

# Shield Therapeutics

Corporate update

## Feraccru performs again in a Phase III study

Shield Therapeutics has announced positive top-line data from a Phase IIIb study (AEGIS-H2H) for Feraccru, a CHMP-approved oral formulation of iron positioned for the treatment of iron deficiency (ID) with or without anaemia. The data demonstrate that Feraccru is non-inferior to the market-leading IV iron (Ferinject) and has triggered a €2.5m payment from its marketing partner Norgine. Additional near-term revenue (royalties and milestones) can be expected as Norgine continues the rollout of Feraccru across Europe in 2020. In the US, we expect Feraccru approval in 2019 and that Shield will seek a marketing partner thereafter. We maintain our valuation of Shield at £178m or 153p/share.

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
12/16	0.30	(13.5)	(12.7)	0.0	N/A	N/A
12/17	0.64	(18.4)	(15.2)	0.0	N/A	N/A
12/18e	11.90	(5.9)	(3.6)	0.0	N/A	N/A
12/19e	3.04	(9.3)	(6.7)	0.0	N/A	N/A

Note: \*PBT and EPS are normalised, excluding amortisation of acquired intangibles and exceptional items.

## Positive data will aid top-line growth for Shield

The AEGIS-H2H marketing study, comparing Feraccru (an oral iron treatment) to the market-leading IV iron (Ferinject), has reported promising top-line data; demonstrating that Feraccru is a non-inferior treatment option for IDA patients compared to Ferinject. We believe this data will increase clinical uptake and positively impact pricing negotiations and reimbursement. This will aid sales growth as partner Norgine continues to roll out Feraccru in Europe. We expect US Feraccru approval later this year (PDUFA date 27 July 2019). The AEGIS-H2H data strengthen Feraccru's profile and will make the asset more attractive to a potential US marketing partner.

## Feraccru demonstrates a non-inferiority complex

AEGIS-H2H was a multi-national Phase IIIb study in 242 inflammatory bowel disease (IBD) patients with iron deficiency anaemia (IDA). Shield has [announced](#) today that the primary endpoint of the study was met and after 12 weeks treatment on Feraccru, patients showed improvement in their haemoglobin levels within 9% (p = 0.022) to those receiving Ferinject (the current standard of care). The data demonstrate that Feraccru provides an alternative to IV iron in treating IDA. A more detailed analysis of the secondary endpoints can be expected at the company's FY18 preliminary results (due in April 2019).

## Valuation: £178m or 153p/share

Our valuation of Shield remains unchanged at £178m or 153p/share. As detailed in our initiation note '[Fortified for growth](#)', our valuation is based on a risk-adjusted NPV model of Feraccru for IDA in Europe and for CKD/IBD-related IDA in the US market. Our NPV calculation is based on Feraccru achieving 2029 peak sales of £334m in Europe (€133m) and the US (\$251m), utilised a 10% discount rate and risk-adjusted the US opportunity accordingly (75% probability of success).

Pharma & biotech

4 March 2019

**Price** **54p**

**Market cap** **£63m**

US\$/£0.76, €/£0.87, US\$/€0.87

Net cash (£m) at 31 December 2018 9.8

Shares in issue 116.4m

Free float 28%

Code STX

Primary exchange AIM

Secondary exchange N/A

### Share price performance



% 1m 3m 12m

Abs 7.4 59.6 201.4

Rel (local) 5.8 57.6 204.6

52-week high/low 58p 16p

### Business description

Shield Therapeutics is a commercial-stage pharmaceutical company. Its proprietary product, Feraccru, is approved by the EMA for iron deficiency and is undergoing review with the US FDA. Feraccru is currently marketed through partners Norgine, AOP Orphan and Ewopharma.

### Next events

FY18 preliminary results April 2019

Feraccru US PDUFA date 27 July 2019

Feraccru launches in additional European countries 2020

### Analysts

Dr Susie Jana +44 (0)20 3077 5700

Dr Daniel Wilkinson +44 (0)20 3077 5734

Dr Sean Conroy +44 (0)20 3681 2534

[healthcare@edisongroup.com](mailto:healthcare@edisongroup.com)

[Edison profile page](#)

**Shield Therapeutics**  
Shield Therapeutics is a research client of Edison Investment Research Limited

**Exhibit 1: Financial summary**

Accounts: IFRS, Yr end: December, GBP: Thousands	2016A	2017A	2018E	2019E	2020E	2021E
Revenue	304.0	637.0	11,900.0	3,036.9	2,702.2	14,591.7
Operating revenues	304.0	637.0	11,900.0	3,036.9	2,702.2	14,591.7
Cost of sales	(100.0)	(155.0)	(300.0)	(531.1)	(1,532.2)	(6,170.0)
Gross profit	204.0	482.0	11,600.0	2,505.8	1,170.0	8,421.7
Gross margin %	n/a	n/a	n/a	n/a	0.9	0.9
SG&A (expenses)	(10,675.0)	(16,722.0)	(12,451.0)	(7,326.8)	(6,671.8)	(6,028.4)
R&D costs	(2,029.0)	(4,711.0)	(5,000.0)	(4,500.0)	(4,500.0)	(3,500.0)
Other income/(expense)	40.0	0.0	0.0	0.0	0.0	0.0
EBITDA (reported)	(10,524.0)	(18,514.0)	(3,600.0)	(6,994.2)	(7,830.0)	921.7
Depreciation and amortisation	(1,936.0)	(2,437.0)	(2,251.0)	(2,326.8)	(2,171.8)	(2,028.4)
Reported Operating Income	(12,460.0)	(20,951.0)	(5,851.0)	(9,321.1)	(10,001.9)	(1,106.7)
Exceptionals and adjustments	(2,157.0)	(2,571.0)	0.0	0.0	0.0	0.0
Adjusted Operating Income	(10,303.0)	(18,380.0)	(5,851.0)	(9,321.1)	(10,001.9)	(1,106.7)
Finance income/(expense)	(3,143.0)	(43.0)	(20.0)	0.0	(200.0)	(200.0)
Reported PBT	(15,603.0)	(20,994.0)	(5,871.0)	(9,321.1)	(10,201.9)	(1,306.7)
Adjusted PBT	(13,446.0)	(18,423.0)	(5,871.0)	(9,321.1)	(10,201.9)	(1,306.7)
Income tax expense	587.0	1,406.0	1,800.0	1,800.0	1,200.0	600.0
Reported net income	(15,016.0)	(19,588.0)	(4,071.0)	(7,521.1)	(9,001.9)	(706.7)
Basic average number of shares, m	101.2	112.4	112.4	112.4	112.4	112.4
Year-end number of shares, m	101.2	112.4	112.4	112.4	112.4	112.4
Basic EPS (p)	(14.84)	(17.43)	(3.62)	(6.69)	(8.01)	(0.63)
Adjusted EPS (p)	(12.71)	(15.15)	(3.62)	(6.69)	(8.01)	(0.63)
Dividend per share (p)	0.00	0.00	0.00	0.00	0.00	0.00
<b>Balance sheet</b>						
Property, plant and equipment	19.0	13.0	15.1	16.6	17.6	18.3
Goodwill	0.0	0.0	0.0	0.0	0.0	0.0
Intangible assets	28,984.0	29,961.0	30,963.9	28,891.6	26,974.8	25,201.7
Other non-current assets	0.0	0.0	0.0	0.0	0.0	0.0
Total non-current assets	29,003.0	29,974.0	30,979.0	28,908.2	26,992.4	25,220.0
Cash and equivalents	20,978.0	13,299.0	9,803.6	4,669.8	5,088.8	6,150.8
Inventories	418.0	125.0	329.7	583.6	1,683.8	3,390.1
Trade and other receivables	1,985.0	1,572.0	2,225.3	1,889.9	5,938.8	14,121.0
Other current assets	0.0	0.0	0.0	0.0	0.0	0.0
Total current assets	23,381.0	14,996.0	12,358.6	7,143.3	12,711.4	23,661.9
Non-current loans and borrowings	0.0	0.0	0.0	0.0	8,000.0	8,000.0
Other non-current liabilities	0.0	0.0	0.0	0.0	0.0	0.0
Total non-current liabilities	0.0	0.0	0.0	0.0	8,000.0	8,000.0
Trade and other payables	3,827.0	3,501.0	5,439.6	5,106.6	9,260.7	18,645.5
Current loans and borrowings	0.0	0.0	0.0	0.0	0.0	0.0
Other current liabilities	161.0	262.0	262.0	262.0	262.0	262.0
Total current liabilities	3,988.0	3,763.0	5,701.6	5,368.6	9,522.7	18,907.5
Equity attributable to company	48,396.0	41,207.0	37,636.0	30,683.0	22,181.1	21,974.4
<b>Cashflow statement</b>						
Reported net income	(15,016.0)	(19,588.0)	(4,071.0)	(7,521.1)	(9,001.9)	(706.7)
Depreciation and amortisation	1,936.0	2,437.0	2,251.0	2,326.8	2,171.8	2,028.4
Share based payments	288.0	560.0	500.0	500.0	500.0	500.0
Other adjustments	3,382.0	39.0	0.0	0.5	0.5	0.5
Movements in working capital	(846.0)	(186.0)	1,080.6	(183.6)	(995.0)	(503.7)
Interest paid / received	0.0	0.0	0.0	0.0	0.0	0.0
Income taxes paid / received	0.0	587.0	0.0	0.0	0.0	0.0
Cash from operations (CFO)	(10,256.0)	(16,151.0)	(239.4)	(4,877.8)	(7,325.0)	1,318.0
Capex	(3,175.0)	(3,408.0)	(3,256.0)	(256.0)	(256.0)	(256.0)
Acquisitions & disposals net	0.0	0.0	0.0	0.0	0.0	0.0
Other investing activities	177.0	0.0	0.0	0.0	0.0	0.0
Cash used in investing activities (CFIA)	(2,998.0)	(3,408.0)	(3,256.0)	(256.0)	(256.0)	(256.0)
Net proceeds from issue of shares	33,507.0	11,880.0	0.0	0.0	0.0	0.0
Movements in debt	0.0	0.0	0.0	0.0	8,000.0	0.0
Other financing activities	0.0	0.0	0.0	0.0	0.0	0.0
Cash from financing activities (CFF)	33,507.0	11,880.0	0.0	0.0	8,000.0	0.0
Cash and equivalents at beginning of period	725.0	20,978.0	13,299.0	9,803.6	4,669.8	5,088.8
Increase/(decrease) in cash and equivalents	20,253.0	(7,679.0)	(3,495.4)	(5,133.8)	419.0	1,062.0
Cash and equivalents at end of period	20,978.0	13,299.0	9,803.6	4,669.8	5,088.8	6,150.8
Net (debt) cash	20,978.0	13,299.0	9,803.6	4,669.8	(2,911.2)	(1,849.2)

Source: Shield Therapeutics 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 Edison analyst 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 of 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.

**Copyright:** Copyright 2019 Edison Investment Research Limited (Edison). All rights reserved FTSE International Limited ("FTSE") © FTSE 2019. "FTSE®" is a trade mark of the London Stock Exchange Group companies and is used by FTSE International Limited under license. All rights in the FTSE indices and/or FTSE ratings vest in FTSE and/or its licensors. Neither FTSE nor its licensors accept any liability for any errors or omissions in the FTSE indices and/or FTSE ratings or underlying data. No further distribution of FTSE Data is permitted without FTSE's express written consent.

---

## Australia

Edison Investment Research Pty Ltd (Edison AU) is the Australian subsidiary of Edison. Edison AU is a Corporate Authorised Representative (1252501) of Myonlineadvisers Pty Ltd who holds an Australian Financial Services Licence (Number: 427484). 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

Neither this document and associated email (together, the "Communication") constitutes or form part of any offer for sale or subscription of, or solicitation of any offer to buy or subscribe for, any securities, nor shall it or any part of it form the basis of, or be relied on in connection with, any contract or commitment whatsoever. Any decision to purchase shares in the Company in the proposed placing should be made solely on the basis of the information to be contained in the admission document to be published in connection therewith.

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 (nor will such persons be able to purchase shares in the placing).

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

The Investment Research is a publication distributed in the United States by Edison Investment Research, Inc. Edison Investment Research, Inc. is registered as an investment adviser with the Securities and Exchange Commission. 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  
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