. We note that sales reps and support staff requirements within the context of COVID-19 imply greater efficiencies in targeting hospitals (virtual meetings with multiple P&T committees), and as such an initial deployment of 30 reps growing to ~60 reps is the optimal size for now. Market access activities such as prescription drug coverage and obtaining access to US hospital pharmacy formulary lists will be the critical element to sales execution. As previously highlighted, significant risk remains around commercial execution, particularly related to financial investment to launch the products, which will require STX to raise funds in 2021 to fulfil its STX-led US strategy.

STX estimates 'the amount required for the group to reach the point at which it generates cash is $30–40m', which includes potential US launch costs, expenses related to non-US operations and

funding for the planned paediatric study (expected to start in mid-2021). According to STX's illustrative example for year five, US sales of $200m would require 200,000 patients treated per annum, at a net sales price of $200–250 per month and treatment duration of four to five months. STX estimates that in year five, the potential operating profit and cash generation would be ~$130m, taking into account 5% COGS, 5% pay-away to Vitra Pharmaceuticals and the SG&A costs highlighted above. Taking these metrics into account, Exhibit 2 illustrates the profitability potential of a US STX-led strategy at the operating profit level based on STX's estimates (including European sales contributions). We note that net income will be affected by the financing strategy undertaken, particularly if highly leveraged. Under the below assumptions of a STX-led launch, break-even at the operating profit level would be in 2023. We note there remains a degree of sales execution risk in either scenario.

Exhibit 2: Potential financials for US STX-led commercialisation used in DCF analysis

	2020e	2021e	2022e	2023e	2024e	2025e	2026e
Indicative financials (£m)							
Feraccru US sales (US$m)	0.000	6.332	31.263	100.469	166.933	192.692	202.990
Sales by Shield	0.000	4.635	22.884	73.543	122.195	141.051	148.589
Royalties on partner sales	0.709	3.876	10.012	15.784	24.328	29.330	41.006
Milestone payments	8.719	0.887	0.887	9.676	0.732	1.098	2.218
Total revenue	**9.428**	**9.399**	**33.784**	**99.003**	**147.255**	**171.479**	**191.814**
Cost of sales	(0.432)	(2.796)	(7.241)	(13.991)	(22.827)	(26.241)	(29.599)
Total operating expenses	**(12.050)**	**(26.898)**	**(33.079)**	**(31.450)**	**(34.490)**	**(38.041)**	**(39.587)**
R&D expenses	(2.500)	(2.500)	(2.500)	(1.000)	(1.000)	(1.000)	(1.000)
Selling expenses	0.000	(18.300)	(25.620)	(25.620)	(29.280)	(32.940)	(34.587)
General & administrative expenses	(7.300)	(4.000)	(3.000)	(3.000)	(2.500)	(2.500)	(2.500)
Depreciation and amortisation	(2.250)	(2.098)	(1.959)	(1.830)	(1.710)	(1.601)	(1.500)
Operating income (reported)	**(3.054)**	**(20.295)**	**(6.536)**	**53.562**	**89.938**	**107.197**	**122.627**
Operating margin %	N/A	N/A	N/A	54.1%	61.1%	62.5%	63.9%

Source: Edison Investment Research, Note: *cost of sales includes pay-away to Vitra Pharmaceuticals.

Potential impact on six-year DCF analysis

An STX-led US launch implies a more than doubling in the six year DCF vs our base case scenario assumptions of a US partnering deal based on cash flows generated between 2021 and 2026 using a 12.5% discount rate (Exhibit 3). For our partnering assumption we calculate the DCF generated over six years as £48.8m, based on Accrufer sales of $325m in 2026. The main caveats to this are that our licence model is conservative at a 20% royalty rate and upfront of £10m ($14m), and we do not reflect potential sales milestones. For an STX-led launch and based on management's estimates of $200m sales potential in 2026, we calculate the DCF at £251.8m for the same period. If we assume sales potential of $100m in 2026, the indicative DCF (2021–26) is £84.8m, assuming the same level of SG&A costs as outlined by management. Even at $100m sales an STX-led strategy would extract more value that a partnering deal at our assumptions outlined due to significantly more profit per unit sold. We have not taken financing costs into consideration and acknowledge the risk factors and impact of dilution or costly debt financing. The difference in overall returns between the two strategies, reflects the different investment risk, financing risk and the difficulty in finding an appropriate partner, which are impossible to individually quantify. Sales execution risk applies to both scenarios.

Exhibit 3: NPV of US commercialisation options (based on cash flow between 2021-2026)

	US licence deal ($325m sales in 2026)	STX-led launch ($200m sales in 2026)	STX-led launch ($100m sales in 2026)
DCF (£m) (2021–26)	48.8	251.8	84.8

Source: Edison Investment Research

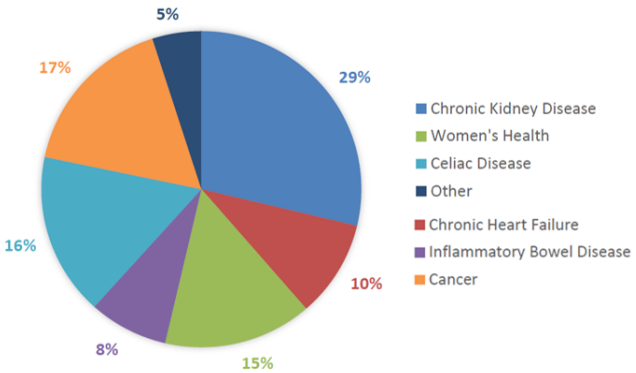
Feraccru: Uniquely positioned to treat iron deficiency

An estimated four to five billion people suffer from iron deficiency globally, of which approximately two billion are anaemic. The US iron market in particular is huge at ~10 million patients per annum, with ~10m oral prescriptions and ~2.3m IV doses annually. The US represents the largest value proposition for Feraccru/Accrufer. ID is caused by malnutrition or bleeding and is a common comorbidity associated with numerous indications including IBD, CKD, women's health, oncology, congestive heart failure and ageing, Exhibit 4.

ID is treated with either oral salt-based iron products (ferrous salts) or IV iron therapy and although there are a number of approved products, there is still a significant unmet need. Oral iron salts are typically prescribed as the first-line standard of care as they are convenient (taken as an oral pill) and inexpensive (as many are available as generics). However, although widely used, a significant proportion of patients suffer from gastro-intestinal side effects (eg nausea, pain, constipation, diarrhoea, black stools) leading to high treatment discontinuation rates (up to 70%) due to non-adherence and treatment failure. Additionally, these treatments are slow at restoring iron levels due to poor absorption. IV iron therapy is generally reserved as a 2L treatment as although it is highly effective at quickly restoring normal iron levels, it is more expensive and must be administered in a hospital setting due to the risk of anaphylaxis (which can be fatal) and iron overload.

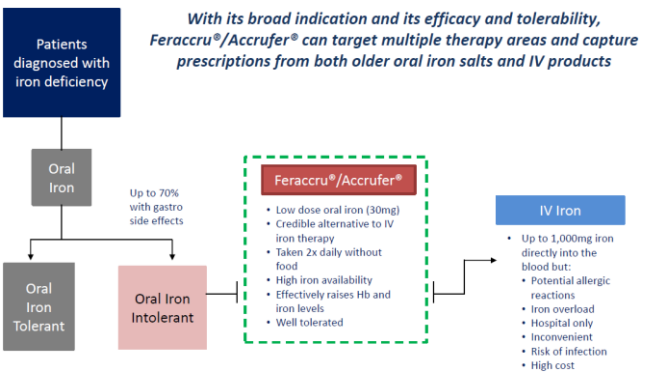
Feraccru has been positioned, and is being marketed, as a 2L treatment option for ID patients who are intolerant to 1L oral ferrous supplements and would normally progress to requiring treatment with IV iron therapy, Exhibit 5. Feraccru is a differentiated treatment for ID with or without anaemia; it is a unique oral (non-salt) formulation, which, unlike salt-based oral irons, does not release free iron in the intestine, mitigating the gastrointestinal side effects caused by oral iron salts. Iron levels in the body are regulated at this point of absorption and as such Feraccru cannot circumvent this regulated process that maintains iron homeostasis. IV iron circumvents this process by being administered directly into systemic circulation, carrying a risk of iron overload and allergic reaction (anaphylaxis), and requiring hospital admission and close monitoring. Feraccru's convenient oral dosing and clinical data package (efficacy and tolerability) will appeal to a proportion of patients who may be reluctant to be treated by IV iron (hospital stay, cost, parental iron infusion side effects).

Exhibit 4: Demographics of iron deficiency patient population in the US



Source: STX corporate presentation

Exhibit 5: Feraccru/Accrufer positioning to address both oral and IV segments



Source: STX corporate presentation

Exhibit 6 highlights Feraccru's positioning to the leading branded IV iron (Vifor Pharma's Ferinject/Injectafer) and salt-based oral irons and its key differentiating features to its competitors. Feraccru will not replace the need for IV iron; rather it provides an alternative option for patients intolerant to salt-based oral irons.

Exhibit 6: Treatment options for iron deficiency anaemia

	Salt-based oral iron (ie ferrous sulphate)	Feraccru (ferric maltol)	IV iron (ie Ferinject)
Intervention	**1L** – mild to moderate iron deficiency anaemia	**2L** – mild to severe iron deficiency anaemia	**2L** – moderate to severe iron deficiency anaemia
Dosage	**Oral** – 200–300mg thrice daily, recommended to be taken with food	**Oral** – 30mg twice daily, on an empty stomach	**Intravenous** – multiple infusions administered in an acute care setting
Efficacy	**Efficacious** – when intestinal absorption is not impaired	**Efficacious** – improves both haemoglobin levels and iron stores, clinical evidence established in CKD and IBD patient populations	**Efficacious** – fast repletion of iron stores and particularly effective when intestinal absorption is impaired
Safety & tolerability	**Safe but poorly tolerated** in certain patients due to gastrointestinal side-effects (particularly in patients with IBD) leading to poor-compliance and worsening of condition	**Safe and well tolerated** with placebo-like side-effects. Formulation enables individuals to absorb as much iron as needed; unrequired drug is excreted and with no concerns of iron overload	**Safe – but has an associated risk with iron overload** (haemochromatosis), hypophosphatemia and anaphylaxis
Cost effectiveness	**~£5–10 per 12-week course** Cheap and broadly prescribed	**~£150 per 12-week course** Priced in-line with IV iron but mitigates cost of acute care	**~£100–300 per treatment course** Additional costs incurred due to administration inpatient hospital care setting

Source: Edison Investment Research. Note: CKD – chronic kidney disease, IBD – inflammatory bowel disease.

2021 additional factors to drive iron treatment uptake

Due to the current limited treatment options for ID, there is appetite for an intermediary product to fill the gap in the market between oral salt-based iron products and IV iron therapy. Feraccru/Accrufer is an improved oral iron formulation that is highly tolerable and efficacious, that could supplant available oral therapies and mitigate the need for IV iron in some patients. However, Feraccru's ability to capture this broader opportunity will be determined by a paradigm shift in physicians diagnosing ID (tested through ferritin, transferrin saturation levels) and prescribing Feraccru to prevent anaemia.

There are a number of additional factors that could drive the uptake of Feraccru in 2021. Currently, and for the foreseeable future, most global healthcare resources are focused on combating the COVID-19 pandemic. Many ID/IDA patients have underlying comorbidities including CKD, cancer and heart failure that put them at a higher risk of developing severe disease if infected with COVID-19. This has led to limitations on hospital visits and is causing a paradigm shift in healthcare delivery and recommendations for the care of at-risk patients. Where possible it is desirable to provide home treatments, which means switching from IV to oral therapies to minimise hospital visits. Feraccru is ideally positioned as an oral treatment for patients unable to tolerate the gastrointestinal side effects associated with salt-based oral iron therapies.

Furthermore, the potential approval and launch of the first HIF inhibitor roxadustat for patients with anaemia of CKD is expected in H121 (PDUFA date 20 March). AstraZeneca/FibroGen's oral HIF-PH inhibitor is the first in a new class of medicines that promotes red blood cell production and based on its clinical data many patients will likely still require supplemental iron. We see this as a complementary product to Feraccru as it is preferable to prescribe an iron treatment that is also administered orally (vs IV, which would require a separate hospital visit) and is well tolerated due to the increasing focus on tolerability when treatments are used in combination.

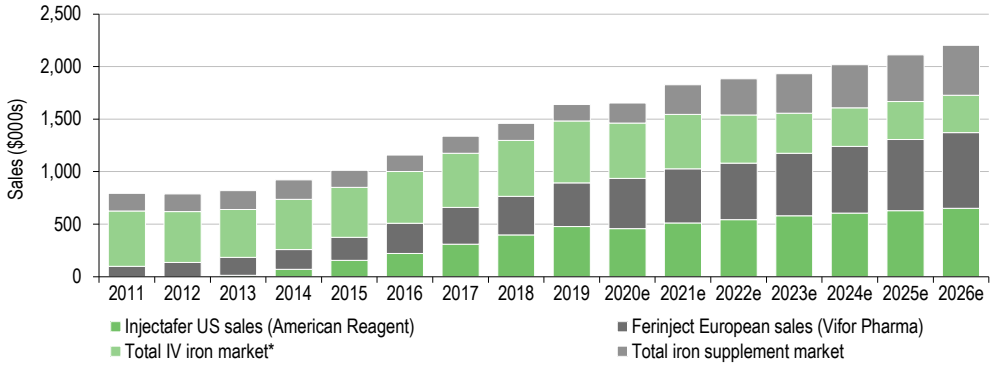
Commercial opportunity determined by IV iron market

Vifor Pharma's Ferinject (marketed as Injectafer in the US by American Reagent, part of Daiichi Sankyo) is the leading product (c 60% of IV iron sales in 2019) and has an improved safety profile to the older generation of IV iron products (which were largely associated with a higher risk of anaphylaxis). Vifor has grown the market through higher pricing and a strong commercial presence and has driven clinical adoption and uptake across a range of therapeutic specialities including patient blood management, cardiology, gastroenterology, nephrology, oncology and women's health. Ferinject global sales grew from $28m in 2008 to $892m in 2019 (EvaluatePharma), a

function of growth in Europe where the product was initially launched, US launch in 2013 (under brand name Injectafer) plus data from additional indications such as heart failure as well as new EU oncology and European Society of Cardiology guidelines published in 2015 and 2016, respectively. EvaluatePharma estimates $1.4bn global sales potential (in 2026) for Ferinject/Injectafer driven by RoW launches (Japan and China) and extension of use into cardiology indications. The establishment of this expanded iron market by Vifor is a positive for Feraccru; however, we would expect aggressive counter detailing as Vifor defends its market leading position. That said, Feraccru's clinical data package (efficacy and tolerability) will appeal to a proportion of patients who may be reluctant to be treated by intravenous iron (due to hospital stay, cost, parental iron infusion side effects).

Evaluate Pharma estimates the market for iron products in 2020 was c $1.7bn globally, of which IV iron constituted $1.5bn (c 88%); consensus forecasts suggest the IV iron market will grow to $1.7bn in 2026 (source: EvaluatePharma), largely driven by increased uptake of higher-priced branded IV iron and favourable demographic changes (eg ageing population, growing incidence of chronic diseases, rising diabetic population and patients with chronic kidney disease).

Exhibit 7: Consensus sales forecasts for Ferinject/Injectafer in the US and Europe

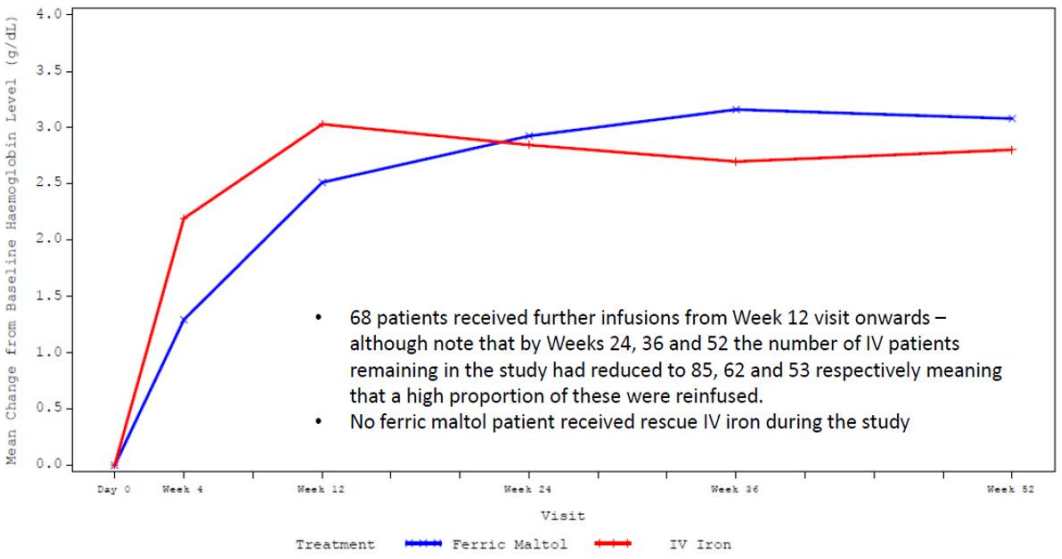


Source: EvaluatePharma. Note: *Combined sales of Ferinject, Injectafer, Venofer, Feraheme and INFeD.

AEGIS-H2H implications for pricing and reimbursement negotiations

In August 2020 STX announced that the re-analysis of the AEGIS head-to-head (AEGIS-H2H) study demonstrates that Feraccru/Accrufer is a 'credible alternative' to IV iron therapy for IDA in the long term. AEGIS-H2H reported that 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), Exhibit 8. 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, pricing strategies and reimbursement negotiations, 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. The headline results that long-term Hb correction are comparable to IV iron for chronic conditions of anaemia position Feraccru favourably to gain market share as a convenient and well tolerated oral alternative.

Exhibit 8: AEGIS-H2H study – comparison of Feraccru with leading IV therapy

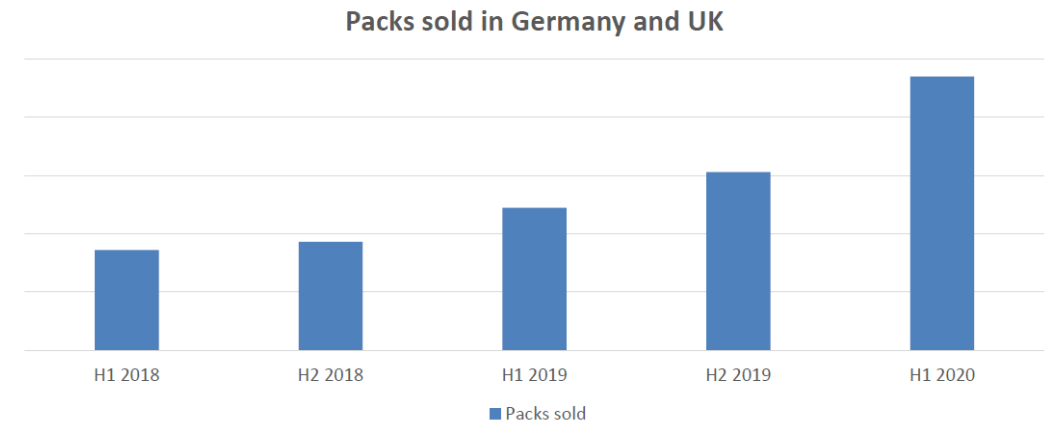


Source: STX corporate presentation. Note: Ferric maltol (Feraccru).

Norgine partnership key to Feraccru's success in Europe

In September 2018 Norgine licensed the rights to commercialise Feraccru in Europe (excluding countries covered by AOP Orphan and Ewopharma), Australia and New Zealand. Norgine has full responsibility for commercialisation, reimbursement and regulatory affairs in Europe; STX will be responsible for the manufacture and supply of Feraccru, as well as the initiation and completion of the Phase III paediatric study (expected to start in mid-2021) that could lead to an expansion of the label and addressable market. Feraccru is making inroads in Europe, with sales volumes growing ~70% y-o-y (Germany and UK) in 2020 (unaudited revenue arising from these sales is expected to be £0.7m). Exhibit 9 highlights the slow but steady growth since Norgine launched the product back into the market in H119. Further uplift in Europe will be determined by launches from late 2021 in additional countries. We have adjusted our sales trajectory down, reflecting the need for further launches outside of Germany and UK during 2021 and 2022. Norgine is now utilising the updated AEGIS-H2H detailed study results to reconfirm pricing and in reimbursement negotiations for Feraccru in the major European markets of France, Italy and Spain.

Exhibit 9: Europe commercialisation net packs sold by Norgine



Source: STX corporate presentation Note: Net sales of Feraccru® in Europe for first six months of 2020 up 50% over previous six months.

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, and led to receipt of an $11.4m upfront payment. STX is eligible for tiered royalties ranging from 10–15% on net sales. 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 launch in China in 2023.

Following discussions with the Chinese regulatory authority, the National Medical Product Administration (NMPA), it is likely that one further Feraccru/Accrufer Phase III study will be required, which is expected to be in IBD (120 patients). ASK Pharm has now filed the IND in China and the IBD study in patients in China could start in H121, once the Center for Drug Evaluation (CDE) confirms the exact submission requirements. Following successful completion of the study and regulatory approval, Feraccru could launch in China in 2023. STX is due to receive an $11.4m milestone payment upon approval and 10–15% tiered royalties on sales.

Current peak forecasts assume a US licence deal

Our Feraccru peak sales forecasts are unchanged. In Europe we forecast peak sales of €130m (£115m) in 2028 (and 2.5% growth pa until 2035). In the US we forecast peak sales of $410m (£300m) in 2029 (and 2.5% growth pa until 2035). In China we forecast peak sales of $126m (£92m) in 2031; our forecasts for China benefit from a larger population and higher prevalence of IDA offset by lower pricing assumptions. Our forecasts have been derived from a bottom-up, epidemiology-based approach for the patient population we believe Feraccru will be marketed in; we rationalised this with a top-down view on the portion of Ferinject/Injectafer sales we believe Feraccru can capture across both Europe and the US based on consensus forecasts of sales in 2024. We have highlighted the basis of our assumptions in Exhibit 10. Furthermore, STX believes that Feraccru's long-term economic potential resides in the treatment of iron deficiency (with or without anaemia). The estimated number of ID patients (with or without anaemia) is huge (management estimates 40 million in Europe). However, Feraccru's ability to capture this broader opportunity will be determined on a paradigm shift in physicians diagnosing ID (tested through ferritin, transferrin saturation levels) and prescribing Feraccru to prevent anaemia.

Exhibit 10: Feraccru peak sales forecasts

Product	Country (partner)	Indication	Launch year/ peak sales	Assumptions
Feraccru	EU5 (Norgine)	IDA	2019/2028 €130m (£115m)	Population covered by Norgine: c 400m; prevalence of IDA: 11.2m (3%); on OFPs: 8.4m (75%); intolerant due to GI side-effects: 2.5m (30%). **IDA population eligible in 2018**: **2.5m (+2.5% growth pa)**. Peak penetration 12.5% in 2028: 393,000 patients on Feraccru in 2028; flat pricing €55/month (current UK £47.60); three months per treatment course as per label, plus an additional three months to ensure iron stores are replenished and prevent anaemia recurring as per clinical guidelines: €330 per six months treatment duration; **peak sales in 2028: €130m**.
	US (partnered)	IDA	2022/2029 $410m (£300m)	Population of US c 328m; prevalence of IDA: 9.2m (3%); on OFPs: 6.9m (75%); intolerant due to GI side effects: 2.1m (30%). Peak penetration 11.2% in 2029: 304,000 patients on Accrufer in 2029; flat pricing $300/month, net price £225; three months per treatment course as per the EMA label plus three months to ensure iron stores are replenished; **peak sales in 2029: $410m**.
	China (ASK Pharm)	IDA	2023/2031 $126m (£92m)	Population of China c 1,386m; prevalence of IDA: 139.3m (10%); on OFPs 104.5m (75%); intolerant due to GI side effects: 31.3m (30%). Peak penetration 5% in 2031: 1.68m patients on Feraccru in 2031; flat pricing $25/month, three months per treatment course; **peak sales in 2031: $126m**.

Source: Edison Investment Research, EvaluatePharma. Note: FX rate US$/€ – 0.83, US$/£ – 0.73, €/£ – 0.89. OFP: oral ferrous product, GI: gastrointestinal.

Sensitivities

STX is subject to various sensitivities common to speciality pharmaceutical companies, including commercialisation (pricing, reimbursement, uptake and competition), manufacturing and financing risks. The key sensitivities for STX relate to the US commercialisation strategy and associated funding risk. Additionally, our sales forecasts and valuation are dependent on the successful European commercialisation of Feraccru by licensing partner Norgine. Furthermore, with the focus on one asset in the short term, the valuation is skewed to and dependent on Feraccru/Accrufer; failure to meet our peak sales expectations and sales growth trajectory would have a serious and detrimental effect on STX's long-term strategy and our valuation. The US strategy for commercialisation is critical; if Accrufer fails to launch in the US, it would have a serious and detrimental effect on STX's long-term strategy and our valuation. If STX launches the product itself then this would ensure the product reaches the US market, but significant commercial risks, including the group's ability to recruit, train and retain adequate numbers of effective sales and marketing personnel and obtaining market access, will come into focus.

Valuation

Our revised valuation of STX is £298.5m (or 254p/share vs £379.1m or 324p/share previously) is based on a risk-adjusted net present value (NPV) model of Feraccru (Exhibit 11) for treatment of IDA in Europe (as covered by Norgine), the US market (assumed partnering deal) and China (as covered by ASK Pharm). The major changes to our valuation include adjustment of the European sales ramp up, and the delay of the US launch to 2022. We have reduced the potential upfront payment from a US partner to £10m (vs £15m previously) and delay this payment to 2021. We have also reduced the probability of success to 90% from 100% for the US to better reflect its pre-launch status. Adding in unaudited net cash at 31 December 2020 of £2.9m and using a discount rate of 10% for Europe, where the product is launched, and 12.5% for the US and China, we reach our risk-adjusted NPV of £298.5m or 254p/share. We have rolled forward our model and updated FX to reflect current spot rates. All other forecasts are unchanged.

Exhibit 11: Valuation

Product	Market	Indication	Launch	Peak	Peak sales	NPV (£m)	Probability	rNPV (£m)	rNPV/share (p)
Feraccru/Accrufer	EU5	IDA	2019	2028	€130m	115.4	100%	115.4	98.1
	US	IDA	2022	2029	$410m	144.0	90%	129.6	110.2
	China	IDA	2023	2031	$126m	74.9	75%	50.6	43.0
Net cash at 31 December 2020 (unaudited)						2.9	100%	2.9	2.5
Valuation						**337.2**		**298.5**	**253.7**

Source: Edison Investment Research

Europe assumptions: From the European market (as covered by Norgine), revenues to STX comprise a tiered royalty (25–40%) on sales; development milestones (€4.5m) and sales related milestones (up to €50m). COGS comprise the cost of manufacturing Feraccru (c 10% of sales) and a pay-away to Vitra Pharmaceuticals for royalties on Norgine sales (5%). STX will receive reimbursement for manufacture and supply and this amount will be netted against the royalty received during each period.

US assumptions: For the US, we have risk adjusted the opportunity by assigning a probability of success of 90%, in line with our treatment of assets at approved stage of development. We assume revenues comprise a flat 20% royalty rate on sales and a conservative £10m ($14m) upfront payment from a potential US partner for valuation purposes. We do not include the potential US upfront payment in our financial forecasts given the uncertainty of the timing and amount. COGS

are comprised of the cost of manufacturing Accrufer (c 3% of sales) and a pay-away to Vitra Pharmaceuticals for royalties on sales (5%).

China assumptions: For China, we have also risk adjusted the opportunity, assigning a probability of success of 75%, in line with our treatment of assets at Phase III stage of development. 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. Vitra Pharmaceuticals has elected to receive 10% of the upfront and sales-related milestones instead of royalties on future sales. 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.

In calculating the NPV, we split R&D costs and G&A evenly between Europe and the US as STX will utilise data from the paediatric study to extend Feraccru/Accrufer paediatric use in the US and apply for paediatric data exclusivity. We model both US and European sales to composition of matter patent expiry in 2035.

We have performed a sensitivity analysis (Exhibit 12), which highlights how our forecast peak sales of Feraccru/Accrufer affect our valuation of STX (which assumes a US partnering deal). Given the current share price and market cap (54.5p/share and £64m), investors are attributing zero value to both the US and China opportunities.

Exhibit 12: STX rNPV valuation (£m) sensitivity to changes in peak sales

		European peak sales (penetration) in 2028 through partner Norgine			
		€77.9m (7.5%)	€103.9m (10.0%)	**€129.8m** (12.5%)	€155.8m (15.0%)
US peak sales (penetration) in 2029 through partner	$0.0m (0.0%)	103.1	137.6	168.8	197.2
	$205.0m (5.6%)	166.9	201.4	232.6	261.0
	$409.9m (11.2%)	232.7	267.2	**298.5**	326.8
	$549.0m (15.0%)	277.3	311.9	343.1	371.4

Source: Edison Investment Research.

Financials

STX's revenues remain wholly dependent on the success of Feraccru/Accrufer. Highlights from STX's unaudited 2020 trading statement, published 15 January, are FY20 revenues of c £9.4m (FY19: £0.7m), which included the £8.7m ($11.4m) upfront licence payment from ASK Pharm and £0.7m in royalty revenue from Norgine relating to Feraccru sales in Europe. In 2021, we now forecast revenues of £4.8m (this consists of £3.9m in European royalties and a £0.9m sales milestone from partner Norgine). Our 2022 revenue forecasts assume a 20% royalty received on US sales although we do not factor any milestones (upfront or sales milestones) from a US deal into our financial forecasts.

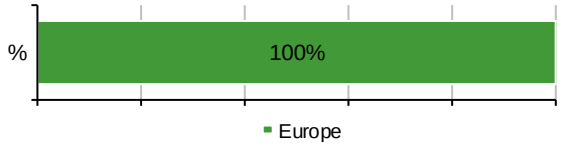
We expect R&D expenses of £2.5m in 2021 and 2022 to reduce significantly thereafter as the paediatric study wraps up. Currently we do not include any potential R&D costs for a once-a-day formulation or any other post marketing clinical trials. Selling and marketing costs are assumed as zero. Based on the operational and price assumptions outlined above, we forecast that STX will reach sustainable profitability by the end of 2022 and, in the longer term, operating margins could reach some 50% by 2024; this assumes a US partner.

Following the £8.7m ($11.4m) upfront licence payment in 2020, STX has £2.9m (unaudited) in cash as of 31 December 2020 and zero debt. Loan facilities from two major shareholders amounting to approximately £4.4m would extend the cash runway until late 2021. STX is dependent in the near term on the royalty and milestone income from partners. To fund operations beyond 2021 we forecast that an additional c £10m will need to be raised in 2021. We note that, for simplicity, in our model we currently illustrate this as a debt raise.

Exhibit 13: Financial summary

Accounts IFRS, year end 31 December	£000s	2017	2018	2019	2020e	2021e	2022e
Profit & loss							
Revenue		637	11,881	719	9,428	4,764	16,028
Cost of sales		(155)	(311)	(485)	(432)	(2,332)	(7,013)
Gross profit		482	11,570	234	8,996	2,432	9,015
Gross margin %		76%	97%	33%	95%	51%	56%
SG&A (expenses)		(16,722)	(12,429)	(6,773)	(9,550)	(6,098)	(4,959)
R&D costs		(4,711)	(4,300)	(2,496)	(2,500)	(2,500)	(2,500)
Other income/(expense)		0	0	0	0	0	0
EBITDA		(18,514)	(2,469)	(6,414)	(804)	(4,068)	3,515
Depreciation and amortisation		(2,437)	(2,690)	(2,621)	(2,250)	(2,098)	(1,959)
Reported Operating Income		(20,951)	(5,159)	(9,035)	(3,054)	(6,167)	1,556
Exceptionals and adjustments		(2,571)	0	0	0	0	0
Adjusted Operating Income		(18,380)	(5,159)	(9,035)	(3,054)	(6,167)	1,556
Finance income/(expense)		(43)	8	(31)	0	(250)	(250)
Reported PBT		(20,994)	(5,151)	(9,066)	(3,054)	(6,417)	1,306
Profit Before Tax (norm)		(18,423)	(5,151)	(9,066)	(3,054)	(6,417)	1,306
Income tax expense		1,406	3,359	266	1,200	600	(196)
Reported net income		(19,588)	(1,792)	(8,800)	(1,854)	(5,817)	1,110
Average Number of Shares Outstanding (m)		112.4	116.4	117.0	117.6	117.6	117.6
Year-end number of shares, m		112.4	116.4	117.0	117.6	117.6	117.6
Basic EPS (p)		(17.4)	(2.0)	(7.5)	(1.6)	(4.9)	0.9
EPS - normalised (p)		(15.1)	(1.5)	(7.5)	(1.6)	(4.9)	0.9
Dividend per share (p)		0.0	0.0	0.0	0.0	0.0	0.0
Balance sheet							
Property, plant and equipment		13	155	26	18	13	9
Goodwill		0	0	0	0	0	0
Intangible assets		29,961	30,957	29,898	27,906	26,063	24,358
Other non-current assets		0	0	0	0	0	0
Total non-current assets		29,974	31,112	29,924	27,924	26,075	24,367
Cash and equivalents		13,299	9,776	4,141	2,886	8,702	17,099
Inventories		125	109	948	475	1,281	1,927
Trade and other receivables		1,572	1,031	356	1,558	6,389	8,319
Other current assets		0	1,500	950	950	950	950
Total current assets		14,996	12,416	6,395	5,869	17,322	28,294
Non-current loans and borrowings		0	0	0	0	10,000	10,000
Other non-current liabilities		0	0	0	0	0	0
Total non-current liabilities		0	0	0	0	10,000	10,000
Trade and other payables		3,501	2,548	3,547	2,376	7,047	14,450
Current loans and borrowings		0	0	0	0	0	0
Other current liabilities		262	403	607	607	607	607
Total current liabilities		3,763	3,098	4,174	2,983	7,654	15,057
Equity attributable to company		41,207	40,430	32,145	30,791	25,474	27,084
Cash flow statement							
Reported net income		(19,588)	(1,792)	(8,800)	(1,854)	(5,817)	1,110
Depreciation and amortisation		2,437	2,690	2,621	2,250	2,098	1,959
Share based payments		560	1,013	456	500	500	500
Other adjustments		39	4	33	0	0	0
Movements in working capital		(186)	(255)	555	(1,901)	(966)	4,828
Interest paid / received		0	0	0	0	0	0
Income taxes paid / received		587	(1,500)	1,040	0	0	0
Cash from operations (CFO)		(16,151)	151	(4,066)	(1,005)	(3,934)	8,647
Capex		(3,408)	(3,345)	(1,384)	(250)	(250)	(250)
Acquisitions & disposals net		0	0	0	0	0	0
Other investing activities		0	50	18	0	0	0
Cash used in investing activities (CFIA)		(3,408)	(3,295)	(1,366)	(250)	(250)	(250)
Net proceeds from issue of shares		11,880	0	0	0	0	0
Movements in debt		0	0	0	0	10,000	0
Other financing activities		0	0	0	0	0	0
Cash from financing activities (CFF)		11,880	(379)	(203)	0	10,000	0
Cash and equivalents at beginning of period		20,978	13,299	9,776	4,141	2,886	8,702
Increase/(decrease) in cash and equivalents		(7,679)	(3,523)	(5,635)	(1,255)	5,816	8,397
Cash and equivalents at end of period		13,299	9,776	4,141	2,886	8,702	17,099
Closing net (debt)/cash		13,299	9,776	4,141	2,886	(1,298)	7,099

Source: Shield Therapeutics accounts, Edison Investment Research

Contact details	Revenue by geography
Northern Design Center Studio 6 3rd Floor Gateshead NE8 3DF United Kingdom +44 (0)19 1511 8500 www.shieldtherapeutics.com	

Management team

Chairman: James Karis	CEO: Tim Watts
James Karis has been a non-executive director of Shield Therapeutics since February 2016 and was appointed non-executive chairman in January 2019. He has over 35 years of experience in the pharmaceutical, healthcare services, technology and medical device industries and has previously held senior management and executive roles at CollabRx, Entelos, Inc., PAREXEL International, Pharmaco International and Baxter International. He has a BS in management and economics from Purdue University and an MA in applied economics from The American University.	Tim Watts joined Shield as CFO in August 2018 and was appointed CEO in April 2020. Tim has over 25 years' experience in the pharmaceutical and biotech sectors. He was previously CFO at Oxford Biomedica (2012–17) and Archimedes Pharma (2007–11), and spent 22 years at ICI, moving to FD of Zeneca Pharmaceuticals and then group financial controller of AstraZeneca in 2001. Tim is a qualified chartered accountant.

Principal shareholders	(%)
W. Health L.P.	47.6
AOP Orphan International AG	10.7
BlackRock Inc	4.3
Christian Schweiger	3.5
Jupiter Fund Management PLC	3.4

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