



## Pharmaceuticals &amp; Biotechnology



Source: LSEG, 2024

## Market data

EPIC/TKR	STX/SHIEF
Price (p/\$)	2.70/0.037
12m high (p/\$)	7.80/0.084
12m low (p/\$)	1.05/0.014
Shares (m)	782.1
Mkt cap (£m)	21.1
EV (£m)	32.1
Free float*	59%
Country/Ccy	UK/USD
Markets	AIM/OTCQX

\*As defined by AIM Rule 26  
Priced on 11 November 2024

## Description

Shield Therapeutics (Shield) is a specialty pharma company with an iron replacement product, Feracru/Accrufer, approved in Europe and the US for the treatment of iron deficiency in adults, with or without anaemia. In Europe, Feracru is marketed by Norgine, with Shield receiving royalties. In the US, Accrufer is co-marketed by Shield and Viatris, with the aim of rapidly expanding its market share.

## Company information

CEO	Anders Lundstrom
CFO	Santosh Shanbhag
Chairman	Hans Peter Hasler

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[www.shieldtherapeutics.com](http://www.shieldtherapeutics.com)

## Key shareholders

Directors	2.2%
AOP Orphan AG	39.8%
Hargreaves Lansdown	8.2%
Inventages	7.2%

## Analyst

Dr Martin Hall [mh@hardmanandco.com](mailto:mh@hardmanandco.com)

## SHIELD THERAPEUTICS

## Proactive cash management to cashflow-breakeven

Shield is a commercial-stage pharma company delivering specialty products that address the needs of patients with iron deficiency (ID). Since its July 2021 US launch, Shield and Viatris have increased physician awareness of the differentiating characteristics of ACCRUFER® as an oral ID drug, in order to generate sales traction. The 3Q'24 trading update reiterated the interim statement dialog: sales continue to progress, while costs are being actively managed. Shield is being proactive, extending its working capital financing from \$10m to \$15m and issuing \$10m new shares to AOP, to manage the company through to cashflow-breakeven in 2H'25.

- **Strategy:** Shield and co-marketing partner Viatris are commercialising Accrufer in the US. Elsewhere, Shield's strategy is to out-license commercial rights to partners with appropriate expertise in target markets, which has been achieved so far in Europe, China, Republic of Korea and Canada.
- **3Q'24 trading:** In 3Q'24, sales grew 4% over 2Q'24, to \$7.2m, on the back of 20% Rx growth, offset by a weaker selling price in July, which gave an average of \$167 per Rx for the quarter. Prices improved greatly, to \$190+, in August and September. Gross cash to end-September was \$7.7m, down from \$8.1m at end-June, with management proactively strengthening the cash resources.
- **ACCRUFER Rx:** Sequential 3Q'24 Rx growth of 20%, to 43,500, was modestly below expectations (28%). Combined with the weak July selling price, sales, at \$7.2m, were below our \$7.9m forecast. However, the higher \$192 selling price in the latter months of 3Q'24 is expected to be maintained throughout 4Q'24.
- **Forecasts:** Modestly lower Rx growth has a knock-on effect on 4Q'24 expectations, but this is being offset by a selling price that is \$20 higher than forecast, at \$192. While this reduces overall 2024 sales by \$1.0m, additional cost savings mean that our EBITDA and EBIT forecasts remain unchanged.
- **Investment summary:** The 3Q'24 trading statement indicates that Shield is continuing to move in the right direction and that the new CFO has a firm grip on cash. The trend for lower ACCRUFER Rx growth, coupled with much-improved pricing (lower discounting), leaves forecasts broadly unchanged. Management is being very proactive in the management of gross cash in order to take the company through to cashflow-breakeven in 2H'25.

## Financial summary and valuation

Year-end Dec (\$m)	2020	2021	2022	2023	2024E	2025E
Product sales	0.94	1.40	5.50	13.09	30.64	71.48
R&D	-3.31	-0.80	-1.32	-1.81	-1.30	-0.50
Other income	11.40	0.79	1.11	4.41	6.05	1.90
EBITDA	-0.29	-24.46	-28.55	-30.26	-18.18	-4.99
Underlying EBIT	-3.77	-27.50	-31.40	-31.33	-19.38	-6.19
Underlying PBT	-3.76	-27.50	-30.99	-31.83	-21.98	-7.99
Underlying EPS (p)	-3.20	-13.27	-13.49	-4.52	-2.81	-1.02
Statutory EPS (p)	-3.79	-13.11	-21.25	-4.59	-2.81	-1.02
Gross cash	4.01	16.33	3.40	13.95	5.28	12.96
Net cash/(debt)	3.97	16.12	-3.95	-6.30	-14.72	-12.04
Equity issues	0.01	40.21	2.67	28.16	0.00	10.00
EV/sales (x)	-	-	-	2.4	1.0	0.4

Source: Hardman &amp; Co Research

## YTD performance

### Operational highlights

- ▶ **ACCRUFer:** Shield reported a 125% increase in ACCRUFer Rx for the nine months ending September 2024. Given that 1Q'24 growth was broadly flat on 4Q'24, due to the well-documented change in the Texas PBM, this growth was driven by excellent 2Q'24 and 3Q'24, reflecting the 12-month anniversary of the expanded and trained US sales team. Sequential quarterly growth in ACCRUFer Rx is expected to continue moving forward.
- ▶ **ACCRUFer discounts:** There is clear evidence that the efforts being made by the Shield-Viatis sales team to reduce the level of subsidised Rx are being rewarded, with the average Rx generating \$139 in 1Q'24, \$171 in 2Q'24, and \$167 in 3Q'24. The latter figure was reduced by summer buying patterns, but is now running at about \$190 per Rx, as the commercial strategy moves away from consignment volumes.
- ▶ **Partnering:** Progress has been made during 2024 with several partners. The sales performance of Norgine in Europe was better than expected, Kye received ACCRUFer regulatory approval in Canada, Korea filed for regulatory approval in Korea, and ASK continued to enrol patients into its Phase III regulatory trial.

### Financial highlights

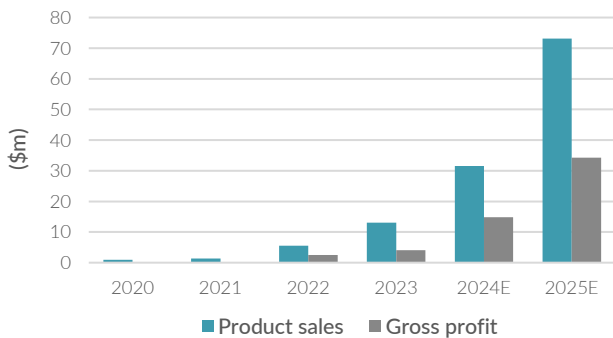
- ▶ **Sales:** ACCRUFer has generated YTD sales of \$18.1m (+132%) through a combination of Rx growth and lower discounts. This is being supported by European royalties of \$1.07m (+80%) and modest sales from Korea.
- ▶ **COGS:** Manufacturing and supply costs are being managed with a modest improvement in gross margins expected – currently ca.45.0% (44.3%). COGS is dictated by the percentage of US sales payable to Viatis and the 5% royalty.
- ▶ **SG&A:** Despite the cost of employing the enlarged sales team for the whole of 1H'24, the underlying SG&A costs increased only 8% to \$18.23m (\$16.89m). Underlying SG&A is expected to be around this level again in 2H'24.
- ▶ **Net cash/(debt):** At 30 September, Shield had gross cash of \$7.7m. Financial flexibility has been enhanced by a receivables financing deal with Sallyport of up to \$15m, of which \$6.4m was drawn down on 30 June. Flexibility has been further enhanced through the China milestone monetisation agreement with AOP (+\$5.7m) and regulatory approval in Canada (+\$0.32m).

Interim results summary – actual vs. expectations					
Year-end Dec (\$m)	1H'23 actual	1H'24 actual	Growth CER	1H'24 *forecast	Delta Δ
Product sales	4.33	12.13	+224%	11.53	+0.60
COGS	-2.09	-6.68	n/m	-6.92	+0.24
SG&A	-16.89	-18.23	+8.0%	-18.55	+0.32
Share-based costs	-0.18	-0.58	n/m	-0.44	-0.14
R&D	-0.43	-0.75	+73%	-0.65	-0.10
Other income	4.30	0.00	-	0.00	-
<b>Underlying EBIT</b>	<b>-11.54</b>	<b>-14.06</b>	<b>+22%</b>	<b>-15.03</b>	<b>+0.97</b>
Gross cash	13.59	8.10	-	6.85	+1.25
Debt/leases	-5.77	-19.97	-	-20.00	+0.03
<b>Net cash/(debt)</b>	<b>7.82</b>	<b>-11.87</b>	<b>-</b>	<b>-13.15</b>	<b>+1.28</b>

\*Prior to release of business update statement on 24 July  
 Note: numbers may not add up exactly due to rounding  
 Source: Hardman & Co Research

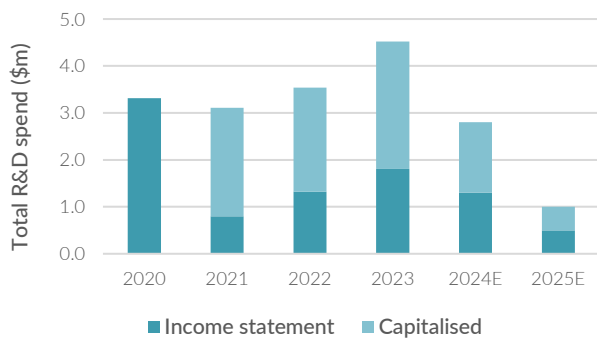
## Shield Therapeutics

### Product sales and gross profit



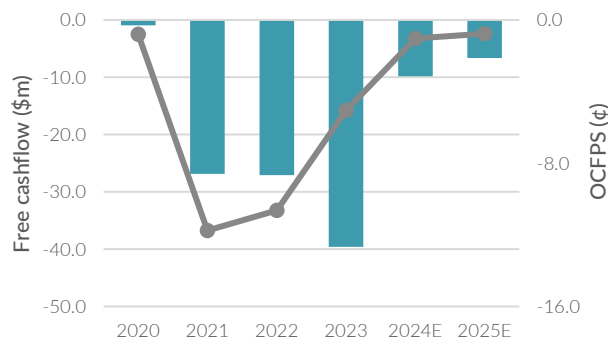
- ▶ The US is the only market in which Shield records product sales. In other countries, it partners with distributors.
- ▶ Shield is recording 100% of net sales of ACCRUFer in the US, with Viatri's 45% proportion being charged to COGS, reducing the gross margin from 85% to ca.45%.
- ▶ Sales milestones and royalties from commercial partners are treated as "other income", and are not included in our sales.

### Total R&D investment



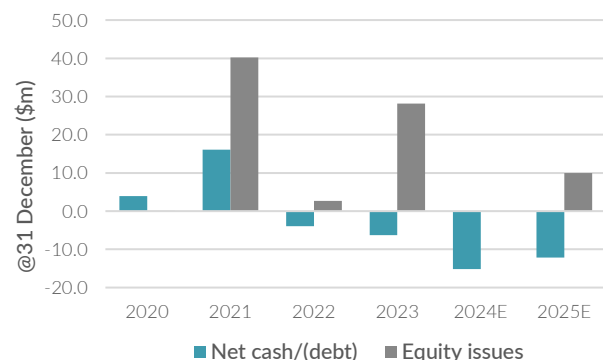
- ▶ Total R&D spend in 2023 peaked at \$4.5m. However, only 40% was recorded through the income statement; the other 55% was capitalised.
- ▶ Main investment is a paediatric study with Feraccru/ACCRUFer initiated at the end of 2021; this was forecast to cost \$6.5m-\$7.0m over a three-year period. Most of these costs are now behind the group, allowing R&D spend to ease off.

### Free cashflow and OFCPS



- ▶ Shield has been cashflow-negative during the investment phase and commercialisation of Feraccru/ACCRUFer.
- ▶ 2024 cashflows will continue to be dominated by ramp-up in ACCRUFer marketing spend for the co-promotional programme agreed with Viatri.
- ▶ Acceleration of ACCRUFer Rx and sales in 2024 and 2025 is expected to see Shield become cashflow-breakeven in 2H'25 and beyond.

### Net cash/(debt) and equity issues



- ▶ Gross cash, at 30 September 2024, was \$7.7m, offsetting ca.\$25.0m of debt.
- ▶ More favourable covenants on the SWK debt facility were negotiated in April 2024.
- ▶ Shield has arranged a flexible accounts receivable facility up to \$15m with Sallyport to provide greater working capital flexibility.
- ▶ In July 2024, Shield monetised its potential China regulatory milestone to raise an additional \$5.7m to strengthen the balance sheet further.

Source: Company data; Hardman & Co Research

# Operational update

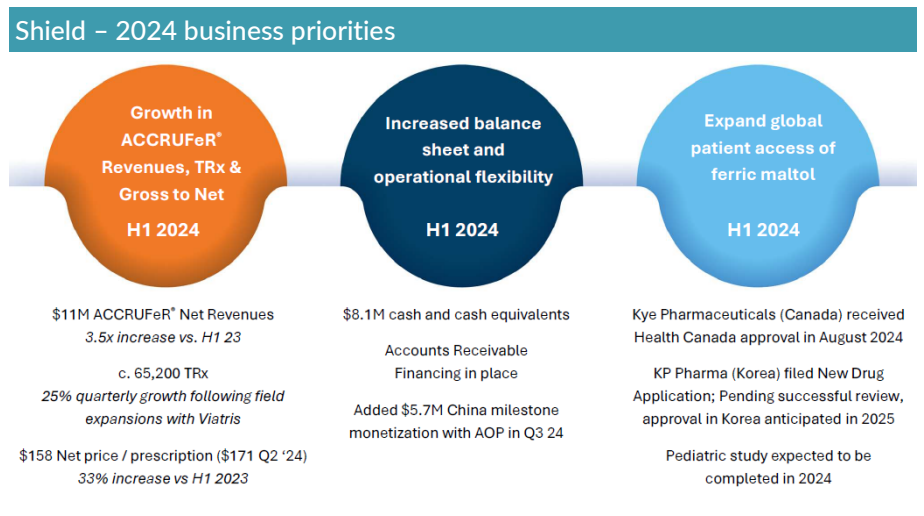
## Progress against 2024 business objectives

**Progress against three clearly defined goals**

In its presentation of fiscal 2023 results, management set out three clear business objectives for 2024:

- ▶ Maximise revenues (product sales and royalties) directly in the US through the commercial deal with Viartis and indirectly through its overseas partners. In the US, the aim was to grow ACCRUFER RX and reduce the discounting and subsidies frequently used in the industry when a drug is first used.
- ▶ Increase balance sheet and operational flexibility through tight control of operating expenses and enhancements to working capital. A clear focus on making investments that were directly tied to supporting ACCRUFER.
- ▶ Expand global patient access to ferric maltol by working closely with overseas partners.

The following slide, extracted from Shield’s interim results presentation, shows that the company has made considerable progress against all three business objectives in 1H’24, and this has continued further, so far in 2H’24.



Source: Shield interim results presentation

## ACCRUFER

### ACCRUFER Rx progress

**Good recovery in 2Q'24 after poor start in 1Q'24 in Texas**

2024 did not start well for Shield when the largest state (Texas) user of ACCRUFER decided to change its Pharmacy Benefit Manager (PBM), throwing the whole process of pre-approvals into disarray for a short period, until a new PBM was appointed starting from April. Really good performances in other states – notably New York and California – only just offset the impact from Texas, with 1Q'24 ACCRUFER Rx rising 1%.

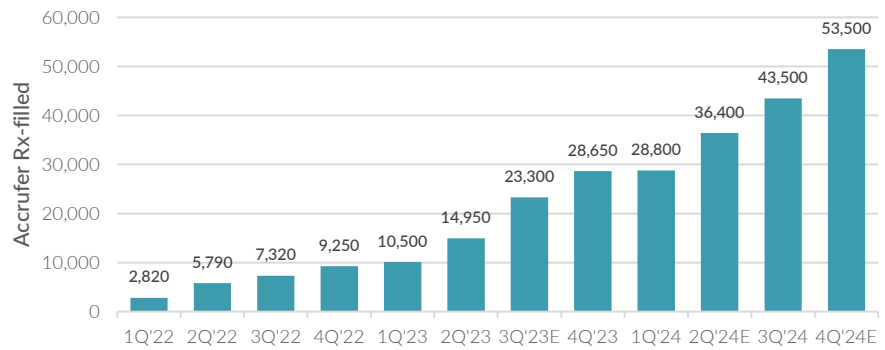
**Return to sequential quarterly Rx growth**

2Q'24 saw the Texas State Medicaid programme return to normal and, with continued growth elsewhere, ACCRUFER Rx's have grown 125% compared with the first nine months of 2024. The top states for ACCRUFER, currently, are California, Florida, New York, and Texas.

Continually addressing the volume:price balance

One characteristic of the large state Medicaid programmes is something called consignment volume, whereby higher discounts are demanded for high volumes. During 2024, Shield-Viatris has continued its goal to redress the balance between price and volume, gradually reducing the number of subsidised Rx.

ACCRUFer Rx progression



Source: Hardman & Co Research

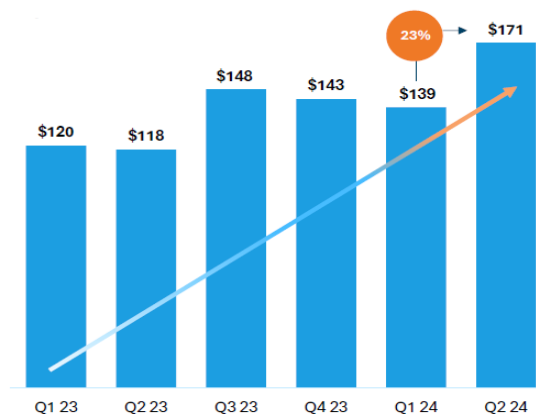
ACCRUFer pricing trend

In order to increase awareness of ACCRUFer among physicians and to establish the drug in the market, ACCRUFer was given away either for free, or on a heavily subsidised basis, when it was first launched. This is normal industry practice. As new products become better known, more established, and included under Medicaid and Medicare formulary coverage, the aim is to reduce the discount levels. A key goal of the Shield-Viatris commercial team over the past 12 months has been to reduce the average discount that each ACCRUFer Rx attracted.

2Q'24 Rx price outcome of \$171 was best to date

During 2024, Shield has made significant progress in reducing these discounts with the long-term aim of achieving an average price per Rx of \$220. The following chart shows the average net ACCRUFer price, on a quarterly basis, since 1Q'23. In the same way that Rx levels in the industry tend to be lower in the early part of each year, pricing also tends to be lower. This can be seen in the dip between 4Q'23 and 1Q'24. In 2Q'24, Shield recorded its best quarter for pricing with the average price reaching \$171. Although the 3Q'24 figure of \$167 was affected by summer buying patterns, in August and September, the average price was \$192, and it is expected to run around this rate for 4Q'24.

Quarterly ACCRUFer net price per Rx



Source: Shield interim results presentation

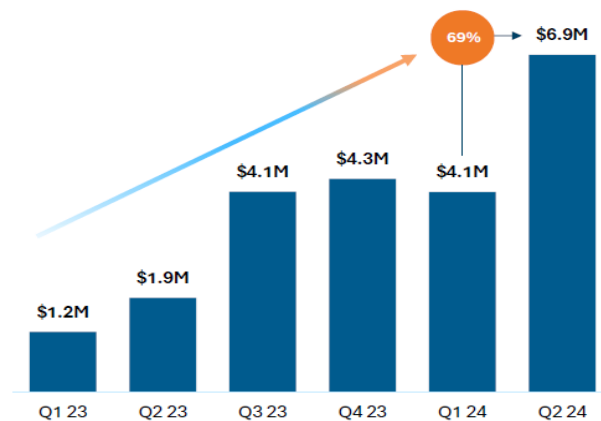
## ACCRUFer sales

Sales beginning to dominate the focus

While ACCRUFer Rx growth and average net prices remain very important and are both contributory factors, a general observation that we have made in recent trading updates and results announcements is a subtle change in emphasis on to sales.

Clearly, sales are dependent on both Rx levels and price; however, moving forward, we envisage that Shield-Viatris is trying to move away from notching up an Rx at any price, thereby improving the quality of each Rx filled. This might result in a slight reduction in the quarterly Rx growth rate reported but at continually improving average price. Consequently, we see greater focus on sales and sales growth. To that end, the company provided accurate back information on quarterly ACCRUFer sales, corrected for all the well-documented issues in 2023.

### Quarterly ACCRUFer net sales



Source: Shield interim results presentation

Data quality has improved under new CFO

In our opinion, this is also a reflection of the desire of the new CFO to put his stamp on the quality and consistency of the information being provided in recent trading updates and financial reports. There is no doubt that the 1H'24 report and presentation had much greater transparency and that the data can be relied upon by investors.

## Changes to ACCRUFer forecasts

Slight tweak to forecasts due to volume versus price balance

On the basis that Shield-Viatris is trying to reduce the level of consignment volume and improve process, we have tweaked downwards our growth expectations for ACCRUFer Rx but slightly raised our average price per Rx. Although this has resulted in a slight fall in ACCRUFer US sales, it is compensated for, at the group level, by an increased forecast for the contribution from Norgine in Europe.

### Changes to ACCRUFer forecasts

	1Q'24	2Q'24	3Q'24	4Q'24E	2024E
ACCRUFer Rx growth rate					
Old	+1%	+26%	+28%	+23%	169,100
New			+20%	+23%	162,200
ACCRUFer average net Rx price					
Old	\$130	\$171	\$176	\$181	\$173
New			\$169	\$190	\$175
ACCRUFer net sales					
Old	\$4.1m	\$6.9m	\$8.1m	\$10.1m	\$29.2
New			\$7.2m	\$10.2m	\$28.3

Source: Hardman & Co Research

## Global partnerships

To date in 2024, Shield has made progress with each of its non-US partners, which are summarised in the following graphic.

Global (ex-US) partnerships			
 <b>EU+<sup>1</sup></b>	 <b>Canada</b>	 <b>Republic of Korea</b>	 <b>China +<sup>2</sup></b>
Currently commercialized across Europe	Approved by Health Canada in August 2024	Filed for approval; Pending successful review, approval anticipated in 2025	Phase 3 Study ongoing Approval expected in H2 2026
Royalties and milestone payment upon approval for Pediatrics in EU	Revenue-based milestone payments and Double-digit royalties on net sales	Mid-teens royalties on net sales	Approval Milestone Double-digit royalties on net sales

Source: Shield interim results presentation

### Norgine

The slow progress of Norgine – EU, UK, Norway, Australia, New Zealand plus some other non-EU Countries – has been a frustration, particularly in Europe. However, progress does appear to be evolving, as evidenced by the 80% increase in royalties received in 1H'24, which was much greater than forecast. After some initial problems with NICE and the payors in the UK, Feraccru is now being accepted on many more hospital formularies. We expect a continuation of this progress in 2H'24.

### Kye

Kye filed for approval of ACCRUFer with the Canadian regulator in 2023 and approval was always anticipated in 2H'24. This duly arrived at the end of August, triggering an approval milestone of £250k/\$325k, which is due to be paid imminently. Kye is now going through the pre-launch phase and is expected to formally launch in Canada in 1Q'25.

### Korea Pharma

Following the successful completion of the required pharmacokinetic study, Korea Pharma has submitted ACCRUFer to the regulator for approval in the Republic of Korea. A decision is expected during 2025.

### ASK Pharma

For approval in China, ASK is required to undertake a pivotal Phase III clinical trial. The protocol is similar to those used to obtain regulatory approval from the EMA and the FDA. Although, as discussed previously, recruitment has been slower than anticipated, good progress has been made in 1H'24 and full enrolment is targeted for completion towards the end of 2024. Trial results are expected in 2025 and, if successful, the regulatory submission is also expected to occur next year.

### Paediatric study

As part of the regulatory process in Europe and the US, Shield was required to undertake a Phase III paediatric study (FORTIS/ST10-01-305) comparing the safety, tolerability and effectiveness of an oral liquid suspension of ferric maltol with oral ferrous sulphate liquid in children with iron deficiency anaemia. This trial has now completed with positive outcomes.

Imminent receipt of £0.24m/\$0.32m milestone

## Financing update

Since his appointment at the end of 2023, the new CFO has undertaken a complete review of the company's finances and spending plans. As stated earlier, in our opinion, there has been a noticeable improvement in the quality of the information being provided and that investors can rely on these data.

He inherited a stretched balance sheet, with the market generally of the view that more capital was required. However, through a series of operational decisions and changes, and some financing deals, the balance sheet has improved and the current and forecast gross cash position is expected to see the company through to cashflow-breakeven in 2025, assuming that internal and external forecasts are met.

### Operating costs

#### Hands-on control of operating cost

The first thing that the new CFO addressed was to reschedule some of the company's operating costs to ensure that investment was in a focused and timely manner to grow ACCRUFER in the US.

In 1H'24, US selling costs increased by 10.2%, reflecting the full contribution from the expanded sales team, which was only in the recruitment phase in 1Q'23. General administration costs (excluding share-based payments) were reduced by 1.4% to \$5.12m (\$5.19m), despite the negative impact of translating the UK administrative costs into USD. D&A rose substantially in 1H'24. Taking all of these points into account, the underlying SG&A costs rose only 8.0% in 1H'24. During the 1H'24 analyst meeting, management stated that costs would be largely similar in 2H'24 compared with 1H'24, but, at that stage, we prudently allowed for a ca.\$1.5m increase in our forecasts. However, in the 3Q'24 trading update, with further proactive cash management, Shield indicated that it was looking to reduce these costs by 10% over the coming 12 months, so forecasts have been maintained on slightly reduced sales expectations.

SG&A costs						
\$m	1H'23	2H'23	2023	1H'24	2H'24E	2024E
US selling costs	-11.20	-10.52	-21.72	-12.34	-13.28	-25.62
General administration	-5.19	-9.11	-14.30	-5.12	-5.10	-10.21
D&A	-0.50	-0.58	-1.07	-0.77	-0.77	-1.54
<b>Underlying SG&amp;A</b>	<b>-16.89</b>	<b>-20.20</b>	<b>-37.09</b>	<b>-18.23</b>	<b>-19.69</b>	<b>-37.93</b>
Share-based costs	-0.18	-0.70	-0.88	-0.58	-0.58	-1.17
Reported SG&A	-17.06	-20.90	-37.96	-18.82	-19.72	-39.10

Source: Hardman & Co Research

It should be noted that the general administration costs were abnormally high in 2H'23. This was due to the inclusion of various financing costs within this figure, which are not expected to be repeated.

### Financing deals

Shield has undertaken three financing/refinancing deals so far in 2024 to strengthen the balance sheet and provide increased flexibility to its working capital.




#### SWK Funding LLC

#### Revised sales covenants are on a rolling 12-month basis

Shield renegotiated its existing \$20m debt financing agreement with SWK to provide more favourable covenant terms. On a rolling 12-month basis, the minimum ACCRUFER sales targets are \$16.5m, \$22.5m, \$31.5m, \$38.9m, and \$45.7m in 2Q'24, 3Q'24, 4Q'24, 1Q'25, and 2Q'25 and beyond, respectively. Shield maintained that its internal forecasts would consistently comply with these revised minimum sales requirements.



### Financing deals in 2024\*

 <b>\$20M Term Loan</b>	 <b>\$10M AR Factoring</b>	 <b>\$5.7M Milestone Monetization</b>
Sept. 2028 maturity Interest rate SOFR + 9.25% Nine quarters interest only periods 6.5% final payment fee Secured by all assets Minimum liquidity and minimum revenue targets <sup>1</sup> covenants	Through Apr 2025, extendable to 2026 Advance rate on eligible ACCRUFER <sup>®</sup> receivables Interest rate of WSJ Prime + 3.0% Secured by AR and Inventory \$1.0M in restricted cash	Monetization of \$11.4M milestone upon ACCRUFER <sup>®</sup> approval in China ACCRUFER <sup>®</sup> approval in China expected by YE 2026 Secured by the ASK Milestone <sup>2</sup>

\*The AR factoring facility was increased to \$15m in 3Q'24  
 Source: Shield interim results presentation

Accounts receivable facility will vary on a day-to-day basis...but up to \$15m

### Sallyport Commercial Finance

In April 2024, Shield strengthened its balance sheet through an accounts receivable arrangement with Sallyport for up to \$10m. The amount was increased to \$15m during 3Q'24. On issue of an invoice in the US, Shield can draw down the receivable from Sallyport, which is then repaid, less costs, to Sallyport, immediately upon payment receipt from the customer. This improves Shield's working capital position, covering, for example, the average 72-day payments from its largest customer, Cardinal Health.

The amount drawn down will vary on a day-to-day basis. On 30 June, Shield had an outstanding draw down of \$6.84m with Sallyport, showing up in short-term liabilities (note 11 in the accounts). In addition, under the terms of the agreement, Shield is required to hold \$1.0m of restricted cash as a contingency until closure of the agreement, listed under long-term assets.

Accounting for AOP arrangement still uncertain...but we have included whole \$5.7m in "other income"

### AOP Health

On 3 July, Shield announced that it had signed an agreement with its major shareholder, to monetise the anticipated \$11.4m China approval milestone from ASK Pharma. Under the terms of this agreement, AOP has paid Shield \$5.7m immediately, in return for the right to receive the full \$11.4m from ASK within 30 days from the "approval milestone" being achieved. ASK is expected to complete enrolment into the Phase III trial by the end of 2024 and, all being well, the approval milestone is expected to become payable around the end of 2026.

In the event that the approval milestone has not been triggered by 31 December 2026, or in the event that this agreement is terminated, including at Shield's election or due to a breach by Shield of its terms, the \$5.7m advance plus accrued interest and fees at an interest rate of SOFR+9.25% (calculated from the date of the advance until the day of payment) and an exit fee of 6.5% of the advance will be payable by Shield to AOP.

### Summary

Management is totally focused on commercial execution. All of these financing deals, together with close control of costs and working capital are designed to see Shield through to cashflow-breakeven in 2H'25.

# Financials and investment case

## Income statement

- ▶ **Sales:** Strong performance in 1H'24 and the key focus. Modest adjustment to 2024 and 2025 forecasts to reflect the balance between consignment volume and price, with the aim of continually reducing the level of subsidised Rx's.
- ▶ **COGS:** There are three components to Shields's COGS. Apart from the basic product manufacturing costs, there are royalties and Viatris's 45% proportion of net sales. A normalised gross margin is around 45% of net sales.
- ▶ **SG&A:** Management intends to continue its planned investment into marketing in order to drive sales growth. However, it does have some flexibility around the timing of this investment to help with the management of its cash position.
- ▶ **R&D:** Shield is continuing to invest in the paediatric study required by the regulators. However, much of this R&D spend is capitalised.
- ▶ **Other income:** This is a combination of sales milestones from Viatris and regulatory milestones from global partners. 2024 includes \$5.7m received from AOP and the imminent approval milestone from Kye.
- ▶ **Profitability:** Shield is expected to become EBITDA-positive during 2H'25. Timing of profitability is dependent on receipt of sales milestones from Viatris, which look set to commence in fiscal 2026.

Income statement						
Year-end Dec (\$m)	2020	2021	2022	2023	2024E	2025E
Product sales	0.94	1.40	5.50	13.09	30.64	71.48
COGS	-1.74	-1.35	-3.04	-9.06	-16.23	-37.97
Gross profit	-0.80	0.05	2.46	4.03	14.40	33.52
Gross margin	7.2%	60.2%	44.7%	30.8%	47.0%	46.9%
SG&A (underlying)	-10.06	-26.19	-32.73	-37.09	-37.37	-39.94
Share-based costs	-0.99	-1.36	-0.91	-0.88	-1.17	-1.17
R&D	-3.31	-0.80	-1.32	-1.81	-1.30	-0.50
Other income	11.40	0.79	1.11	4.41	6.05	1.90
<b>EBITDA</b>	<b>-0.29</b>	<b>-24.46</b>	<b>-28.55</b>	<b>-30.26</b>	<b>-18.18</b>	<b>-4.99</b>
Depreciation	-0.03	-0.03	-0.04	-0.04	-0.04	-0.04
Amortisation	-3.45	-3.01	-2.81	-1.04	-1.17	-1.17
<b>Underlying EBIT</b>	<b>-3.77</b>	<b>-27.50</b>	<b>-31.40</b>	<b>-31.33</b>	<b>-19.38</b>	<b>-6.19</b>
Exceptional items	0.00	0.00	-18.11	0.00	0.00	0.00
Statutory EBIT	-3.77	-27.50	-49.51	-31.33	-19.38	-6.19
Net interest	0.00	0.01	0.41	-0.50	-2.60	-1.81
Forex gain/loss	0.27	0.38	0.00	-0.54	0.00	0.00
<b>Underlying PBT</b>	<b>-3.76</b>	<b>-27.50</b>	<b>-30.99</b>	<b>-31.83</b>	<b>-21.98</b>	<b>-7.99</b>
Extraordinary items	0.00	0.00	0.00	0.00	0.00	0.00
Statutory PBT	-3.50	-27.11	-49.10	-32.38	-21.98	-7.99
Tax payable/credit	-0.96	0.32	-0.46	-0.92	0.00	0.00
<b>Underlying net income</b>	<b>-3.75</b>	<b>-27.13</b>	<b>-31.45</b>	<b>-32.75</b>	<b>-21.98</b>	<b>-7.99</b>
Statutory net income	-4.45	-26.80	-49.56	-33.29	-21.98	-7.99
<b>Ordinary 1.5p shares:</b>						
Period-end (m)	117.62	215.89	259.39	782.06	782.06	977.37
Weighted average shares (m)	117.40	204.41	233.19	725.22	782.06	928.54
Fully diluted (m)	121.35	211.87	285.79	782.54	844.37	995.86
<b>Underlying basic EPS (¢)</b>	<b>-3.20</b>	<b>-13.27</b>	<b>-13.49</b>	<b>-4.52</b>	<b>-2.81</b>	<b>-0.86</b>
Statutory basic EPS (¢)	-3.79	-13.11	-21.25	-4.59	-2.81	-0.86
Underlying fully dil. EPS (¢)	-3.09	-12.80	-11.00	-4.19	-2.60	-0.80
Statutory fully dil. EPS (¢)	-3.67	-12.65	-17.34	-4.25	-2.60	-0.80
DPS (¢)	0.0	0.0	0.0	0.0	0.0	0.0

Source: Hardman & Co Research

## Balance sheet

- ▶ **Net cash/(debt):** On 30 September 2024, Shield had gross cash of \$7.7m including the part drawdown of the accounts receivable financing deal. The \$20m debt facility from SWK was fully utilised. During 3Q'24, Shield received the \$5.7m China milestone monetisation advance from AOP and payment of the Canada approval milestone.
- ▶ **Loan facility:** In September 2023, Shield entered into a \$20m five-year term loan facility with SWK Holdings. This term loan is interest-only (minimum 14.25%) for eight quarters; thereafter, it will be interest plus \$1m capital repayment per quarter. Sales covenants were renegotiated to more favourable terms in April 2024.
- ▶ **Inventories:** Inventories increased 26%, to \$4.0m, in 1H'24 compared with the level at 31 December 2023. Shield has the flexibility to release some working capital at a suitable time point, again as part of the overall management of gross cash.
- ▶ **Working capital:** Overall, there was a \$3.90m release of working capital in 1H'24, but this includes the drawdown accounts receivable facility from Sallyport. Net cash burn in 3Q'24 was -\$0.4m.
- ▶ **AOP subscription:** Shield has signed a non-binding agreement with AOP Health to subscribe for new Ordinary shares for a minimum of \$10m, at a price of 4.0p per share. This would take AOP's shareholding above 50%, so Shield has requested a waiver from the Panel on Takeovers and Mergers.

Balance sheet						
@31 Dec (\$m)	2020	2021	2022	2023	2024E	2025E
Shareholders' funds	41.33	55.31	6.54	15.03	-6.95	-4.95
Cumulated goodwill	0.00	0.00	0.00	0.00	0.00	0.00
Total equity	41.33	55.31	6.54	15.03	-6.95	-4.95
Share capital	2.41	4.36	5.37	15.01	15.25	19.06
Reserves	38.92	50.95	1.17	0.02	-22.20	-24.00
Provisions/liabilities	0.00	0.00	0.00	0.00	8.00	8.00
Deferred tax	0.00	0.00	0.00	0.00	0.00	0.00
Long-term leases	0.00	0.00	0.00	0.20	0.00	0.00
Short-term leases	0.04	0.21	0.11	0.21	0.00	0.00
Long-term loans	0.00	0.00	7.25	19.84	20.00	25.00
Short-term debt	0.00	0.00	0.00	0.00	0.00	0.00
less: Cash	4.01	16.33	3.40	13.95	5.28	12.96
less: Deposits	0.00	0.00	0.00	0.00	0.00	0.00
less: Non-core investments	0.00	0.00	0.00	0.00	0.00	0.00
<b>Invested capital</b>	<b>37.35</b>	<b>39.19</b>	<b>10.49</b>	<b>21.33</b>	<b>15.76</b>	<b>15.09</b>
Fixed assets	0.04	0.41	0.24	0.67	0.52	0.68
Intangible assets	37.22	36.20	14.21	16.86	17.35	16.87
Inventories	1.88	2.20	1.76	3.20	3.52	4.23
Trade debtors	0.30	1.10	4.09	9.99	10.63	11.81
Other debtors	0.55	2.85	2.40	3.51	3.51	3.51
Tax liability/credit	0.40	0.78	0.53	0.61	0.59	0.00
Trade creditors	-0.54	-1.77	-2.20	-4.05	-6.01	-7.03
Other creditors	-2.50	-2.58	-10.52	-9.47	-14.35	-14.97
Debtors less creditors	-1.79	0.38	-5.71	0.59	-5.63	-6.68
<b>Invested capital</b>	<b>37.35</b>	<b>39.19</b>	<b>10.50</b>	<b>21.33</b>	<b>15.76</b>	<b>15.09</b>
<b>Net cash/(debt)</b>	<b>3.97</b>	<b>16.13</b>	<b>-3.95</b>	<b>-6.30</b>	<b>-14.72</b>	<b>-12.04</b>

Source: Hardman & Co Research

## Cashflow

- ▶ **Net cash/(debt):** Our forecasts assume that Shield will continue to fully utilise its \$20m SWK term loan facility. It will also continue to utilise its accounts payable facility, but this changes on a day-to-day basis based on the timing of the issuance of invoices and the payment receipt for those invoices. Careful management of the timing of planned marketing spend and working capital are expected to maintain a modest gross cash position at the end of each month and at the year-end, obviating the need for an equity injection.
- ▶ **Capitalised R&D:** Although the paediatric study is continuing, much of the cost is contracted and pre-paid to the contract research organisation conducting the trial. A further \$0.98m was capitalised in 1H'24, but we expect this to tail off as the trial proceeds to a conclusion at the end of 2024.
- ▶ **Working capital:** Timing differences between supply of drugs to US wholesalers and payments have resulted in an increase in working capital, which has been offset by utilisation of accounts payable agreement with Sallyport. As ACCRUFer RxS accelerate and net selling discounts reduce, Shield will have more flexibility with its working capital to manage the gross cash position.

Cashflow						
Year-end Dec (\$m)	2020	2021	2022	2023	2024E	2025E
Underlying EBIT	-3.77	-27.50	-31.40	-31.33	-19.38	-6.19
Depreciation	0.03	0.03	0.04	0.04	0.04	0.04
Amortisation	3.45	3.01	2.81	1.04	1.17	1.17
Share-based costs	0.99	1.36	0.91	0.88	1.17	1.17
<i>Inventories</i>	1.20	-0.35	0.22	-1.45	-0.32	-0.70
<i>Receivables</i>	-0.34	-3.96	-2.79	-7.01	-0.64	-1.18
<i>Payables</i>	-2.66	2.26	7.27	1.91	9.96	1.02
Change in working capital	-1.80	-2.05	4.70	-6.55	9.00	-0.87
Exceptionals/provisions	0.00	0.00	0.00	0.00	3.40	0.00
Disposals	0.00	0.00	0.00	0.00	0.00	0.00
Other	0.34	0.71	-0.81	0.17	0.00	0.00
<b>Company op. cashflow</b>	<b>-0.77</b>	<b>-24.44</b>	<b>-23.75</b>	<b>-35.76</b>	<b>-4.61</b>	<b>-4.69</b>
Net interest	0.00	-0.04	-0.37	-0.10	-4.02	-1.81
Finance leases	-0.07	-0.11	-0.23	-0.09	-0.23	-0.23
Tax paid/received	-0.11	0.56	-0.43	-0.72	1.19	0.59
<b>Operational cashflow</b>	<b>-0.94</b>	<b>-24.03</b>	<b>-24.78</b>	<b>-36.66</b>	<b>-7.68</b>	<b>-6.13</b>
Capital expenditure	0.00	-0.51	-0.06	-0.24	-0.15	-0.19
Capitalised R&D	0.00	-2.32	-2.22	-2.71	-1.50	-0.50
Sale of fixed assets	0.00	0.00	0.00	0.00	0.00	0.00
<b>Free cashflow</b>	<b>-0.94</b>	<b>-26.86</b>	<b>-27.06</b>	<b>-39.61</b>	<b>-9.33</b>	<b>-6.82</b>
Dividends	0.00	0.00	0.00	0.00	0.00	0.00
Acquisitions	-0.03	-0.01	0.00	0.00	0.00	0.00
Disposals	0.00	0.00	0.00	0.00	0.00	0.00
Other investments	0.00	0.00	0.00	0.00	0.00	0.00
<b>Cashflow after invests.</b>	<b>-0.97</b>	<b>-26.87</b>	<b>-27.06</b>	<b>-39.61</b>	<b>-9.33</b>	<b>-6.82</b>
Share repurchases	0.00	0.00	0.00	0.00	0.00	0.00
Equity issues	0.01	40.21	2.67	28.16	0.00	10.00
Cost of fundraise	0.00	-2.09	-0.19	-1.35	0.00	-0.50
Currency effect	0.82	0.53	-2.83	0.45	0.50	0.00
Loans/cash acquired	0.00	0.37	7.34	10.00	0.00	0.00
<b>Change in net debt</b>	<b>-0.15</b>	<b>12.15</b>	<b>-20.07</b>	<b>-2.35</b>	<b>-8.83</b>	<b>2.68</b>
OCFPS (p)	-0.80	-11.76	-10.63	-5.06	-0.99	-0.66
Opening net cash/(debt)	4.12	3.97	16.12	-3.95	-6.30	-14.72
<b>Closing net cash/(debt)</b>	<b>3.97</b>	<b>16.13</b>	<b>-3.95</b>	<b>-6.30</b>	<b>-14.72</b>	<b>-12.04</b>

Source: Hardman & Co Research

## Valuation

### Sum-of-the-parts

Taking all recent events into account, valuation drops from 17p to 16p per share

Our analysis, which pulls together the DCF models for each of the key commercial markets for Feraccru/ACCRUFer, has been updated following all the recent events. This has generated a revised sum-of-the-parts EV of \$185m/£143m. The US valuation has reduced modestly along with the slightly reduced sales expectations. However, this has been more than offset by an increase in the European valuation following the better-than-expected performance from Norgine. The recent strength in sterling has negated the overall positive USD outcome. Updating the net debt position leaves our overall NPV per share at 16p.

Sum-of-the-parts valuation			
	NPV (l.c.)	NPV (GBP)	NPV per share
NPV of ACCRUFer in US	\$109m	£85m	11p
NPV of Feraccru royalty stream in Europe	€33m	£28m	4p
Risk-adjusted NPV of China royalty stream	\$35m	£26m	3p
<b>Enterprise value</b>	<b>\$187m</b>	<b>£139m</b>	<b>18p</b>
Net cash/(debt)	-\$15m	-£11m	-1p
<b>Group valuation</b>	<b>\$172m</b>	<b>£128m</b>	<b>16p</b>

Source: Hardman & Co Research

Rerating of shares dependent on sequential quarterly progress at least close to expectations

Although there had been some recovery in the share price to ca.5.0p, following the 3Q'24 trading update, the market has become more concerned about the continuing commercial risk and the debate about gross cash. This was exacerbated by the updated view that Shield needed to agree a share subscription for a minimum of \$10m from its major shareholder, AOP Health, to get it to cashflow-breakeven. The market needs to see further benefits of the enlarged sales team in each sequential quarter in order to have the confidence to rerate the shares.

### Comparator valuations

Covis acquired AMAG for \$647m in November 2020, and CSL bid CHF11.1bn for Vifor in December 2021

There are no directly comparable UK peers – so, we continue to observe some global competitors for completeness. In addition, we have been highlighting the need of the pharma majors for M&A activity to bolster R&D pipelines and commercial portfolios. Iron replacement therapy is no exception. Covis (private company) paid an EV of \$647m in November 2020 for AMAG (EV/sales: 2.4x), and CSL bought Vifor for CHF11.1bn in December 2021 (EV/sales: 9.3x). In the event that ACCRUFer targets are met in the next three years, the stance of Viatrix would become very interesting, in our opinion, especially if the Shield valuation is slow to recover.

Comparative valuation				
Company	*Vifor Pharma	*AMAG (now Covis)	Akebia Therapeutics	Shield Therapeutics
Ticker	VIFN	AMAG	AKBA	STX
Local currency	CHF	\$	\$	£
Share price	173.0	13.8	1.99	0.027
Shares in issue (m)	65.0	36.7	218.2	782.1
Market cap (\$m)	11,245.0	505.0	434.2	36.2
<b>Mkt cap (£m)</b>	<b>8,875.3</b>	<b>385.5</b>	<b>331.4</b>	<b>21.1</b>
Cash	994.5	168.9	34.0	4.9
Debt	-603.6	-311.2	-43.3	-15.6
EV (\$m)	10,854.1	647.3	443.5	44.4
<b>EV (£m)</b>	<b>8,566.8</b>	<b>494.1</b>	<b>338.5</b>	<b>33.9</b>
<b>EV relative to Shield</b>	<b>252.5</b>	<b>14.6</b>	<b>10.0</b>	<b>-</b>

Share prices and currencies taken at close of business on 11 November 2024

\*Based on shares in issue at date of completion of acquisition

Source: Hardman & Co Life Sciences Research

## Company matters

### Registration

Incorporated in the UK with company registration number 09761509.

#### Registered office:

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Baltic Business Quarter  
Gateshead Quays  
Newcastle  
NE8 3DF

+44 (0)191 511 8500

[www.shieldtherapeutics.com](http://www.shieldtherapeutics.com)

### Board of Directors

Board of Directors				
Position	Name	Nominations	Remuneration	Audit
Chairman	Hans Peter Hasler	C	M	M
Chief Executive Officer	Anders Lundstrom			
Non-Executive Director	Fabiana Lacerca-Allen			M
Non-Executive Director	Peter Llewellyn-Davies	M		C
Non-Executive Director	Christian Schweiger	M		
Chief Financial Officer*	Santosh Shanbhag			

M = member; C = chair

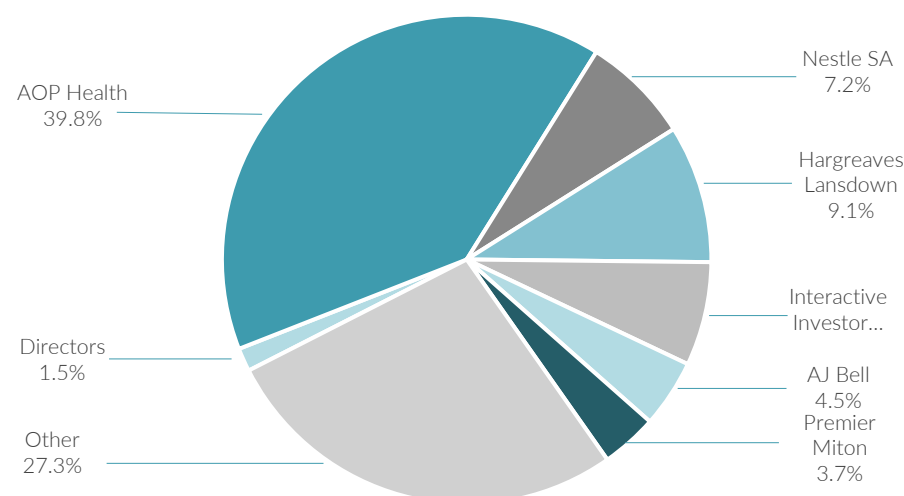
\*Non-board PDMR appointment

Source: Company reports

### Share capital

On 11 November 2024, there were 782,056,367 Ordinary shares in issue. In addition, there are 57.32m options outstanding.

#### Share register



Source: Hardman & Co Research

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