EDISON

Shield Therapeutics

China licence deal

Feraccru out-licensed in China

Pharma & biotech

Shield Therapeutics has kick-started 2020 by securing an out-licensing deal in China for its primary asset, Feraccru/Accrufer. The exclusive deal with China-based Beijing Aosaikang Pharmaceutical (ASK Pharm) covers China, Hong Kong, Macau and Taiwan. 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 China launch in 2023. Shield will receive an upfront licensing payment of $11.4m which, importantly, has extended the cash runway into 2021. The next key inflection point is a US partnering deal, which we assume will occur in the next 12 months; upfront payments from a deal will enhance Shield's balance sheet further. We value Shield at £346.8m

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	2.99	(7.87)	(5.2)	0.0	N/A	N/A
12/20e	11.14	(0.35)	0.7	0.0	N/A	N/A

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

China a large market in volume terms

China represents a large market in volume terms. Although at lower pricing than the US and European opportunity, the licensing deal adds to Feraccru's overall value proposition. Under the deal terms with ASK Pharm, Shield will receive $11.4m as an upfront payment and is eligible for a further $11.4m on approval in China. Shield will receive tiered royalties of 10% or 15% of net sales of Feraccru/Accrufer (throughout the duration of the intellectual property) plus up to $40m in sales-related milestones. ASK Pharma 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 (forecast for 2023).

Financials: Cash runway extended into 2021

Shield reported an H119 cash position of £6.6m, and we estimate 2019 cash burn of £5.6m. The upfront payment of $11.4m from ASK Pharma extends the cash runway into 2021, and we expect a US partnering deal (2020) and associated upfront licensing payment to strengthen the balance sheet, further reducing the requirement for a capital increase. With ongoing growth in Europe and a US launch on the horizon, we forecast that sustainable profitability is achievable from 2022, with gross margins nearing c 50–60% in the long term.

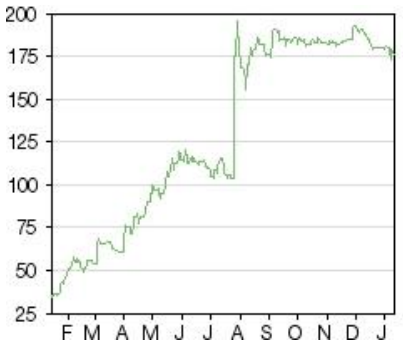
Valuation: £346.8m or 296p/share

Our revised valuation of Shield at £346.8m or 296p/share vs £273m or 233p/share (derived from an rNPV model) reflects the inclusion of the China licensing deal. We have also updated for FX and rolling forward our model. Our NPV calculation is based on Feraccru achieving peak sales of €133m in Europe, $420m in the US and $126m in China, utilises a 10% discount rate and risk-adjusts the China opportunity accordingly (75% probability of success).

13 January 2020

Price	**176.5p**
Market cap	**£207m**
	£0.77/US$; £0.90/€
Net cash (£m) at 30 June 2019	6.6
Shares in issue	116.4m
Free float	29%
Code	STX
Primary exchange	AIM
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(6.1)	(2.8)	451.6
Rel (local)	(10.6)	(9.0)	398.8
52-week high/low		196p	34p

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

Out-licensing US rights to Feraccru	2020
Launches in the US and additional EU states as covered by Norgine	2020/21

Analyst

Dr Susie Jana +44 (0)20 3077 5700

healthcare@edisongroup.com

Edison profile page

China one of two licensing deals delivered in 2020

Higher prevalence of iron deficiency anaemia in China

In the US, the FDA has granted Feraccru/Accrufer the broadest label for the treatment of iron deficiency with or without anaemia. We discuss the prevalence of iron deficiency anaemia (IDA) given the wide availability of data. It is the most common cause of anaemia globally (c 50%) – the Global Burden of Disease Study 2015 estimated that IDA was prevalent in c 1.5 billion people globally. The prevalence of iron deficiency itself is higher than IDA. IDA is the most common nutritional disorder globally, yet it remains underdiagnosed and under treated across all countries. Prevalence of IDA varies by country, but it is estimated that c 3% of the population across Europe and the US is diagnosed with IDA. According to 2002 data from the China National Nutrition and Health Survey, anaemia prevalence in China was 20.1%. Anaemia prevalence rates are higher in women of child-bearing age and the elderly compared to the national average. Nutrition plays a large part in the high prevalence rates in China and the nutritional disease control target proposed by the development of the Chinese Food and Nutrition Program (2014–30) aims at an anaemia prevalence rate of less than 10% for the whole population.

China decent deal dynamics with ASK Pharm

The ASK Pharm licensing terms are comparable to the Norgine partnership deal in Europe, where Shield received a non-refundable upfront licence payment of £11m and is eligible for up to €51.4m in milestone payments. Under the previously agreed European deal, Shield will receive a tiered royalty rate of 25–40% from sales of Feraccru (brand name Europe), and in China the royalty rate has been announced as 10–15%. In Europe, Shield is responsible for the manufacture and supply of Feraccru, as well as the initiation and completion of a Phase III paediatric study. Shield will receive reimbursement for manufacture and supply.Under the terms of the China deal, ASK Pharm is responsible for all clinical and regulatory costs, as well as manufacturing and distribution costs. Given the low number of Chinese patients in the Phase III clinical trials held to date (conducted in the US and EU), we believe the China regulatory body for drug approval, the National Medical Products Administration (NMPA) will require a single confirmatory Phase III trial in Chinese patients as part of the NDA submission. In recent years, the NMPA approval times on drugs, particularly where there is an unmet need, has been swifter and we therefore forecast that launch in 2023 is feasible, assuming a one- to two-year trial duration. We forecast peak sales in China of $126m in 2031 However, given the multiple swing factors in this high-volume market, we have exercised caution and use lower pricing ($25 per month vs €55 per month in Europe) and penetration rates (peak penetration 5% of eligible patients vs 12.5% in Europe) than our EU assumptions. Our China sales forecasts could prove conservative.

US market largest value driver

The US is the largest contributor to our valuation of Feraccru/Accrufer, given higher potential pricing dynamics and a broad prescribing label, as the FDA approved it for the treatment of iron deficiency with or without anaemia. We anticipate the announcement of a commercial partner in 2020 and launch in the US later in the year. Upfront payments from a US deal would bolster Shield's balance sheet further, potentially reducing reliance on a capital raise in the near term. We forecast that sustainable profitability is achievable from 2022, with gross margins nearing c 50–60% in the long term.

Valuation

Our valuation of Shield Therapeutics, at £346.8m or 296p/share vs £273m or 233p/share (Exhibit 1) is based on a risk-adjusted NPV model of Feraccru for the treatment of IDA in Europe (as covered by Norgine) and for CKD/IBD-related ID in the US market. We forecast that Feraccru will achieve peak sales in Europe of €133m after 10 years in 2028 (and grow 2.5% pa until 2035). In the US, we believe peak sales of $420m will be achieved in 2030 (and grow 2.5% pa until 2035). We include China peak sales of $126m (2031) for the first time, which are risk-adjusted at 75% to reflect the requirement for Phase III data in China patients and regulatory risk. In addition, the valuation has benefited from rolling forward the DCF and updating FX rates.

Exhibit 1: Financial summary

Product	Market	Launch/peak		Peak sales	NPV	Probability	rNPV	rNPV/ share
Feraccru	EU5	2019	2028	€133m	£110.2m	100%	£110.2m	94.1p
	US	2020	2030	$420m	£177.0m	100%	£177.0m	151.0p
	China	2023	2031	$126m	£70.7m	75%	£53.0m	45.2p
Net cash at 30 June 2019					£6.6m	100%	£6.6m	5.6p
Valuation					£364.5m		£346.8m	295.9p

Source: Edison Investment Research

Exhibit 2: Financial summary

December	£000s	2017	2018	2019e	2020e	2021e
PEOFIT & LOSS						
Revenue		637	11,881	2,993	11,139	8,501
Cost of sales		(155)	(311)	(536)	(1,729)	(4,106)
Gross profit		482	11,570	2,458	9,410	4,395
Gross margin %		76%	97%	82%	84%	52%
SG&A (expenses)		(16,722)	(12,438)	(7,324)	(6,758)	(6,107)
R&D costs		(4,711)	(4,300)	(3,000)	(3,000)	(3,000)
Other income/(expense)		0	0	0	0	0
EBITDA		(18,514)	(2,814)	(5,542)	1,910	(2,605)
Depreciation and amortisation		(2,437)	(2,354)	(2,324)	(2,258)	(2,107)
Reported Operating Income		(20,951)	(5,168)	(7,867)	(348)	(4,712)
Exceptionals and adjustments		(2,571)	0	0	0	0
Adjusted Operating Income		(18,380)	(5,168)	(7,867)	(348)	(4,712)
Finance income/(expense)		(43)	15	0	0	0
Reported PBT		(20,994)	(5,153)	(7,867)	(348)	(4,712)
Profit Before Tax (norm)		(18,423)	(5,153)	(7,867)	(348)	(4,712)
Income tax expense		1,406	3,359	1,800	1,200	600
Reported net income		(19,588)	(1,794)	(6,067)	852	(4,112)
Average Number of Shares Outstanding (m)		112.4	116.4	116.4	116.4	116.4
Year-end number of shares, m		112.4	116.4	116.4	116.4	116.4
Basic EPS (p)		(17.43)	(2.00)	(5.21)	0.73	(3.53)
EPS - normalised (p)		(15.2)	(1.5)	(5.2)	0.7	(3.5)
Dividend per share (p)		0.00	0.00	0.00	0.00	0.00
BALANCE SHEET						
Property, plant and equipment		13	8	6	4	3
Goodwill		0	0	0	0	0
Intangible assets		29,961	30,957	30,085	28,079	26,223
Other non-current assets		0	0	0	0	0
Total non-current assets		29,974	30,965	30,091	28,083	26,226
Cash and equivalents		13,299	9,776	4,148	7,755	2,829
Inventories		125	109	589	1,900	2,256
Trade and other receivables		1,572	1,031	1,883	6,882	12,605
Other current assets		0	1,500	1,500	1,500	1,500
Total current assets		14,996	12,416	8,120	18,038	19,190
Non-current loans and borrowings		0	0	0	0	0
Other non-current liabilities		0	0	0	0	0
Total non-current liabilities		0	0	0	0	0
Trade and other payables		3,501	2,548	2,944	9,502	12,409
Current loans and borrowings		0	0	0	0	0
Other current liabilities		262	403	403	403	403
Total current liabilities		3,763	2,951	3,347	9,905	12,812
Equity attributable to company		41,207	40,430	34,863	36,215	32,603
CASH FLOW STATEMENT						
Reported net income		(19,588)	(1,794)	(6,067)	852	(4,112)
Depreciation and amortisation		2,437	2,354	2,324	2,258	2,107
Share based payments		560	1,013	500	500	500
Other adjustments		39	4	0	0	0
Movements in working capital		(186)	(255)	(936)	247	(3,171)
Interest paid/received		0	0	0	0	0
Income taxes paid/received		587	(1,500)	0	0	0
Cash from operations (CFO)		(16,151)	(178)	(4,178)	3,857	(4,676)
Capex		(3,408)	(3,345)	(1,450)	(250)	(250)
Acquisitions & disposals net		0	0	0	0	0
Other investing activities		0	0	0	0	0
Cash used in investing activities (CFIA)		(3,408)	(3,345)	(1,450)	(250)	(250)
Net proceeds from issue of shares		11,880	0	0	0	0
Movements in debt		0	0	0	0	0
Other financing activities		0	0	0	0	0
Cash from financing activities (CFF)		11,880	0	0	0	0
Cash and equivalents at beginning of period		20,978	13,299	9,776	4,148	7,755
Increase/(decrease) in cash and equivalents		(7,679)	(3,523)	(5,628)	3,607	(4,926)
Cash and equivalents at end of period		13,299	9,776	4,148	7,755	2,829
Net (debt)/cash		13,299	9,776	4,148	7,755	2,829

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