

Shield Therapeutics

Regulatory update

FDA approval attained, sales execution now key

Shield Therapeutics' primary asset, Feraccru, has been approved by the FDA for the treatment of iron deficiency in patients with any underlying cause – the broadest possible label. It will be marketed in the US as Accrufer. This is upside to our previous assumptions and increases our peak sales potential to c\$420m (vs c \$250m previously). Successfully commercialising Feraccru/Accrufer through partners is now key to Shield realising its value. We expect Shield to out-license the US rights during the next 18 months. An upfront licensing payment would extend Shield's cash reach beyond our current forecast of H220. We now value Shield at £273m.

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
12/17	0.64	(18.42)	(15.2)	0.0	N/A	N/A
12/18	11.88	(5.15)	(1.5)	0.0	N/A	N/A
12/19e	3.14	(9.23)	(6.4)	0.0	N/A	N/A
12/20e	3.17	(9.92)	(7.5)	0.0	N/A	N/A

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

Broadest label possible opens up US market

There remains a significant need globally for a tolerable oral iron therapy and this approval has now de-risked the opportunity in the US. Due to a broader than predicted label, we increase our peak sales forecasts for the US to c \$420m vs \$250m previously. We retain our peak sales forecast of c €130m for the EU5 states, as covered by Norgine. With positive data in hand from the AEGIS-H2H study, demonstrating non-inferiority to the market-leading iv iron (Vifor's Ferinject 2018 sales of c \$0.9bn), Accrufer could quickly generate significant market share in both the US and EU.

Partner execution key to sustaining top-line growth

Out-licensing Accrufer in the US is now the next step to commercialisation. Furthermore, an upfront licensing payment would alleviate the need to raise additional capital by mid-2020. With the approved broad label of Accrufer, we anticipate that Shield will be able to negotiate deal terms in line or better than those achieved with Norgine in Europe. We forecast sustainable profitability from 2022, with gross margins nearing c 50–60% in the long term. With Norgine now actively marketing Feraccru in Germany and the UK, we anticipate an uptick in sales during 2019. Further launches in additional European markets during 2020 (and potentially in the US contingent on a deal) will aid revenue growth (Shield receives royalties on sales).

Valuation: £273m or 231p/share

Our revised valuation of Shield at £273m or 231p/share vs £177m or 152p/share (derived from an rNPV model) reflects the removal of regulatory risk from our valuation and the increased market opportunity as a result of the broad US label. We have also updated for FX and rolling forward our model in time. Uncertainty about the eventual outcomes from patent challenges raised by Teva Pharmaceuticals still represents c 35% downside to our base case (82p/share).

Pharma & biotech

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Price 176p

Market cap £206m

US\$/£0.80; €/£0.90

Net cash (£m) at 31 December 2018 9.8

Shares in issue 117.2m

Free float 29%

Code STX

Primary exchange AIM

Secondary exchange N/A

Share price performance



%	1m	3m	12m
Abs	(9.2)	17.0	168.8
Rel (local)	(10.2)	16.4	176.3

52-week high/low 121p 31p

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 currently marketed through partners Norgine, AOP Orphan and Ewopharma.

Next events

Out-licensing US rights to Feraccru	2019/2020
Publication of AEGIS-H2H data	H219
Launches in the US and additional EU states as covered by Norgine	2020

Analysts

Dr Susie Jana	+44 (0)20 3077 5700
Dr Daniel Wilkinson	+44 (0)20 3077 5734
Dr Sean Conroy	+44 (0)20 3077 5700

healthcare@edisongroup.com
[Edison profile page](#)

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Exhibit 1: Financial summary

Accounts: IFRS, year-end: December, £000s	2016	2017	2018	2019e	2020e
PROFIT & LOSS					
Revenue	304	637	11,881	3,139	3,169
Operating revenues	304	637	11,881	3,139	3,169
Cost of sales	(100)	(155)	(311)	(544)	(1,718)
Gross profit	204	482	11,570	2,595	1,450
Gross margin %	n/a	n/a	n/a	n/a	1
SG&A (expenses)	(10,675)	(16,722)	(12,438)	(7,324)	(6,668)
R&D costs	(2,029)	(4,711)	(4,300)	(4,500)	(4,500)
Other income/(expense)	40	0	0	0	0
EBITDA (reported)	(10,524)	(18,514)	(2,814)	(6,905)	(7,550)
Depreciation and amortisation	(1,936)	(2,437)	(2,354)	(2,324)	(2,168)
Reported Operating Income	(12,460)	(20,951)	(5,168)	(9,229)	(9,718)
Exceptionals and adjustments	(2,157)	(2,571)	0	0	0
Adjusted Operating Income	(10,303)	(18,380)	(5,168)	(9,229)	(9,718)
Finance income/(expense)	(3,143)	(43)	15	0	(200)
Reported PBT	(15,603)	(20,994)	(5,153)	(9,229)	(9,918)
Adjusted PBT	(13,446)	(18,423)	(5,153)	(9,229)	(9,918)
Income tax expense	587	1,406	3,359	1,800	1,200
Reported net income	(15,016)	(19,588)	(1,794)	(7,429)	(8,718)
Basic average number of shares, m	101.2	112.4	116.4	116.4	116.4
Year-end number of shares, m	101.2	112.4	116.4	116.4	116.4
Basic EPS (p)	(14.84)	(17.43)	(2.00)	(6.38)	(7.49)
Adjusted EPS (p)	(12.71)	(15.15)	(1.54)	(6.38)	(7.49)
Dividend per share (p)	0.00	0.00	0.00	0.00	0.00
BALANCE SHEET					
Property, plant and equipment	19	13	8	6	4
Goodwill	0	0	0	0	0
Intangible assets	28,984	29,961	30,957	28,885	26,969
Other non-current assets	0	0	0	0	0
Total non-current assets	29,003	29,974	30,965	28,891	26,973
Cash and equivalents	20,978	13,299	9,776	4,827	6,746
Inventories	418	125	109	598	1,888
Trade and other receivables	1,985	1,572	1,031	1,974	6,964
Other current assets	0	0	1,500	1,500	1,500
Total current assets	23,381	14,996	12,416	8,900	17,097
Non-current loans and borrowings	0	0	0	0	8,000
Other non-current liabilities	0	0	0	0	0
Total non-current liabilities	0	0	0	0	8,000
Trade and other payables	3,827	3,501	2,548	3,887	10,384
Current loans and borrowings	0	0	0	0	0
Other current liabilities	161	262	403	403	403
Total current liabilities	3,988	3,763	2,951	4,290	10,787
Equity attributable to company	48,396	41,207	40,430	33,501	25,283
CASH FLOW STATEMENT					
Reported net income	(15,016)	(19,588)	(1,794)	(7,429)	(8,718)
Depreciation and amortisation	1,936	2,437	2,354	2,324	2,168
Share based payments	288	560	1,013	500	500
Other adjustments	3,382	39	4	1	1
Movements in working capital	(846)	(186)	(255)	(93)	218
Interest paid / received	0	0	0	0	0
Income taxes paid / received	0	587	(1,500)	0	0
Cash from operations (CFO)	(10,256)	(16,151)	(178)	(4,699)	(5,832)
Capex	(3,175)	(3,408)	(3,345)	(250)	(250)
Acquisitions & disposals net	0	0	0	0	0
Other investing activities	177	0	0	0	0
Cash used in investing activities (CFIA)	(2,998)	(3,408)	(3,345)	(250)	(250)
Net proceeds from issue of shares	33,507	11,880	0	0	0
Movements in debt	0	0	0	0	8,000
Other financing activities	0	0	0	0	0
Cash from financing activities (CFF)	33,507	11,880	0	0	8,000
Cash and equivalents at beginning of period	725	20,978	13,299	9,776	4,827
Increase/(decrease) in cash and equivalents	20,253	(7,679)	(3,523)	(4,949)	1,918
Cash and equivalents at end of period	20,978	13,299	9,776	4,827	6,746
Net (debt)/cash	20,978	13,299	9,776	4,827	(1,254)

Source: Company accounts, Edison Investment Research

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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
1,185 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