

Shield Therapeutics

H123 results

Ramped up and heading into a stronger H223

Shield Therapeutics' H123 results were largely as expected. Despite the minor operational adjustments with the commercialisation ramp-up, our long-term expectations remain unchanged. H123 revenue of \$4.3m grew 65.8% y-o-y and was largely driven by US Accrufer sales. Total prescriptions grew 59% (vs H222) to 26,200 and are anticipated to accelerate in H223 with the completed build out of its sales platform. For the medium term, we anticipate additional launches in the EU and regulatory approvals in China and our longer-term assumptions remain unchanged. Our valuation remains largely unchanged at £390.4m (£388.9m previously), reflecting updates to net cash (including the recent \$6.1m equity raise) and our near-term estimate adjustments for volume and operating expenses in line with latest management guidance.

Year end	Revenue (\$m)	PBT* (\$m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
12/22	5.5	(31.2)	(13.6)	0.0	N/A	N/A
12/23e	22.9	(29.7)	(4.0)	0.0	N/A	N/A
12/24e	74.8	(15.2)	(2.0)	0.0	N/A	N/A

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

US prescription revenues led the way in H123

In H123, Shield reported 65.8% y-o-y revenue growth, which was primarily led by growing US Accrufer sales (\$3.7m). Management expects H223 growth to be primarily driven by higher Accrufer prescriptions, driven by its focused (100 individuals) sales team, expanding market access (123m covered lives) and continued brand campaigning. Management has adjusted its FY23 US prescription volume guidance to 100–130k in FY23 (125–160k previously) but maintains its long-term expectations of over 500k in FY25. These sales activities will be supplemented with field experts to assist providers in registrations, which management anticipates will reduce the average gross-to-net discount and as a result increase the average selling price to \$220–240 by FY25 to achieve its revenue target of over \$120m.

Cash position bolstered by raise

At the end of H123, the company had cash of \$13.6m, supported by equity financing (\$20.2m in net proceeds) in H123 and a \$10m convertible shareholder loan from AOP. Post-period end, Shield secured [a \\$20m term loan](#) through SWK Holdings, [raised \\$6.1m \(gross\)](#) through an equity issue and announced [a retail offer to raise an incremental \\$1.4m](#), which is valid until 3 October. Net of these cash injections, we believe the company is sufficiently funded to profitability in FY25.

Valuation: £390.4m or 50p per share

Our valuation is largely unchanged at £390.4m from £388.9m previously. The slight adjustment reflects revisions to our short-term estimates reflecting H123 results and tweaked near-term management guidance, and an updated net cash balance. Our per share valuation decreases to 50p (66p previously) given the higher share count.

Pharma and biotech

29 September 2023

Price **7.7p**
Market cap **£60m**

£0.82/US\$; £0.87/€

Proforma net cash (\$m) at 30 June 2023 14.0
(including \$6.1m fundraise in September)

Shares in issue 775.4m

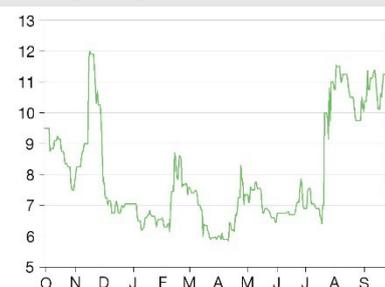
Free float 55%

Code STX

Primary exchange AIM

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs (21.0) 9.2 (16.6)

Rel (local) (23.3) 8.3 (22.6)

52-week high/low 12.5p 5.9p

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 US, Feraccru is marketed internationally through Shield and its commercial partners. Having first followed a self-commercialisation strategy in the US, Shield announced a co-commercialisation deal with Nasdaq-listed Viatrix in December 2022.

Next events

FY23 results April 2024

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Growth prospects driven by US Accrufer prescriptions

Shield reported c \$4.3m in sales in H123, of which over 85% was attributable to US Accrufer sales, indicating the early proliferation of accelerated commercialisation efforts in the US market. During Q223, total US prescriptions grew to 15,808, a 51% (q-o-q) growth over 10,476 prescriptions in Q123. Notably, the company witnessed a strong 157% (q-o-q) growth in first-time writers/prescribers and new prescriptions were up by 63% (q-o-q), along with 73% repeat writers/prescribers from Q123, suggesting favourable clinical responses by the prescribers. In H123, total prescriptions rose to 26,284, which is higher than the total prescription volume of 25,200 in FY22. Based on early indications, the company expects the growth momentum to intensify further, leading management to guide a more profound sequential growth rate of ~80% in Q323 and anticipate US prescriptions in the range of 100,000–130,000 prescriptions in FY23 (details in Exhibit 3).

Exhibit 1: Quarterly prescriptions in 2023



Source: Company presentation, September 2023.
Note: Q323 prescriptions are management estimates based on July and August data.

Exhibit 2: Quarterly prescriptions, FY22–23



Source: Company presentation, September 2023.
Note: Q323 prescriptions are management estimates based on July and August data.

In line with the co-commercialisation deal with Viatrix, Shield implemented several initiatives during the second quarter to access the larger US market potential. Both companies recruited the target sales team of 100 employees by May 2023 (50 each by Viatrix and Shield), which are now ready to target over 12,000 of the highest prescribers. We believe that this larger salesforce (vs 16 in January 2023) will allow broader market coverage and an increased number of touch points with relevant stakeholders, resulting in an incremental flowthrough impact on prescriptions in the near to medium term. Based on current visibility on prescription volumes for H223 and near-to-medium-term preparedness to target the market potential, management has provided revised targets for prescription volumes during FY23–25 (Exhibit 3). We note that the new targets are somewhat lower than previous estimates and we have incorporated these into our model (explained below in the Financials section).

Exhibit 3: Management guidance on US prescription volumes

	FY23e	FY24e	FY25e
Total number of Accrufer prescriptions			
Old	125,000–160,000	370,000–420,000	550,000–600,000
New	100,000–130,000	Greater than 350,000	Greater than 500,000

Source: Company presentation, September 2023

Focus on improving the gross-to-net ratio

Management earlier indicated that a good proportion of prescriptions sales are still subsidised through patient assistant programmes, resulting in the lower average net selling price per prescription. In H123, the average net selling price of Accrufer declined to \$119 per prescription

from \$124 and \$144 per prescription in H222 and FY22, respectively. This translates into a gross-to-net sales price discount of c 75%, which management aims to bring down to its target of 60% by FY25, which is expected to help in improving the average net sales price to US\$220–240 per prescription. We note that this target can be achieved through growing prescription volumes and increased commercial payor and state-run Medicaid coverage and Shield plans to target both:

- **Increase prior authorisations (PA) into payers by healthcare providers (HCP):** Shield plans to modify patient access programmes so that prior PA submission will be required from HCP into payers before patients can access the preferred cash price (implementation expected in early Q4). This is expected to increase PA submissions, approvals and revenue generating prescriptions. Additionally, the company now has a focused field sales team of 100 (in collaboration with Viatrix) in place to target selling activities; therefore, it plans to direct its non-sales team into providing HCP office support for prior authorisations (one per region, 12 total).
- **Extending market access:** the company continues to focus its market access by targeting new payors. Recent wins of two Medicaid programmes (ie Medi-Cal and Medicaid NYR) expanded its access across California and New York. As a result, Shield was able to expand its market access of total covered lives to 123m as of September 2023, compared to 100m at end Q123. As a reminder, Shield is on the formulary list of several key pharmacy benefit managers (PBMs) in the United States, including Express Scripts, Optum and Cigna.

Europe potential yet to be fully tapped

Norgine, Shield's European sales partner for Feraccru, has been recording stable revenues from the region. In H123, the total sales volume of Feraccru packs increased 19% over H222 and 11% over H122. Germany, the UK and the Nordics remain key sales contributors for Norgine in the region, with the UK and Germany collectively accounting for 88% of total sales packs in Europe. The company continues to seek reimbursement in several European countries, such as Spain and Italy. As a reminder, Norgine has been undergoing internal restructuring (after Goldman Sachs Asset Management acquired a majority stake in the company in December 2022) and is working towards shifting its sales strategy to target the primary/women's health market, compared to its earlier focus on the gastro-intestinal market. While this may yield an enhanced sales uplift in the medium term, we estimate a similar growth trend (as seen in H123) for this geography unless approvals in new EU countries are obtained.

Update on global partnerships

Though Shield currently generates revenue from US and Europe markets, it has several partnership agreements in other regions as well, which if successfully executed could provide material upside in revenue potential for the company. One of the key partnership deals is with ASK Pharma in China, which is currently enrolling patients for its Phase III study in China, as required for National Medical Products Administration approval. We note that enrolment for the Phase III programme was affected by the prevalence of COVID-19; however, these challenges have been resolved now with eased restrictions and we continue to estimate a launch in 2025 and ascribe a 75% probability of approval.

KYE Pharmaceuticals (Canada) filed a New Drug Submission for Accrufer with Health Canada in Q122 and anticipates approval by the end of FY23. Korea Pharma (Republic of Korea) is enrolling patients in a pharmacokinetic study, which is required to get approval in the region.

Lapse of AOP takeover offer

In an important development, AOP Health International Management (AOP), Shield's largest shareholder, made a mandatory takeover offer in May 2023. However, the offer lapsed as the company received valid acceptances from only 42.26% of existing shareholders (including 40.75% share capital owned by AOP), which was lower than the threshold limit of 50% for takeover approval. To provide more context to the development, Shield entered into a convertible shareholder loan agreement, worth \$10m, with AOP in July 2022 and drew it fully in August 2022. Further in December 2022, the shareholder loan was extended to provide an additional \$10m convertible loan facility to Shield, which was drawn in January 2023.

Post the initial conversion of the loan into shares ([31.3m](#)) in January 2023, AOP held 26.99% of Shield's total outstanding share capital. Another conversion request from AOP in May 2023 was also approved by the company's board and led to the issue of another 127.3m shares, resulting in AOP holding 41.9% of Shield's share capital post conversion. As per Rule 9 of the City Code on Takeovers and Mergers, AOP made a [mandatory takeover offer](#) for the company at 6.2p per Shield share, at a 13.3% discount to the last trading price before the date of the announcement, valuing the company at £46.1m on a fully diluted basis. While Shield advised its shareholders not to subscribe to the offer, AOP also acknowledged that the mandatory offer was at a discount to the traded price and may not be accepted. We note that AOP is a long-term shareholder of Shield and has been supportive its growth strategy. Later, AOP expressed its willingness to let Shield operate as an independent company. Hence, both companies signed a relationship agreement that permitted Shield to continue to work independently despite the takeover offer. On 15 June, the takeover offer lapsed due to an insufficient number of shareholders agreeing to the takeover terms. At end H123, the total outstanding AOP loan was \$5.7m, which Shield plans to repay from the recently secured term loan of \$20m from SWK Holdings in September 2023 (discussed below).

Financials

In H123, Shield reported total revenue of \$4.3m (65.8% growth over H122 revenue of \$2.6m), which mainly comprised \$3.7m from Accrufer sales in the US and the remaining \$0.6m from royalties from Norgine related to Feraccru sales in Europe. Additionally, the company recognised \$4.3m in other operating income in H123, which is primarily the deferred portion of total \$5m upfront payment received as part of the Viatrix deal at end FY22. Gross profit stood at \$2.2m (vs \$1.5m in H122), translating into a gross margin of 51.9% for H123, lower than 56.4% in the prior period. The decline in gross margin could be due to a lower average selling price of \$119 in H123 compared to \$152 in H122. We note that the cost of sales includes the manufacturing cost of prescriptions sold in Europe and the US, along with a 45% share of US net sales as part of the Viatrix deal and a 5% royalty to Vitra Pharmaceuticals as per the 2010 asset purchase agreement.

SG&A expenses (excluding \$0.5m in amortisation of intangible assets) increased 23.7% y-o-y to \$17.2m due to accelerated commercialisation efforts in the US as per the co-commercialisation deal with Viatrix (headcount growth to 50 at Shield vs 28 at end FY22). The expensed R&D costs of \$0.4m were lower than \$1.3m in H122 and were fully attributable to the company's ongoing paediatric study assessing Feraccru/Accrufer in infants, children and adolescents. The company reported that enrolment is progressing although completion timelines have not been disclosed. We note that \$1.5m of R&D related costs were capitalised during first half of 2023, similar to H122. As a result, the operating loss for the period stood at \$11.5m versus \$15.0m in H122. The operating cash burn rate was reported at \$19.9m in H123, up from \$14.3m in H122.

Based on H123 performance and near-term operational visibility from management, we have made adjustments to our forecasts and updated our FX assumptions (to £0.82/\$ versus £0.80/\$

previously). Additionally, we have converted our estimates into US dollars (vs sterling previously) because Shield has changed its reported currency from sterling to US dollars due to the increased focus on US operations. In line with revised management guidance for US annual prescriptions (lower than previously) during FY23–25 (see Exhibit 3), we have slightly trimmed our forecasts for US prescriptions, resulting in Accrufer sales estimates of \$20.9m (\$22.9m previously) in FY23 and \$71.8m (\$79.0m previously) in FY24. Factoring in a lower pace of sales growth in Europe and low visibility on new market launches, we have also reduced European sales forecasts, to \$2.0m in FY23 and \$3.0m in FY24, versus \$4.6m and \$6.8m previously in the respective periods. Based on directional guidance from management regarding operating expenses (\$42–50m during FY23–25), we have slightly increased our selling expense estimates, hence, our total operating expense estimates are now \$42.2m in FY23 and \$45.6m in FY24. Our revised operating loss estimates stand at \$29.1m in FY23 and \$13.2m in FY24, compared to \$25.3m and \$9.2m, respectively, previously. We note that our longer-term growth assumptions remain unchanged.

We anticipate an increase in interest expenses during FY24–25 as the company raised \$20m via a new term loan of \$20m from SWK Holdings in September 2023 (details below in the valuation section). As a result, we have revised our net loss estimates for FY23 and FY24 to \$29.7m (\$26.1m previously) and \$15.2m (\$10.9m previously), respectively. Though management expects to achieve cash flow break-even by end FY24, we continue to project the company turning EBITDA positive in 2025. Changes to our group-level estimates are presented in Exhibit 4.

Exhibit 3: Changes to estimates

\$'000s	FY23e		FY24e	
	New	Old	New	Old
Total revenues	22,923	27,511	74,793	85,811
– Accrufer sales	20,892	22,899	71,834	78,992
– Feracru Europe sales	2,030	4,612	2,958	6,820
– Other revenue	0	0	0	0
Gross profit	9,775	11,669	33,186	37,919
Gross margin	42.6%	42.4%	44.4%	44.2%
Operating Profit	(29,127)	(25,300)	(13,181)	(9,198)
PBT	(29,663)	(26,105)	(15,219)	(10,889)
EPS (\$)	(0.04)	(0.03)	(0.02)	(0.01)

Source: Edison Investment Research. Note: *An exchange rate of £0.80/US\$ has been used to convert previous estimates into US dollars.

The company closed H123 with a gross cash balance of \$13.6m, supported by \$20.2m (net proceeds) from equity financing and an additional \$10m convertible shareholder loan from AOP, both in January 2023. Shield recently [announced](#) it raised \$6.1m through the subscription and placement of new shares (62.4m shares) to institutional investors (existing as well as new) and [proposed a retail offer](#) to raise another \$1.4m. The issue price for both the share placement for institutional investors and retail investors is set at 8p per new share. Additionally, the company secured a \$20m term loan from SWK Holdings, which has a five-year term and interest payable at 9.25% plus the greater of three-month CMR term SOFR (secured overnight financing rate) or 5%. Interest needs to be paid for the first eight quarters, following which the loan will be amortised at a fixed \$1m per quarter. The loan agreement comes with financial covenants in respect to minimal liquidity (not less than the greater of either trailing one quarter of cash burn or \$2.5m) and minimum revenue targets (Exhibit 5). We believe these revenue targets are achievable based on our current revenue estimates.

Exhibit 5: SWK minimum revenue covenants

Trailing four fiscal quarters ended (LTM)	Minimum group revenue (\$m)
Q323	8.5
Q423	14.5
Q124	22.5
Q224	31.5
Q324	38.9
Q424 and each fiscal quarter thereafter	45.7

Source: company presentation, September 2023

The company plans to utilise the proceeds in repaying the outstanding AOP loan, accelerating commercialisation and growth initiatives, along with managing working capital requirements. We note that management estimates that the company will become cash flow positive by Q424; however, our projections suggest a more conservative timeline of FY25.

Valuation: £390.4m or 50p per share

As we incorporate the above-mentioned changes in our estimates, roll forward our model and update FX and net cash, our valuation slightly adjusts to £390.4m, from £388.9m previously. However, our per share valuation has reduced to 50p, versus 66p, due to the increased base of shares outstanding of 775.4m, versus 587.5m previously. For valuation purposes, we have considered pro-forma net cash of £11.5m (\$14.0m), which includes [the recently announced equity raise of \\$6.1m](#). The increase in net cash has made a positive contribution to our valuation, while the revised estimates brought down the rNPV of valued assets to £378.9m, from £382.1m previously.

Exhibit 6: 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	230	411.5	100%	411.5	0.53
Feraccru in IDA	Europe	2019	37	41.8	100%	41.8	0.05
Feraccru in IDA	China	2025	62	68.3	75%	51.3	0.07
Corporate costs				(125.5)		(125.5)	(0.16)
Pro-forma net cash at 30 June 2023				11.5		11.5	0.01
Total equity value						390.4	0.50

Source: Edison Investment Research

Exhibit 7: Financial summary

	\$000s	2022*	2023e	2024e
Year end 31 December				
PROFIT & LOSS				
Revenue		5,492	22,923	74,793
Cost of Sales		(3,038)	(13,148)	(41,607)
Gross Profit		2,454	9,775	33,186
Other operating income		859	4,298	0
Sales, General & Administrative		(30,707)	(40,987)	(44,388)
Net Research & Development		(1,315)	(1,000)	(800)
EBITDA		(28,709)	(27,914)	(12,002)
Depreciation & amortisation of intangible assets		(2,904)	(1,212)	(1,179)
Operating profit before exceptionals		(31,613)	(29,127)	(13,181)
Exceptionals including asset impairment		(17,748)	0	0
Other		0	0	0
Reported Operating Profit		(49,361)	(29,127)	(13,181)
Net Finance income (costs)		408	(536)	(2,038)
Profit Before Tax (norm)		(31,205)	(29,663)	(15,219)
Profit Before Tax		(48,953)	(29,663)	(15,219)
Tax		(447)	0	0
Profit After Tax and minority interests (norm)		(31,652)	(29,663)	(15,219)
Profit After Tax and minority interests		(49,400)	(29,663)	(15,219)
Average Number of Shares Outstanding (m)		233.2	744.2	775.4
EPS - normalised (c)		(13.6)	(4.0)	(2.0)
EPS - normalised fully diluted (c)		(12.3)	(3.8)	(1.8)
EPS - (IFRS) (c)		(21.2)	(4.0)	(2.0)
Dividend per share (p)		0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets		14,446	14,734	14,905
Intangible Assets		14,208	14,496	14,667
Tangible Assets		238	238	238
Other fixed assets		0	0	0
Current Assets		12,172	45,382	34,283
Short-term investments		0	0	0
Cash		3,402	32,490	20,773
Other		8,770	12,892	13,510
Current Liabilities		(12,828)	(18,443)	(22,734)
Creditors		(12,828)	(18,443)	(22,734)
Short term borrowings		0	0	0
Long Term Liabilities		(7,245)	(26,267)	(26,267)
Long term borrowings		(6,683)	(25,705)	(25,705)
Other long term liabilities		(562)	(562)	(562)
Net Assets		6,545	15,406	188
CASH FLOW STATEMENT				
Operating profit		(49,361)	(29,127)	(13,181)
Movements in working capital		6,377	1,600	3,673
Net interest and financing income (expense)		(400)	536	2,038
Depreciation & other		2,848	1,212	1,179
Taxes and other adjustments		19,045	(536)	(2,038)
Net Cash Flows from Operations		(21,491)	(26,315)	(8,330)
Capex and capitalised expenditures		(2,285)	(1,500)	(1,350)
Acquisitions/disposals		0	0	0
Interest received & other investing activities		36	326	812
Net Cash flows from Investing activities		(2,249)	(1,174)	(538)
Net proceeds from share issuances		5	26,270	0
Net movements in long-term debt		10,000	30,000	0
Dividends		0	0	0
Other financing activities		(636)	(969)	(2,850)
Net Cash flows from financing activities		9,369	55,301	(2,850)
Effects of FX on Cash & equivalents		1,372	1,276	0
Net Increase (Decrease) in Cash & equivalents		(12,999)	29,088	(11,717)
Cash & equivalents at beginning of period		16,401	3,402	32,490
Cash & equivalents at end of period		3,402	32,490	20,773
Closing net debt/(cash)		3,281	(6,785)	4,932

Source: Company reports, Edison Investment Research. Note: *The company has provided restated FY22 numbers in US dollars (pound sterling previously) due to recent change in reporting currency. Our estimates for FY23 and FY24 have been converted into US dollars accordingly.

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