EDISON

Shield Therapeutics

H122 update

Tangible progress in US Accrufer launch

Pharma and biotech

Shield Therapeutics reported H122 results reflecting the fact that its commercial activities for Accrufer are bearing fruit. US total prescriptions soared fourfold to 11,223 compared to H221, including an 87% q-o-q increase in Q222. This compares well with our existing and unchanged forecast for 26,700 prescriptions for 2022. We maintain our long-term Accrufer growth assumptions, and continued successful execution could lead to material upside in the shares, in our view, but we reiterate that Shield will need additional capital to execute its growth plans.

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
12/20	10.4	0.8	0.1	0.0	112.0	N/A
12/21	1.5	(17.5)	(8.4)	0.0	N/A	N/A
12/22e	5.8	(20.0)	(8.3)	0.0	N/A	N/A
12/23e	15.9	(17.9)	(6.5)	0.0	N/A	N/A

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

US market gains drive sales growth

Shield reported £2.0m (+322% y-o-y) in H122 sales, of which £1.2m was attributable to US Accrufer sales (H121: zero) and £0.66m (+42% y-o-y) from sales royalties for Feraccru sales in Europe from licensing partner Norgine. The company reported gross profit of £1.15m in H122, reflecting a 56.4% margin, and an H122 EBITDA loss of £10.6m. We expect further market share gains will be needed to cover Shield's overhead costs and continue to forecast profitability in FY25.

Further funding needed to optimise sales opportunity

Shield finished H122 with £2.4m in gross cash with no debt, and in August borrowed $10m (£8.7m) from shareholder AOP in the form of a convertible loan maturing at year-end 2023. The company expects this shareholder loan to provide funding to the end of 2022, and we expect it will need an additional £28m by end FY24 to reach operating profitability. Shield indicates that it is engaging with various parties to secure additional financing opportunities or strategic partnerships to extend its cash runway.

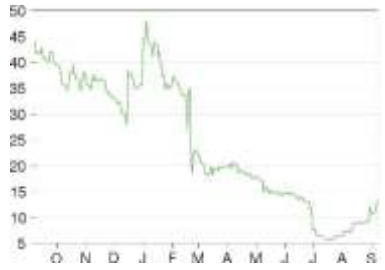
Valuation: Higher rNPV offset by increased S/O

Our longer-term growth and margin expectations are unchanged, but we have revised our FX assumptions (£0.87/US$ versus £0.84/US$ previously). We now obtain a valuation of £377.0m, up from £371.0m previously. However, given the increased share count following the August conversion of £2.275m of the AOP loan into 41.2m new shares, our per-share equity valuation is now 146p/share, down from 172p/share previously.

8 September 2022

Price	**13.1p**
Market cap	**£34m**
	£0.87/US$; £0.86/€
Net cash (£m) at 30 June 2022	2.4
Shares in issue	257.4m
Free float	55%
Code	STX
Primary exchange	AIM
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	82.6	(9.9)	(69.6)
Rel (local)	88.8	(4.9)	(68.5)
52-week high/low		48.0p	5.8p

Business description

Shield Therapeutics is a commercial-stage pharmaceutical company. Its proprietary product, Feraccru/Accrufer, is approved by the EMA and FDA for iron deficiency. Outside the United States, Feraccru is marketed internationally through Shield and its commercial partners.

Next events

Launches in additional EU states as covered by Norgine	H222
Further acceptance of Accrufer into key US PBM formularies	H222

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Edison profile page

Accrufer sales momentum evident in H1 results

Shield's H122 results demonstrated that its US commercial initiatives for Accrufer, its novel FDA-approved iron therapy, are bearing fruit, as US total prescriptions soared fourfold to 11,223 compared to H221 (versus 2,516). Momentum continued to be strong in the latter part of the period, with prescriptions growing 87% q-o-q in Q222, following a sequential doubling in Q122 (versus Q421). The total number of prescriptions reported in H122 compares well with our existing forecast for 26,700 prescriptions for FY22 as a whole. The company also reported that its average net selling price for Accrufer in H122 was $152 (versus $34 in H221), reducing the gross-to-net sales price adjustment from 93% to 70%, which it attributes to increased commercial payer and state-run Medicaid coverage. We believe that Shield's longer-term goal, as it strengthens its PBM, insurer and distributor relationships, is for this discount to level off at c 50% over the coming years.

The strong growth level in H121 is impressive but not surprising, given we stated in our last note that Accrufer's July 2021 US launch had been preceded by limited pre-marketing activities, resulting in relatively low market awareness at the time of launch and curtailing H221 uptake. Shield has made significant strides in raising product awareness and securing reimbursement, as Accrufer now has coverage of more than 100 million insured lives.

Shield reported £2.0m (+322% y-o-y) in H122 sales, of which £1.2m was attributable to US Accrufer sales (H121: zero) and £0.66m (+42% y-o-y) from sales royalties for Feraccru sales in Europe from licensing partner Norgine. Shield also recognised £0.1m as an upfront licence payment from its commercial partner in Canada, KYE Pharmaceuticals. Shield reported gross profit of £1.15m in H122, reflecting a 56.4% margin, with cost of sales comprising manufacturing costs for prescriptions sold in the US and Europe, plus a 5% royalty on net sales payable to Vitra Pharmaceuticals (the original owner of the intellectual property associated with Accrufer/Feraccru).

SG&A costs of £10.8m in H122 (excluding intangible amortisation of £1.1m) were up from £4.8m in H121, with the increase primarily attributable to US commercialisation activities. This is essentially in line, when considered on an annualised basis, with our existing FY22 estimate of £22.3m. H122 R&D costs of £1.0m (down 36% y-o-y, but above our prior FY22 estimate of £0.67m) were largely attributable to Shield's ongoing paediatric study assessing Feraccru/Accrufer in infants, children and adolescents. The company reported that enrolment is progressing as planned, with more than 75% of study sites now active.

We calculate an H122 EBITDA loss of £10.6m, which suggests that further Accrufer sales and market penetration will be required to cover Shield's overhead costs, as we expected. We are encouraged that Accrufer's sales growth trajectory is robust and consistent with our expectations. The net loss was £11.8m (up from a £7.3m loss in H121) and the net H122 operating cash burn was £8.8m. Shield had also capitalised development expenditures of £1.3m in relation to the paediatric study, and we calculate H122 free cash outflow at £10.1m.

Financials

In its outlook, Shield commented that it expects continued Accrufer sales growth in H222, driven by increased demand and payer coverage, and higher royalties from increased European sales. Its objective in H222 will be to drive US Accrufer sales growth momentum by raising product awareness, generating clinical experience data and further expanding payer coverage. It is also looking to increase its sales and marketing resources by potentially expanding its salesforce and engaging in targeted marketing initiatives. Shield currently has a 30-person US sales team, and we estimate the need for a 160–175-person sales team in the long term to target the 65,000 high prescribing physicians (out of a total of c 550,000) who, according to market research prepared for

Shield, write 60% of oral iron prescriptions in the United States. Given the current cash burn rate and the need to further expand resources to optimise the Accrufer sales opportunity, the company commented that it is engaging with various parties to secure additional financing opportunities or strategic partnerships to extend its cash runway.

Shield finished H122 with £2.4m in gross cash with no debt. In August 2022, it completed its loan transaction with shareholder AOP, enabling it to borrow $10m (£8.7m) from AOP in the form of a single-tranche convertible loan maturing at year-end 2023 and bearing interest at 9.1% above the secured overnight financing rate (SOFR). Following finalisation of the loan agreement, AOP converted £2.275m of the loan into 41.2m shares at a conversion price of 5.5215p per share. Shield expects the loan to provide funding to the end of 2022.

As trends for SG&A and prescription growth in H122 are largely in line with our existing estimates, we have made only relatively minor changes to our forecasts. We have lowered our average net FY22 US revenue per Accrufer prescription from $192.9 to $170, and mildly reduced our gross margin estimates for FY22 and FY23. These effects are offset by the appreciation of the US dollar (as we now use a £0.87/US$ assumption versus £0.84/US$ previously). We now expect FY22 and FY23 revenue of £5.8m and £15.9m, respectively (versus our previous forecasts of £6.2m and £16.2m, respectively) and for gross profit margin of 67.4% and 73.2% (versus 71.6% and 75.1%, previously). We have raised our FY22 and FY23 R&D cost expectations by c £1.3m in both years due to the higher-than-expected study costs shown in the H122 results.

We now forecast an EBITDA loss of £20.2m in FY22 and £16.3m in FY23 versus our prior estimates of £18.0m and £14.0m, respectively. We also model and free cash outflow of £20.1m in FY22 and £20.4m in FY23 versus our prior estimates of £20.2m and £16.2m, respectively.

We continue to expect Shield to achieve positive operating profit by FY25 and, consistent with company guidance, assume that following the $10m (£8.4m) convertible debt financing arrangement with AOP, its cash on hand will fund operations into FY23. We estimate the need to raise a further £28m (up from £25m previously) before the end of FY24 (modelled as illustrative debt) before Shield reaches the point of generating sustained profitability from Accrufer/Feraccru-related revenue. We note that if future financing needs are met through equity issues rather than debt, there could be material dilution to current shareholders (depending on the prevailing share price).

Valuation

We continue to evaluate the company based on a risk-adjusted net present value (rNPV) model of Feraccru/Accrufer for the treatment of iron deficiency anaemia (IDA) in Europe (as covered by Norgine), the United States (Shield-led commercialisation) and China (as covered by ASK Pharm). For the United States and Europe, where the drug is already launched and approved, we have used a probability of success of 100% and a 10% discount rate, while for China (where the product has not been launched yet) we assume a 75% probability of success and a 12.5% discount rate.

We have not made any material changes to our long-term Accrufer sales and gross margin forecasts, but have adjusted our FY22 and FY23 estimates, as mentioned previously, and our FX assumptions (we now use a £0.87/US$ assumption versus £0.84/US$ previously). Our valuation also assumes a 30 June 2022 pro forma net cash position of £4.7m to reflect the August 2022 conversion of a portion of the AOP convertible debt, as described above.

Exhibit 1: Shield Therapeutics rNPV valuation

Product	Market	Launch	Sales* (£m) in 2030	NPV (£m)	Probability of success	rNPV (£m)	rNPV/basic share (£)
Accrufer in IDA	US	2021	221	403.7	100%	403.7	1.57
Feraccru in IDA	Europe	2019	37	41.6	100%	41.6	0.16
Feraccru in IDA	China	2024	66	60.7	75%	45.5	0.18
Corporate costs				(118.6)		(118.6)	(0.46)
Net cash at 30 June 2022 (adjusted for post-period end debt-to-equity conversion)				4.7		4.7	0.02
Total equity value						377.0	1.46

Source: Edison Investment Research. Note: *Reflects end-market net sales. Shield is expected to receive a percentage of net sales as royalty revenue in Europe and China, and recognise product sales in the US.

As a result of these changes, we increase our valuation to £377.0m (from £371.0m previously). However, given the increased share count following the conversion of a portion of the AOP convertible debt to equity, our per-share valuation is now 146p/share, down from 172p/share previously.

We highlight that the US opportunity remains a key value driver and represents more than 80% of our valuation for the company (excluding corporate costs). Given that Shield is self-commercialising in the United States, successful execution remains a key sensitivity.

We also note that the debt-to-equity conversion feature of the remaining c £6.43m shareholder loan, if actioned and converted at the current trading price of c 13p, would result in the issue of c 49.4m shares and the added dilution would result in the valuation being adjusted to 125p/share. We highlight that the current share price is at a substantial discount to our revised valuation, which we believe is largely due to investors pricing in risks associated with the uncertainty as it relates to how future financing needs will be met. That said, we believe that if Shield can manage its financing needs with minimal dilution and can execute on its US commercialisation strategy for Accrufer, there could be material upside in the shares, as suggested by our valuation analysis.

Exhibit 2: Financial summary

£'000s	2020	2021	2022e	2023e	2024e
31-December	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	10,387	1,519	5,810	15,879	40,988
Cost of Sales	(1,354)	(980)	(1,896)	(4,254)	(8,437)
Gross Profit	9,033	539	3,915	11,625	32,551
Sales, General & Administrative	(5,903)	(17,816)	(22,287)	(26,294)	(35,112)
Net Research & Development	(2,579)	(579)	(1,827)	(1,653)	(696)
EBITDA	551	(17,856)	(20,199)	(16,322)	(3,258)
Depreciation & amortisation of intangible assets	(2,705)	(2,207)	(2,166)	(2,254)	(2,250)
Normalised Operating Profit (ex. amort, SBC, except.)	551	(17,856)	(20,199)	(16,322)	(3,258)
Operating profit before exceptionals	(2,154)	(20,063)	(22,365)	(18,577)	(5,507)
Exceptionals including asset impairment	0	111	0	0	0
Other	0	0	0	0	0
Reported Operating Profit	(2,154)	(19,952)	(22,365)	(18,577)	(5,507)
Net Finance income (costs)	268	387	218	(1,597)	(2,229)
Profit Before Tax (norm)	819	(17,469)	(19,981)	(17,920)	(5,486)
Profit Before Tax (FRS 3)	(1,886)	(19,565)	(22,147)	(20,174)	(7,736)
Tax	(744)	229	(354)	0	0
Profit After Tax and minority interests (norm)	75	(17,240)	(20,335)	(17,920)	(5,486)
Profit After Tax and minority interests (FRS 3)	(2,630)	(19,336)	(22,501)	(20,174)	(7,736)
Average Basic Number of Shares Outstanding (m)	117.2	204.0	243.8	276.3	276.3
EPS - normalised (p)	0.1	(8.4)	(8.3)	(6.5)	(2.0)
EPS - normalised and fully diluted (p)	0.1	(8.4)	(8.3)	(6.5)	(2.0)
EPS - (IFRS) (p)	(2.2)	(9.5)	(9.2)	(7.3)	(2.8)
Dividend per share (p)	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed Assets	27,298	27,155	28,575	28,121	27,221
Intangible Assets	27,266	26,851	27,868	26,914	25,464
Tangible Assets	32	304	707	1,207	1,757
Investments in long-term financial assets	0	0	0	0	0
Current Assets	5,230	17,258	6,685	5,322	6,486
Short-term investments	0	0	0	0	0
Cash	2,940	12,117	1,115	700	1,864
Other	2,290	5,141	5,570	4,622	4,622
Current Liabilities	(2,252)	(3,380)	(3,252)	(3,252)	(3,252)
Creditors	(2,252)	(3,380)	(3,252)	(3,252)	(3,252)
Short term borrowings	0	0	0	0	0
Long Term Liabilities	0	0	(6,425)	(26,425)	(34,425)
Long term borrowings	0	0	(6,425)	(26,425)	(34,425)
Other long-term liabilities	0	0	0	0	0
Net Assets	30,276	41,033	25,583	3,766	(3,970)
CASH FLOW STATEMENT					
Operating Income	(2,154)	(19,952)	(22,365)	(18,577)	(5,507)
Movements in working capital	(2,711)	(1,415)	(557)	948	0
Net interest and financing income (expense)	268	387	218	(1,597)	(2,229)
Depreciation & other	0	0	0	0	0
Taxes and other adjustments	3,197	4,242	5,152	611	2,250
Net Cash Flows from Operations	(1,400)	(16,738)	(17,552)	(18,615)	(5,486)
Capex and capitalised expenditures	(23)	(2,064)	(2,503)	(1,800)	(1,350)
Acquisitions/disposals	0	0	0	0	0
Interest received & other investing activities	3	13	235	0	0
Net Cash flows from Investing activities	(20)	(2,051)	(2,268)	(1,800)	(1,350)
Net proceeds from share issuances	6	27,705	2,332	0	0
Net movements in long-term debt	0	0	6,425	20,000	8,000
Dividends	0	0	0	0	0
Other financing activities	(53)	(121)	0	0	0
Net Cash flows from financing activities	(47)	27,584	8,757	20,000	8,000
Effects of FX on Cash & equivalents	266	382	61	0	0
Net Increase (decrease) in cash & equivalents	(1,201)	9,177	(11,002)	(415)	1,164
Cash & equivalents at beginning of period	4,141	2,940	12,117	1,115	700
Cash & equivalents at end of period	2,940	12,117	1,115	700	1,864
Closing net debt/(cash)	(2,940)	(12,117)	5,310	25,725	32,561
Lease debt	28	156	0	0	0
Closing net debt/(cash) inclusive of IFRS 16 lease debt	(2,912)	(11,961)	5,310	25,725	32,561
Free cash flow	(1,423)	(18,802)	(20,055)	(20,415)	(6,836)

Source: Company accounts, Edison Investment Research

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