

Shield Therapeutics

Business update

Viatrix strategic partnership to expedite scale-up

Shield Therapeutics has announced a co-commercialisation deal for Accrufer in the US with Nasdaq-listed Viatrix, which will involve an expanded salesforce and a 55%/45% revenue/cost split between the two companies. Although this is a clear departure from Shield's stated self-commercialisation strategy in the US, we see merits in the deal, with the combined resources allowing Shield a faster sales ramp-up and quicker time to profitability. The decision coincides with a US\$18.5m (£15.1m) equity raise and an additional \$10m in funding from its largest shareholder, AOP Heath. We estimate that this raise should be sufficient to take the company to break-even, provided revenue targets are achieved. We have updated our estimates to incorporate the deal economics and fund-raise. Our overall valuation increases to £403.4m (versus £377.0m previously), but our implied per-share valuation declines to 79p/share (versus 146p/share previously) due to the higher post-equity raise share count.

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
12/20	10.4	0.8	0.1	0.0	N/A	N/A
12/21	1.5	(17.5)	(8.4)	0.0	N/A	N/A
12/22e	8.8	(15.7)	(6.5)	0.0	N/A	N/A
12/23e	24.4	(21.3)	(4.2)	0.0	N/A	N/A

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

Viatrix deal: A strategic decision with merit

The co-marketing deal with Viatrix will be based on a 'principal-agent' model, which will see the companies splitting revenues and costs in a 55/45 ratio. Shield will recognise all revenues with Viatrix's share adjusted in COGS. Importantly, the deal will see the Accrufer-dedicated salesforce expand to 100 (50 each from Shield and Viatrix) vs 30 currently, which should result in broader and more effective market coverage in the target primary care and obstetrician/gynaecologist (OBGYN) space and allow Shield to leverage Viatrix's established relationship with payors. Shield will also receive a \$5m upfront payment and a further \$30m in staggered milestone payments, with a FY25 US sales target of \$150m and cash flow positivity in Q424.

New funding offers potential headroom to profitability

Concurrent with the deal, Shield announced an additional \$10m convertible debt raise from its largest shareholder AOP (interest-free until 2024, repayment by end 2026) and an equity issue (£15.1 placement and subscription and £3.9m open offer) to raise up to £19m to aid salesforce expansion and support the company's growth plans. Based on our cash burn projections, these combined funds should be sufficient to take the company to cash flow positivity, which we anticipate in Q125.

Valuation: Higher rNPV offset by increased shares outstanding

We update our estimates for Accrufer in the US to incorporate the deal economics with Viatrix. Our overall valuation increases to £403.4m from £377.0m previously. However, given the anticipated increase in share count following the proposed equity raise (estimated 251.5m shares, 97.7% of current shares outstanding), our implied per-share valuation declines to 79p/share, from 146p/share previously.

Pharma and biotech

16 December 2022

Price **7.13p**
Market cap **£18m**

£0.81/US\$; £0.86/€

Est. net cash (£m) at 31 December 2022 13.8

Shares in issue (excluding December 2022 equity raise) 257.4m

Free float 55%

Code STX

Primary exchange AIM

Secondary exchange N/A

Share price performance



%	1m	3m	12m
Abs	(40.4)	(35.2)	(76.1)
Rel (local)	(40.5)	(36.2)	(76.0)
52-week high/low		48p	6p

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. Having followed a self-commercialisation strategy in the United States until now, Shield announced a co-commercialisation deal with Nasdaq-listed Viatrix in December 2022.

Next events

Launches in additional EU states as covered by Norgine	H123
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Further acceptance of Accrufer into key US PBM formularies	H123
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Viartis collaboration: Strategically sound

Nasdaq-listed Viartis is well-recognised in the generics/branded generics space, with a market capitalisation of \$13.7bn and reported sales of \$17.8m in 2021. It was formed in November 2020 with the merger of leading generics player Mylan and Pfizer's off-patent branded and generics division Upjohn. Given Viartis's broad market footprint, established relationships with healthcare-focused shareholders and resources at hand, we see this co-marketing agreement as a positive development for Shield and its growth plans for the US market. In our last [note](#), we highlighted the need for broader on-ground salesforce coverage, market share expansion and access to capital to optimise the potential for Accrufer in the iron deficiency (with or without anaemia) space. We believe this collaboration will allow Shield to accelerate its scale-up plans for Accrufer and achieve break-even more quickly, a key consideration given the challenges associated with accessing incremental external capital to fund growth.

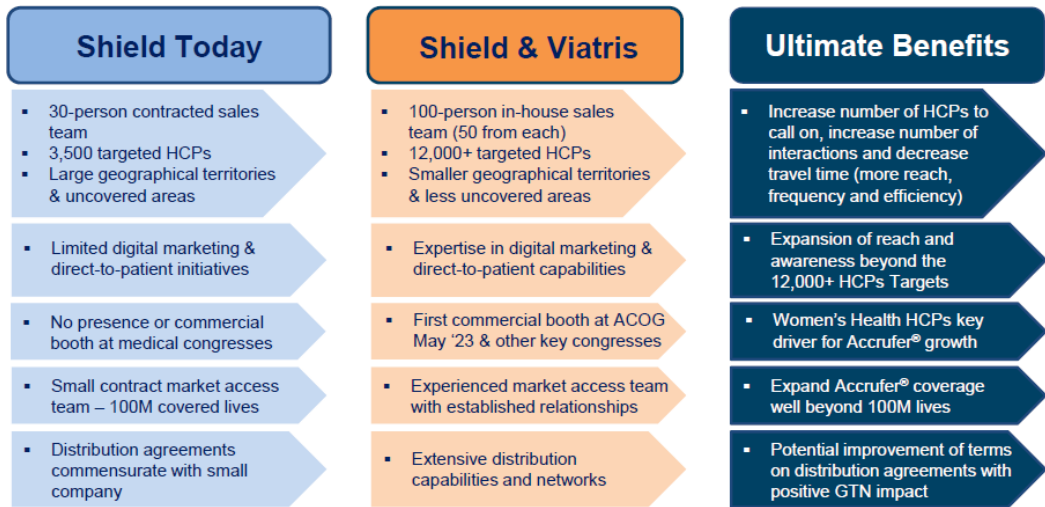
Favourable deal economics...

As part of the co-marketing and commercialisation deal, Shield and Viartis will each employ a dedicated team of 50 sales personnel to market Accrufer to relevant health care professionals (HCPs), which in this case include primary care physicians and OB-GYNs, who together account for more than 80% of oral iron prescriptions in the US, according to Shield. The revenue and costs split will be 55%/45% in favour of Shield, with each company funding its own selling and marketing expenses. Shield will receive an upfront payment of \$5m (expected to be received before end December 2022) and is eligible to receive up to \$30m in milestone payments based on achieving certain revenue targets (\$7.5m each for every incremental \$50m increase in revenue between \$100 and \$250m). Shield will book 100% of the combined collaboration revenues with Viartis's share reflected as COGS.

...with opportunity to accelerate sales ramp-up

Notwithstanding the reduced gross margins because of the aforementioned financial treatment, we see the collaboration bringing several benefits for Shield. Firstly, the expanded salesforce (100 vs the current 30) should allow for broader market coverage and an increased number of touch points with relevant stakeholders, which we believe will have an incremental flowthrough impact on prescription figures. With its current salesforce, Shield is targeting c 3,500 HCPs and expects this number to ramp up to 12,000 with the additional hires. Viartis also has a well-developed digital marketing infrastructure and established relationships with US payors/pharmacy benefit managers and distributors, which it can leverage to improve market awareness of and access for Accrufer. Increased prescriptions should, in turn, translate into accelerated revenues which, combined with the benefits of the shared costs, should allow the company to reach break-even faster than anticipated previously. While management estimates that the company will become cash flow positive by Q424, our projections suggest a slightly more conservative timeline of Q125. Exhibit 1 shows the potential benefits from the Viartis deal.

Exhibit 1: Potential benefits from the Viatris partnership

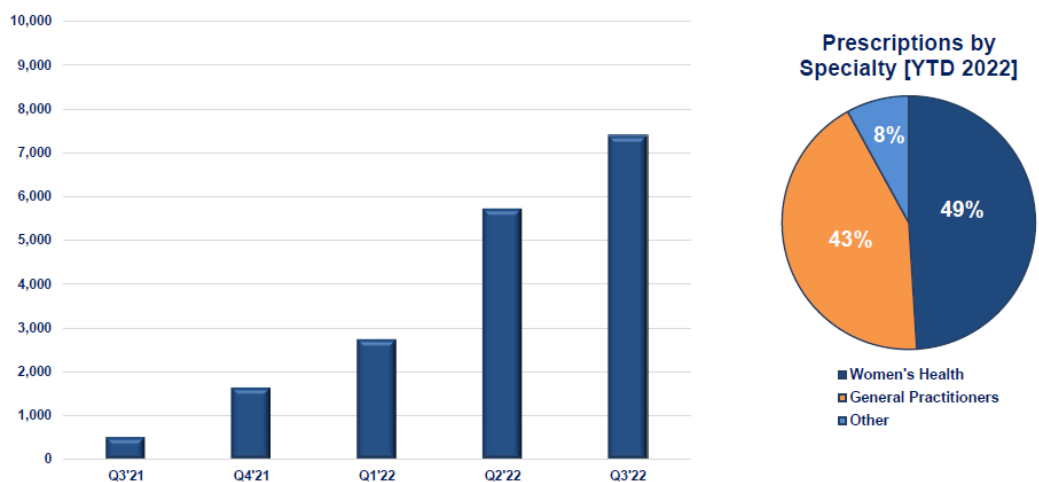


Source: Shield Therapeutics presentation, December 2022

Sales momentum driven by growth in prescription demand

Shield reported c £3m in sales in the first nine months of FY22 (9M22) versus c £1m in Q322, of which c £2m was attributable to US Accrufer sales (Q322: c £1m), a £0.2m upfront licence payment from commercial partner KYE Pharma in Canada and £0.8m (Q322: c £0.14m) from sales royalties for Feraccru sales in Europe from licensing partner Norgine. US total prescriptions continue to track up, growing to 15,872 at the end of Q322 vs 8,477 in H122 (Q322: 7,395) (Exhibit 2). Management expects Q422 prescriptions to be around 9,700, which adds up to around 25,600 prescriptions for the full year, broadly in line with our previous estimate of 26,700. Based on Q322 US sales and prescriptions, we calculate the average net selling price for Accrufer of \$151 in Q322, similar to the H122 average price of \$152. This translates to a gross-to-net sales price discount of 70%, which management plans to bring down to the eventual target of 50% by FY25, driven by growing prescription volumes and increased commercial payor and state-run Medicaid coverage. Accrufer now has coverage of more than 100 million insured lives (40% of all covered lives in the US) and is on the formulary list of three of the top four pharmacy benefit managers (PBMs) in the US.

Exhibit 2: Quarter-on-quarter growth in prescription volumes



Source: Shield Therapeutics presentation, December 2022

Following the deal with Viatris, Shield also provided its internal targets for prescription growth volumes across FY23–25 (Exhibit 3). Based on the expected Q422 average salesforce number of 22 and prescription figure of 9,700 (as communicated by management during the investor webinar on 14 December), we calculate the number of prescriptions, per salesperson, per quarter at c 440. Applying these data to a 100-member salesforce translates to 176,000 prescriptions per year (440 x 4 x 100). This is ahead of management’s FY23 target and appears achievable, in our view. The FY24 and FY25 targets are more aggressive in comparison (assuming 2x and 3x growth in prescriptions per salesperson), although not implausible provided the employed salesforce can achieve the required market coverage and Shield gains more traction with payors, with support from Viatris.

Exhibit 3: Management’s internal estimates for prescription volumes

	FY23e	FY24e	FY25e
Total number of Accrufer prescriptions	144,590	395,300	580,000
As percentage of total prescription oral iron market	1.1%	2.9%	4.3%

Source: Shield Therapeutics, 13 December 2022

Balance sheet healthy following recent raises

In parallel with the announcement of the partnership with Viatris, Shield also announced that it would raise up to £27m in additional capital through a combination of convertible debt and equity issues (placement, subscription and open offer):

- An additional \$10m (£8.15m) convertible debt issue to largest shareholder AOP Health (27% current shareholding in Shield). This is an extension of the initial agreement with AOP, signed in August 2022, under which the company invested \$10m in Shield 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. Of this, \$2.8m was immediately converted into 41.2m shares in Shield at a conversion price of 5.5215p per share. The new offering will attract the same interest rate but after a 12-month, interest-free period. The loan maturity has been extended to end 2026, with Shield holding the option to close the loan earlier. As part of the extension, 5.2m warrants were issued to AOP with a strike price of 6.75p and an expiration date of 6 January 2033.
- \$18m through a placement and equity subscription. The issue was oversubscribed with the company raising \$18.5m (£15.1m) in gross proceeds in exchange for 251,495,378 ordinary shares at an issue price of 6p (at a 11.1% discount to the closing price of 6.75p on 12 December). AOP has subscribed to 22.7% of the share issue (57.1m shares), while 4.6% (11.5m shares) has been subscribed for by Shield’s directors and management. The new shares represent 97.7% of pre-issue shares outstanding and are expected to enter circulation by 6 January 2023 (and no later than 31 January 2023).
- The company is also undertaking an open offer to qualifying shareholders to issue an aggregate of 64,346,927 shares for gross proceeds of up to £3.9m. One additional share will be offered for every four held. We note that the open offer is not underwritten, so final proceeds raised may vary from the target.

Management aims to utilise the total funds received – c \$38m including an upfront payment of \$5m from Viatris, \$18.5m raised for the share subscription and placement, an additional \$10m received from AOP and a potential \$4.8m (£3.9m) from the open offer – to support the committed salesforce expansion (\$13m), amplify its digital marketing efforts (\$8m), expand payor access and distribution channels (\$3m) and for ongoing working capital needs (\$8m).

We see these fund raises as a well-planned move by Shield in tandem with the partnership with Viatris, as it removes the funding overhang (gross cash at end-November 2022 was only £0.7m)

and allows the company to accelerate and focus on its expansion efforts. Based on our cash burn projections, we believe this additional capital is sufficient to take Shield to profitability in Q125.

Estimate revisions

We have updated our forecasts to reflect the Viatris deal and our updated outlook for the Accrufer sales trajectory in the US.

For FY22, we have adjusted our FX assumptions (£0.81/US\$ versus £0.87/US\$ previously) and incorporated the \$5m upfront payment received from Viatris while keeping our previous assumptions on prescriptions unchanged. We also reduce our estimated revenue realised per prescription from \$170 to \$160 based on the nine-month trend. For Europe, we have cut our FY22 estimates from £1.7m to £1.1m to reflect the softer Q3. Overall, our FY22 revenue estimate changes from £5.8m to £8.8m. Our costs and margin assumptions remain unchanged for this year.

For FY23 and beyond, while our ex-US estimates are unchanged, we update our revenue model for US Accrufer sales to reflect the new deal terms with Viatris. We increase our sales projections for Accrufer US to \$25.7m in FY23 (previously \$14.1m) and \$88.9m in FY24 (\$40.4m previously) to reflect expected faster prescription growth driven by the enhanced salesforce (management anticipates achieving full strength by April 2023). We also now include Viatris's 45% revenue share as part of COGS, which has resulted in the long-term gross margin figure coming down from 90% to c 50%. We also capture management guidance of c \$45m SG&A costs in FY23–25 but factor in a more gradual ramp-up (\$36m in FY23 to \$44.5m in FY25) in our model. We also update our EPS estimates as we now factor in the additional 251.5m shares issued from the \$18.5m placement. Note that we are not including potential additional shares issued under the £3.9 open offer as these figures are yet to be finalised. Overall, we now expect Shield to become EBITDA positive in early 2025 (versus Q225 earlier). Changes to group-level estimates are presented in Exhibit 4.

Exhibit 4: Key changes to forecasts

£'000s	FY22e			FY23e			FY24e		
	Old	New	Change (%)	Old	New	Change (%)	Old	New	Change (%)
Total revenues	5,810	8,759	50.8%	15,879	24,408	53.7%	40,988	77,329	88.7%
-- Accrufer US sales	3,949	7,510	90.2%	12,263	20,791	69.5%	35,121	71,981	104.9%
-- Feraccru Europe sales	1,712	1,099	-64.2%	3,615	3,617	0.0%	5,867	5,348	-8.8%
-- Other revenue	150	150	0.0%	0	0	0.0%	0	0	0.0%
Gross profit	3,915	7,106	81.5%	11,625	10,938	-5.9%	32,551	36,186	11.2%
Gross margin	67.4%	81.1%		73.2%	44.8%		79.4%	46.8%	
Adjusted EBITDA	(20,199)	(15,891)	-21.3%	(16,322)	(19,927)	22.1%	(3,258)	(348)	-89.3%
Adjusted PBT	(19,981)	(15,727)	-21.2%	(17,920)	(21,238)	18.5%	(5,486)	(2,032)	-63.0%
Adjusted EPS (p)	(8.3)	(6.5)	-21.7%	(6.5)	(4.2)	-35.4%	(2.0)	(0.4)	-80.0%

Source: Shield Therapeutics reports, Edison Investment Research

Valuation

We value Shield 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- and Viatris-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. For the US, we have updated our top-line and margin estimates following the partnership agreement with Viatris, as detailed in the previous section. Our valuation also assumes a pro forma estimated net cash position of £9.9m to reflect the contribution from the recent equity and convertible debt raises.

Exhibit 5: 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	227	414.0	100%	414.0	0.81
Feraccru in IDA	Europe	2019	37	43.5	100%	43.5	0.09
Feraccru in IDA	China	2025	61	64.4	75%	48.3	0.09
Corporate costs				(116.3)		(116.3)	(0.23)
Estimated net cash at 31 December 2022				9.9		13.8	0.03
Total equity value						403.4	0.79

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. **Based on estimated post-raise shares outstanding figure of 508.9m.

As a result of these changes, we increase our valuation to £403.4m (from £377.0m previously). However, given the increased share count following the recent equity raise, our per-share valuation is now 79p/share, down from 146p/share previously.

Exhibit 6: Financial summary

	£000s	2020	2021	2022e	2023e	2024e
31-December						
PROFIT & LOSS						
Revenue		10,387	1,519	8,759	24,408	77,329
Cost of Sales		(1,354)	(980)	(1,652)	(13,470)	(41,143)
Gross Profit		9,033	539	7,106	10,938	36,186
Sales, General & Administrative		(5,903)	(17,816)	(21,297)	(29,326)	(35,724)
Net Research & Development		(2,579)	(579)	(1,701)	(1,539)	(810)
EBITDA		551	(17,856)	(15,891)	(19,927)	(348)
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)	(15,891)	(19,927)	(348)
Operating profit before exceptionals		(2,154)	(20,063)	(18,057)	(22,182)	(2,597)
Exceptionals including asset impairment		0	111	0	0	0
Other		0	0	0	0	0
Reported Operating Profit		(2,154)	(19,952)	(18,057)	(22,182)	(2,597)
Net Finance income (costs)		268	387	165	(1,311)	(1,684)
Profit Before Tax (norm)		819	(17,469)	(15,727)	(21,238)	(2,032)
Profit Before Tax (FRS 3)		(1,886)	(19,565)	(17,893)	(23,493)	(4,281)
Tax		(744)	229	(354)	0	0
Profit After Tax and minority interests (norm)		75	(17,240)	(16,081)	(21,238)	(2,032)
Profit After Tax and minority interests (FRS 3)		(2,630)	(19,336)	(18,247)	(23,493)	(4,281)
Average Basic Number of Shares Outstanding (m)		117.2	204.0	247.1	508.9	508.9
EPS - normalised (p)		0.1	(8.4)	(6.5)	(4.2)	(0.4)
EPS - normalised and fully diluted (p)		0.1	(8.4)	(6.5)	(4.2)	(0.4)
EPS - (IFRS) (p)		(2.2)	(9.5)	(7.4)	(4.6)	(0.8)
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	33,222	9,113	5,732
Short-term investments		0	0	0	0	0
Cash		2,940	12,117	27,774	4,491	1,110
Other		2,290	5,141	5,448	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	(13,925)	(13,925)	(13,925)
Long term borrowings		0	0	(13,925)	(13,925)	(13,925)
Other long term liabilities		0	0	0	0	0
Net Assets		30,276	41,033	44,620	20,056	15,775
CASH FLOW STATEMENT						
Operating Cash Flow		(2,154)	(19,952)	(18,057)	(22,182)	(2,597)
Movements in working capital		(2,711)	(1,415)	(435)	826	0
Net interest and financing income (expense)		268	387	165	(1,311)	(1,684)
Depreciation & other		0	0	0	0	0
Taxes and other adjustments		3,197	4,242	935	1,184	2,250
Net Cash Flows from Operations		(1,400)	(16,738)	(17,393)	(21,483)	(2,032)
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	21,332	0	0
Net movements in long-term debt		0	0	13,925	0	0
Dividends		0	0	0	0	0
Other financing activities		(53)	(121)	0	0	0
Net Cash flows from financing activities		(47)	27,584	35,257	0	0
Effects of FX on Cash & equivalents		266	382	61	0	0
Net Increase (Decrease) in Cash & equivalents		(1,201)	9,177	15,657	(23,283)	(3,382)
Cash & equivalents at beginning of period		4,141	2,940	12,117	27,774	4,491
Cash & equivalents at end of period		2,940	12,117	27,774	4,491	1,110
Closing net debt/(cash)		(2,940)	(12,117)	(13,848)	9,434	12,816

Source: Company accounts, Edison Investment Research

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