EDISON

Shield Therapeutics

FY20 results

2021 all eyes on Accrufer US launch

Pharma & biotech

Shield Therapeutics' (STX) FY20 results reported total revenue of £10.4m reflecting an $11.4m (£9.7m) upfront payment received from ASK Pharm (Feraccru out-licensing deal that covers China) and £0.7m from royalties on Feraccru sales from European partner Norgine. In March 2021, STX raised net funds of £27.8m, which will be utilised to support the US launch and commercialisation of Accrufer (iron deficiency). The focus for STX now is to establish and expand its US-based operations ahead of a Q221 launch; management will provide an update on progress in mid-May. STX expects to reach break-even on a monthly basis within 15–18 months after US launch. We value STX at £505.7m – the current share price reflects the European opportunity only according to our valuation.

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
12/19	0.7	(9.1)	(7.5)	0.0	N/A	N/A
12/20	10.4	(1.9)	(2.2)	0.0	N/A	N/A
12/21e	6.7	(22.3)	(11.1)	0.0	N/A	N/A
12/22e	27.1	(8.4)	(3.3)	0.0	N/A	N/A

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

Accrufer coming to America in June

The US commercialisation of Accrufer is key to unlocking value and FDA approval (2019) led to the broadest possible label to encompass iron deficiency of any cause. Timely launch (and subsequent market access coverage) is critical, as 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. STX has in place four US-based individuals with the relevant sales, medical liaison, supply chain and market access experience. It has also recently appointed Hans-Peter Rudolf as the group's CFO.

Financials: Cash runway to FY23

In the near term management expects initial SG&A costs of $25–30m per year (2021/22), increasing to $40–45m in year three to fund US operations to the critical mass required. The fund-raise and open offer in March has extended the cash runway to forecast break-even in FY23. Profitability in FY23 is achievable on the basis of our current forecast revenue streams ex-US (royalties of £16.2m and milestones of £13.1m) plus a minimum US sales contribution of c $25m.

Valuation: £505.7m or 234p/share

Our revised valuation is £505.7m or 234p/share versus £471.4m or 218p/share (derived from an rNPV model). Our underlying assumptions for STX remain unchanged and reflect STX-led US commercialisation. Our valuation includes reported net cash of £28.2m at 31 March 2021, we update for FX and roll forward our model. Our NPV calculation is based on Feraccru achieving peak sales of €130m in Europe, $256m in the United States and $126m in China.

4 May 2021

Price	**49p**
Market cap	**£105m**
	£0.72/US$; £0.87/€
Reported net cash (£m) at 31 March 2021	28.2
Shares in issue	215.8m
Free float	54%
Code	STX
Primary exchange	AIM
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	12.8	(3.1)	(57.2)
Rel (local)	9.0	(9.8)	(65.7)
52-week high/low		139p	33p

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. Outside of the United States Feraccru is marketed through partners Norgine, AOP Orphan and Ewopharma.

Next events

US Accrufer launch	June 2021
Launches in additional EU states as covered by Norgine	End 2021/ Early 2022
Start of Phase III paediatric study	Mid-2021

Analysts

Dr Susie Jana +44 (0)20 3077 5700

Dr John Priestner +44 (0)20 3077 5700

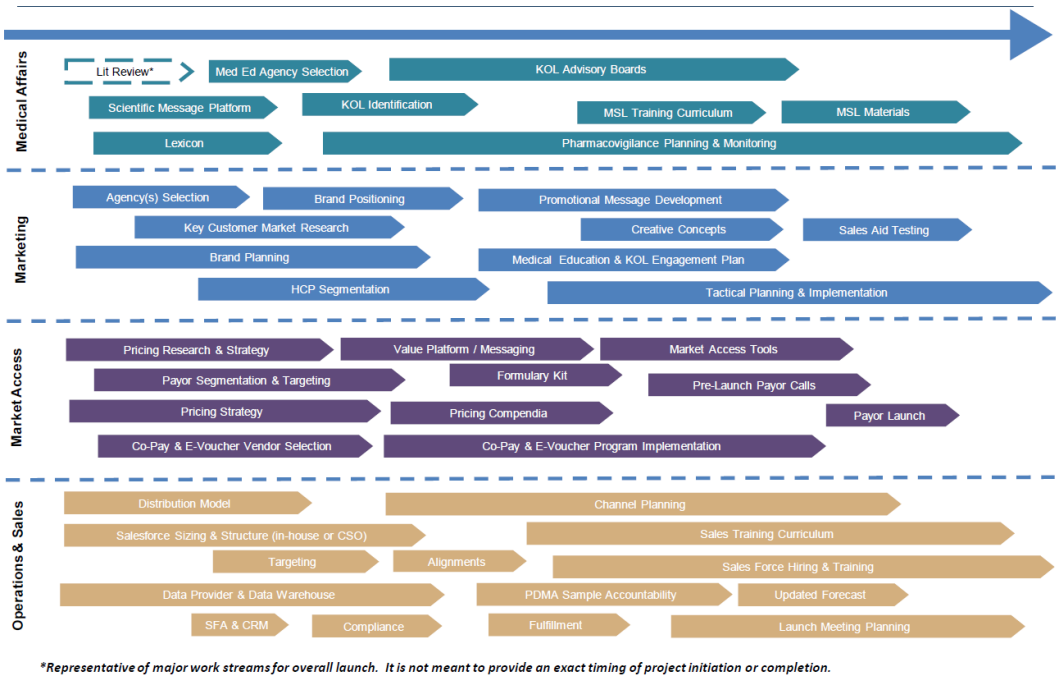
healthcare@edisongroup.com

Edison profile page

Planning a successful US launch of Accrufer

STX is working diligently to establish medical affairs, market access and sales and marketing infrastructure ahead of Accrufer's imminent US launch. Exhibit 1 highlights the major work streams in progress that are required for launch and sales execution. The US operations team consists of four executives and is now ramping up additional staff; STX will provide a market update in two to three weeks' time. Importantly, STX market research demonstrates that US prescribers believe there is unmet need and Accrufer's profile is viewed positively in terms of a clinically meaningful profile and improvement versus existing oral iron salts (good tolerability and efficacy). While 460,000 US physicians prescribe mostly oral iron tablets, STX is specifically targeting 11,000 physicians who write 30% of all US prescriptions initially, through a salesforce of 30 reps in FY21 rising to 60 reps in FY22.

Exhibit 1: Major work streams in US commercialisation process



**Representative of major work streams for overall launch. It is not meant to provide an exact timing of project initiation or completion.*

Source: STX company presentation

Norgine partnership

The commercialisation of Feraccru in Europe, Australia (recently approved) and New Zealand is in the hands of partner Norgine, and the product is now marketed by Norgine in Germany, the UK, Scandinavia (since Q420, previously AOP) and Belgium (since January 2021). Despite the significant headwind from the COVID-19 pandemic, sales volumes in Germany and the UK increased by 70% in FY20 (£0.7m royalty revenue). An unexpected reanalysis of the AEGIS-H2H data confirmed Feraccru as a credible alternative to IV therapy over the long term and will be used to negotiate pricing and reimbursement in the key markets of France, Italy and Spain. Additionally, data from the German healthcare setting (presented at the European Crohn's and Colitis Organisation (ECCO) 2020 conference) concludes that total patient drug costs were 1.6x higher for treatment with IV iron compared with Feraccru. We note that the withdrawal of Teva Pharmaceutical's European patent challenge means Feraccru's patent protection will continue to October 2035.

China launch potential in 2023

The ASK Pharm deal covers China, Hong Kong, Macau and Taiwan**.** Shield received $11.4m upfront. ASK Pharm has submitted the IND application to the Chinese regulatory authority (CDE), the agency has indicated it is likely to require a short Phase III study in inflammatory bowel disease patients before approval. The study is expected to complete in 2022, leading to potential approval and launch in 2023. STX is eligible to receive a further $11.4m milestone upon regulatory approval in China, plus royalties of 10% or 15% on net sales (depending on the level), and up to $40m in cumulative sales-related milestones. ASK Pharm is responsible for all clinical and regulatory costs and activities in addition to all manufacturing and distribution costs of goods sold in the territory.

Valuation

Our revised STX valuation of £505.7m or 234p/share (versus £471.4m or 218p/share previously) is based on a risk-adjusted net present value (NPV) model of Feraccru/Accrufer (Exhibit 2) for the treatment of iron deficiency anaemia (IDA) in Europe (as covered by Norgine), the US (STX-led commercialisation) and China (as covered by ASK Pharm). Adding reported net cash at 31 March 2021 of £28.2m and using a discount rate of 10% for Europe, where the product is launched, and 12.5% for the United States and China, we reach our risk-adjusted NPV of 234p/share. We have rolled forward our model and updated for spot FX rates. All other forecasts are unchanged.

Exhibit 2: Valuation

Product	Market	Indication	Launch	Peak	Peak sales	NPV (£m)	Probability	rNPV (£m)	rNPV/share (p)
Feraccru/Accrufer	EU5	IDA	2019	2028	€130m	114.6	100%	114.6	53.1
	US	IDA	2021	2027	$256m	346.3	90%	311.7	144.4
	China	IDA	2023	2031	$126m	75.8	75%	51.2	23.7
Net cash at 31 March 2021						28.2	100%	28.2	13.1
Valuation						**564.9**		**505.7**	**234.3**

Source: Edison Investment Research

Financials

STX's revenues remain wholly dependent on the success of Feraccru/Accrufer. STX reported FY20 revenues of £10.4m (FY19: £0.7m), which included the £9.7m ($11.4m) upfront licence payment from ASK Pharm and £0.7m in royalty revenue from Norgine relating to Feraccru sales in Europe. We forecast total revenues of £6.7m (this includes £2.0m US Accrufer sales, plus £3.8m in royalties and £0.9m sales milestone from partner Norgine on European Feraccru sales) in FY21. We expect total revenues to increase to £27.1m in FY22 (including US sales of £16.4m, plus £9.8m in royalties and a £0.9m sales milestone from Norgine).

During FY20 SG&A expenses increased to £8.6m (FY19: £6.8m) and R&D expenses were mainly flat at £2.6m (FY19: £2.5m). This resulted in an operating loss for the period of £2.2m (FY19: £9.0m). Based on its financial guidance we expect STX to move into sustainable profitability on an annualised basis from FY23. Specifically, we assume operating profit of £37.0m in FY23 based on total revenues of £84.8m (assuming potential US sales of £55.5m, European royalty contributions plus an $11.4m forecast China approval milestone payment from partner ASK Pharm). We expect rapid margin expansion and forecast operating margins could reach 52% by 2024, given 90% gross margins and that the main operating costs for the business will likely relate to US SG&A. We will monitor how sales ramp up and note that sales are dependent on gaining broad market access.

Following the post period share placing (raising £27.8m net) STX reported an unaudited cash balance of £28.2m at 31 March 2021. Management expects this is sufficient to take it to the point at which it is cash flow positive, which it expects to reach on a monthly basis within 15–18 months after US launch. Our forecast cash requirement and break-even assumptions are reliant on STX reaching our 2022 total revenue forecast of £27.1m.

Exhibit 2: Financial summary

Accounts: IFRS, Year end: 31 December	£000s	2017	2018	2019	2020	2021e	2022e
PROFIT & LOSS							
Revenue		637	11,881	719	10,387	6,651	27,076
Cost of sales		(155)	(311)	(485)	(1,354)	(2,515)	(6,559)
Gross profit		482	11,570	234	9,033	4,136	20,517
Gross margin %		76%	97%	33%	87%	62%	76%
SG&A (expenses)		(16,722)	(12,429)	(6,773)	(8,608)	(23,980)	(26,427)
R&D costs		(4,711)	(4,300)	(2,496)	(2,579)	(2,500)	(2,500)
Other income/(expense)		0	0	0	0	0	0
EBITDA		(18,514)	(2,469)	(6,414)	551	(20,289)	(6,493)
Depreciation and amortisation		(2,437)	(2,690)	(2,621)	(2,705)	(2,055)	(1,917)
Reported operating income		(20,951)	(5,159)	(9,035)	(2,154)	(22,344)	(8,410)
Exceptionals and adjustments		(2,571)	0	0	0	0	0
Adjusted operating income		(18,380)	(5,159)	(9,035)	(2,154)	(22,344)	(8,410)
Finance income/(expense)		(43)	8	(31)	268	0	0
Reported profit before tax		(20,994)	(5,151)	(9,066)	(1,886)	(22,344)	(8,410)
Adjusted profit before tax		(18,423)	(5,151)	(9,066)	(1,886)	(22,344)	(8,410)
Income tax expense		1,406	3,359	266	(744)	600	1,261
Reported net income		(19,588)	(1,792)	(8,800)	(2,630)	(21,744)	(7,148)
Average number of shares outstanding (m)		112.4	116.4	117.0	117.2	195.5	215.8
Year-end number of shares, m		116.4	116.4	117.2	117.6	215.8	215.8
Basic EPS (p)		(17.4)	(2.0)	(7.5)	(2.2)	(11.1)	(3.3)
EPS - normalised (p)		(15.1)	(1.5)	(7.5)	(2.2)	(11.1)	(3.3)
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	32	22	16
Intangible assets		29,961	30,957	29,898	27,266	25,471	23,811
Other non-current assets		0	0	0	0	0	0
Total non-current assets		29,974	31,112	29,924	27,298	25,493	23,826
Cash and equivalents		13,299	9,776	4,141	2,940	8,518	4,160
Inventories		125	109	948	1,379	1,382	1,802
Trade and other receivables		1,572	1,031	356	619	9,528	14,399
Other current assets		0	1,500	950	292	292	292
Total current assets		14,996	12,416	6,395	5,230	19,720	20,653
Non-current loans and borrowings		0	0	0	0	0	0
Other non-current liabilities		0	0	0	0	0	0
Total non-current liabilities		0	0	0	0	0	0
Trade and other payables		3,501	2,548	3,547	1,471	7,600	13,515
Current loans and borrowings		0	0	0	0	0	0
Other current liabilities		262	550	627	781	781	781
Total current liabilities		3,763	3,098	4,174	2,252	8,381	14,296
Equity attributable to company		41,207	40,430	32,145	30,276	36,832	30,184
CASH FLOW STATEMENT							
Reported net income		(19,588)	(1,792)	(8,800)	(2,630)	(21,744)	(7,148)
Depreciation and amortisation		2,437	2,690	2,621	2,705	2,055	1,917
Share based payments		560	1,013	456	771	500	500
Other adjustments		39	3	31	(3)	0	0
Movements in working capital		(186)	(255)	555	(2,630)	(2,783)	624
Interest paid/received		0	(8)	31	(268)	0	0
Income taxes paid/received		587	(1,500)	1,040	655	0	0
Cash from operations (CFO)		(16,151)	151	(4,066)	(1,400)	(21,972)	(4,108)
Capex		(3,408)	(3,345)	(1,384)	(23)	(250)	(250)
Acquisitions & disposals net		0	0	0	0	0	0
Other investing activities		0	50	18	3	0	0
Cash used in investing activities (CFIA)		(3,408)	(3,295)	(1,366)	(20)	(250)	(250)
Net proceeds from issue of shares		11,880	0	0	0	27,800	0
Movements in debt		0	0	0	0	0	0
Other financing activities		0	(379)	(203)	(47)	0	0
Cash from financing activities (CFF)		11,880	(379)	(203)	(47)	27,800	0
Cash and equivalents at beginning of period		20,978	13,299	9,776	4,141	2,940	8,518
Increase/(decrease) in cash and equivalents		(7,679)	(3,523)	(5,635)	(1,467)	5,578	(4,358)
Effect of FX on cash and equivalents		0	0	0	266	0	0
Cash and equivalents at end of period		13,299	9,776	4,141	2,940	8,518	4,160
Closing net (debt)/cash		13,299	9,776	4,141	2,940	8,518	4,160

Source: Shield company accounts, Edison Investment research

General disclaimer and copyright

This report has been commissioned by Shield Therapeutics and prepared and issued by Edison, in consideration of a fee payable by Shield Therapeutics. Edison Investment Research standard fees are £49,500 pa for the production and broad dissemination of a detailed note (Outlook) following by regular (typically quarterly) update notes. Fees are paid upfront in cash without recourse. Edison may seek additional fees for the provision of roadshows and related IR services for the client but does not get remunerated for any investment banking services. We never take payment in stock, options or warrants for any of our services.

Accuracy of content: All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable, however we do not guarantee the accuracy or completeness of this report and have not sought for this information to be independently verified. Opinions contained in this report represent those of the research department of Edison at the time of publication. Forward-looking information or statements in this report contain information that is based on assumptions, forecasts of future results, estimates of amounts not yet determinable, and therefore involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of their subject matter to be materially different from current expectations.

Exclusion of Liability: To the fullest extent allowed by law, Edison shall not be liable for any direct, indirect or consequential losses, loss of profits, damages, costs or expenses incurred or suffered by you arising out or in connection with the access to, use of or reliance on any information contained on this note.

No personalised advice: The information that we provide should not be construed in any manner whatsoever as, personalised advice. Also, the information provided by us should not be construed by any subscriber or prospective subscriber as Edison's solicitation to effect, or attempt to effect, any transaction in a security. The securities described in the report may not be eligible for sale in all jurisdictions or to certain categories of investors.

Investment in securities mentioned: Edison has a restrictive policy relating to personal dealing and conflicts of interest. Edison Group does not conduct any investment business and, accordingly, does not itself hold any positions in the securities mentioned in this report. However, the respective directors, officers, employees and contractors of Edison may have a position in any or related securities mentioned in this report, subject to Edison's policies on personal dealing and conflicts of interest.

Australia

Edison Investment Research Pty Ltd (Edison AU) is the Australian subsidiary of Edison. Edison AU is a Corporate Authorised Representative (1252501) of Crown Wealth Group Pty Ltd who holds an Australian Financial Services Licence (Number: 494274). This research is issued in Australia by Edison AU and any access to it, is intended only for "wholesale clients" within the meaning of the Corporations Act 2001 of Australia. Any advice given by Edison AU is general advice only and does not take into account your personal circumstances, needs or objectives. You should, before acting on this advice, consider the appropriateness of the advice, having regard to your objectives, financial situation and needs. If our advice relates to the acquisition, or possible acquisition, of a particular financial product you should read any relevant Product Disclosure Statement or like instrument.

New Zealand

The research in this document is intended for New Zealand resident professional financial advisers or brokers (for use in their roles as financial advisers or brokers) and habitual investors who are "wholesale clients" for the purpose of the Financial Advisers Act 2008 (FAA) (as described in sections 5(c) (1)(a), (b) and (c) of the FAA). This is not a solicitation or inducement to buy, sell, subscribe, or underwrite any securities mentioned or in the topic of this document. For the purpose of the FAA, the content of this report is of a general nature, is intended as a source of general information only and is not intended to constitute a recommendation or opinion in relation to acquiring or disposing (including refraining from acquiring or disposing) of securities. The distribution of this document is not a "personalised service" and, to the extent that it contains any financial advice, is intended only as a "class service" provided by Edison within the meaning of the FAA (i.e. without taking into account the particular financial situation or goals of any person). As such, it should not be relied upon in making an investment decision.

United Kingdom

This document is prepared and provided by Edison for information purposes only and should not be construed as an offer or solicitation for investment in any securities mentioned or in the topic of this document. A marketing communication under FCA Rules, this document has not been prepared in accordance with the legal requirements designed to promote the independence of investment research and is not subject to any prohibition on dealing ahead of the dissemination of investment research.

This Communication is being distributed in the United Kingdom and is directed only at (i) persons having professional experience in matters relating to investments, i.e. investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "FPO") (ii) high net-worth companies, unincorporated associations or other bodies within the meaning of Article 49 of the FPO and (iii) persons to whom it is otherwise lawful to distribute it. The investment or investment activity to which this document relates is available only to such persons. It is not intended that this document be distributed or passed on, directly or indirectly, to any other class of persons and in any event and under no circumstances should persons of any other description rely on or act upon the contents of this document.

This Communication is being supplied to you solely for your information and may not be reproduced by, further distributed to or published in whole or in part by, any other person.

United States

Edison relies upon the "publishers' exclusion" from the definition of investment adviser under Section 202(a)(11) of the Investment Advisers Act of 1940 and corresponding state securities laws. This report is a bona fide publication of general and regular circulation offering impersonal investment-related advice, not tailored to a specific investment portfolio or the needs of current and/or prospective subscribers. As such, Edison does not offer or provide personal advice and the research provided is for informational purposes only. No mention of a particular security in this report constitutes a recommendation to buy, sell or hold that or any security, or that any particular security, portfolio of securities, transaction or investment strategy is suitable for any specific person.

Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
1185 Avenue of the Americas
3rd Floor, New York, NY 10036
United States of America

Sydney +61 (0)2 8249 8342
Level 4, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia