



Shield Therapeutics plc
("Shield" or the "Company" or the "Group")

Business Update for Q1 2024 and Confirmation of Key Financials for FY 2023

Total U.S. Accrufer® prescriptions increased to c. 77,000 in 2023 and totalled c. 28,800 in Q1 2024

Cash and financial foundation strengthened via a \$10m accounts receivable financing and improvement of revenue covenants associated with the existing \$20m debt financing

Guidance reiterated to turn cashflow positive in H2 2025

London, UK, April 30, 2024: Shield Therapeutics plc (LSE: STX), a commercial-stage pharmaceutical company that delivers Accrufer®/Feraccru® (ferric maltol), an innovative and differentiated specialty pharmaceutical product, to address a significant unmet need for patients suffering from iron deficiency (with or without anaemia) provides a business update for Q1 2024 and confirms its key financials for the year ended 31 December 2023. Whilst the Company's audit process for the year ended 31 December 2023 is significantly advanced, additional time is required to finalise the translation of the Group's presentational currency from GBP to USD. The Company now expects to issue its fully audited results for FY23 before 10 May 2024. The details provided in the [full year trading](#) update remain unchanged.

2023 Key Business Metrics: confirmed as previously reported on [21 February 2024](#)

- **Total 2023 revenue and other income:** \$17.5m, a 2.8x increase over FY22
 - **Accrufer® revenue:** \$11.6m, a 3.1x increase over FY22
 - **Ex-U.S. revenue:** \$1.5m of royalty revenue from product sales in Europe
 - **Other income revenue including Viatris milestone payments:** \$4.4m
- **Total 2023 Prescriptions:** c.77,000, a 310% increase over FY22
- **Operating Loss:** \$31.1m compared to \$49.8m in FY22
- **Cash and cash equivalents:** \$13.9m as of 31 December 2023

Q1 2024 Update

During the first quarter of 2024, Shield reported net revenues of \$4.0m from c.28,800 prescriptions of Accrufer®. In addition, the Company strengthened its balance sheet through an accounts receivable financing with Sallyport Commercial Finance (Sallyport) and amended its existing \$20m debt facility agreement with SWK Funding LLC (SWK), with more favourable loan covenant terms. Shield also expects to turn cashflow positive in H2 2025 with its current resources.

Q1 2024 Key Business Metrics:

- **Total US Accrufer revenue:** \$4.0m with an Average Net Selling Price of c. \$140/prescription
- **Total Q1 Prescriptions:** c.28,800, a 1% rise over Q4 2023 and 174% increase over Q1 2023.
 - Shield has worked very closely with its third-party data provider to rectify the prescription reporting issue and has implemented an enhanced multi-source system
- **New Financing:** secured a \$10m accounts receivable financing and signed an amendment to improve the revenue covenants associated with the existing SWK \$20m debt financing (additional details at end of this announcement)
- **Cash and cash equivalents:** \$10.4m as of 31 March 2024

First quarter Accrufer® prescriptions of c.28,800 increased by 174% compared to Q1 2023 and 1% compared to Q4 2023. Strong quarterly growth of c.29% in the largest US states California and New York and positive changes in prior authorisation (PA) submission rates were offset by a 28% decline in Texas due to a transition and lack of a Texas State Medicaid Pharmacy Benefit Manager (PBM) during the quarter, which resulted in significant inconsistencies in PA approvals for Accrufer® Medicaid prescriptions. The new PBM began on 1 April 2024 and

Shield is working on behalf of its Health Care Providers (HCPs) and patients in Texas to enable greater consistency in PA requirements and approvals.

Greg Madison, CEO of Shield Therapeutics, commented: *“We observed several encouraging growth signals during Q1 2024 including rising prescriptions in key states such as California and New York, after receiving access to Medicaid in those populous states. Additionally, our stated initiatives to improve the average net selling price by increasing PA submission rates and more favourable Medicaid pricing following renegotiation of payer contracts, are progressing very well. While the situation in Texas dampened the impact of these positives, we are engaged with the new PBM with the aim of finding a resolution as quickly as possible.”*

“We continue to believe that Accrufer® addresses an important unmet market need for a safe and well tolerated oral iron therapy. We fully expect to continue growth in prescriptions in Q2 and beyond and will continue to focus on increasing our average net selling price with targeted investments such as the new field access team, deployed in early April, to assist HCP offices with PA support and education. The belief, passion and motivation to succeed by both Shield and Viatrix was readily evident at our recent National Sales Meeting. We remain focused on our mission to make Accrufer® the oral iron of choice for patients with iron deficiency, with or without anaemia.”

The information contained within this announcement is deemed by the Company to constitute inside information as stipulated under the Market Abuse Regulation (EU) No. 596/2014 (as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018). Upon the publication of this announcement via the Regulatory Information Service, this inside information is now considered to be in the public domain.

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About Iron Deficiency and Accrufer®/Feraccru®

Clinically low iron levels (aka iron deficiency, ID) can cause serious health problems for adults of all ages, across multiple therapeutic areas. Together, ID and ID with anaemia (IDA) affect about 20 million people in the U.S. and represent a \$2.3B market opportunity. As the first and only FDA approved oral iron to treat ID/IDA, Accrufer® has the potential to meet an important unmet medical need for both physicians and patients.

Accrufer®/Feraccru® (ferric maltol) is a novel, stable, non-salt-based oral therapy for adults with ID/IDA. Accrufer®/Feraccru® has a novel mechanism of absorption compared to other oral iron therapies and has been shown to be an efficacious and well-tolerated therapy in a range of clinical trials. More information about Accrufer®/Feraccru®, including the product label, can be found at: www.accrufer.com and www.feraccru.com.

About Shield Therapeutics plc

Shield is a commercial-stage specialty pharmaceutical company that delivers Accrufer[®]/Feraccru[®] (ferric maltol), an innovative and differentiated pharmaceutical product, to address a significant unmet need for patients suffering from iron deficiency, with or without anaemia. The Company has launched Accrufer[®] in the U.S. with an exclusive, multi-year commercial agreement with Viatris Inc. (Viatris). Outside of the U.S., the Company has licensed the rights to four specialty pharmaceutical companies. Feraccru[®] is commercialised in the UK and European Union by Norgine B.V. (Norgine), which also has marketing rights in Australia and New Zealand. Shield also has an exclusive license agreement with Beijing Aosaikang Pharmaceutical Co., Ltd., for the development and commercialisation of Accrufer[®]/ Feraccru[®] in China, Hong Kong, Macau and Taiwan; with Korea Pharma Co., Ltd. for the Republic of Korea (Korea Pharma); and with KYE Pharmaceuticals Inc. for Canada.

Accrufer[®]/Feraccru[®] has patent coverage until the mid-2030s.

Accrufer[®]/Feraccru[®] are registered trademarks of Shield Therapeutics.

Forward-Looking Statements:

This press release contains forward-looking statements. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements. These forward-looking statements are based on management's current expectations and include statements related to the commercial strategy for Accrufer[®]/Feraccru[®]. These statements are neither promises nor guarantees, but involve known and unknown risks and uncertainties, many of which are beyond our control, that may cause actual results and performance or achievements to be materially different from management's expectations expressed or implied by the forward-looking statements, including, but not limited to, risks associated with the Company's business and results of operations, competition, and other market factors. The forward-looking statements made in this press release represent management's expectations as of the date of this press release, and except as required by law, the Company disclaims any obligation to update any forward-looking statements contained in this release, even if subsequent events cause its views to change.

Additional details on the Sallyport Commercial Finance Accounts Receivable Financing

Shield has implemented an accounts receivable financing facility with Sallyport Commercial Finance for \$10m. The facility has been provided for a period of 12 months with an option to renew at existing terms. The facility will be secured by Accrufer[®] accounts receivables in the U.S. and will bear an interest rate of WSJ Prime + 3.0% on funds deployed.

Additional details on the amendment to the SWK Financing

Shield and SWK Financing have amended the existing agreement on the \$20m term loan with a maturity date of 28 September 2028. The amendment includes an update to the financial covenant of minimum revenue targets, as outlined below, and a change in the final payment fee from 6.0% to 6.5%.

Trailing Four Fiscal Quarters (i.e., 12 months) Ended	Revised minimum revenue targets
Q3 2023	\$8,500,000
Q4 2023	\$14,500,000
Q1 2024	\$15,000,000
Q2 2024	\$16,500,000
Q3 2024	\$22,500,000
Q4 2024	\$31,500,000

Q1 2025	\$38,900,000
Q2 2025+	\$45,700,000