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

Audited results for the year ended 31 December 2024

2024 Group net revenues and other income at $32.3m with ACCRUFeR® net revenues growing 153% to $29.3m

Substantial progress made in expanding global patient access of ACCRUFeR®/FeRACCRU®

London, UK, 24 April 2025: Shield Therapeutics plc (LSE: STX), a commercial-stage pharmaceutical company specialising in iron deficiency, confirms its audited results for the year ended 31 December 2024.

2024 reflected a significant step-up in revenue, alongside making substantial progress in expanding global patient access of ferric maltol. The Company reported total revenues and other income of $32.3m for FY24 (FY23: $17.5m) and has seen strong improvements in ACCRUFeR® prescriptions with a 95% growth in total prescriptions to c.150,000 in 2024 generating $29.3m of ACCRUFeR® revenues (FY23: $11.6m), an increase of 153%.

During the final quarter of 2024, the Company took a decisive step to strengthen its balance sheet by securing $10.0m in equity funding from its largest shareholder AOP Health International Management AG ("AOP"), alongside a small contribution from a RetailBook Offer. This funding, which was completed at a premium to the prevailing share price, was received in January 2025. Shield held cash and cash equivalents of $6.5m as at 31 December 2024 (31 December 2023 was $13.9m), with an additional $10m of gross proceeds received on 3 January 2025. The strengthened balance sheet, along with the previously announced savings to the Group's operating cost base, will help the Company achieve its aim of becoming cash flow positive by the end of calendar 2025.

2024 Financial Highlights

- **Total 2024 net revenue and other income** of $32.3m ($17.5m FY23).
    - **ACCRUFeR® net revenue** of $29.3m, a 153% increase over 2023 reported revenues.
    - **Ex-U.S. revenue** of $2.9m of royalty and milestone related revenue from partners.
- **Loss for the year** of $27.2m compared to $33.3m in FY23.
- **Cash and cash equivalents** of $6.5m as of 31 December 2024, with an additional $10.0m of gross proceeds from the equity funding received post year end, expected to provide sufficient capital to allow the Company to become cash flow positive by the end of the year.

2024 Operational Highlights

- **Commercialisation of ACCRUFeR® in the US:** Continued growth and strong market results with our partner, Viatris Inc.
    - **ACCRUFeR® Prescriptions** of c.150,000 for FY24, almost double FY23.
    - **ACCRUFeR® average net price** of $184 for FY24 and exiting Q4 2024 at $237 driven by successful execution of market access strategies.
    - **Realignment of US sales team** in Q4 2024 focusing on territories with highest potential, optimal coverage and strong ACCRUFeR® performance.
- **Global ACCRUFeR®/FeRACCRU® development programs:** Continued progress in development stage partnerships in Canada, Republic of Korea, China, and the pediatric program.
    - **Kye Pharmaceuticals ("Kye") in Canada**: ACCRUFeR® approved by Health Canada, the only oral iron therapy approved as a prescription drug in Canada. The team at Kye announced the launch of ACCRUFeR® in March 2025. For the remaining term of the agreement, Shield will receive additional revenue-based milestone payments along with double-digit royalties on net sales of ACCRUFeR®.

- **Korea Pharma ("KP") in Korea**: KP filed a New Drug Application for ACCRUFeR® in the Republic of Korea (South Korea) following the successful completion of a pharmacokinetic (PK) study. Pending a successful review, approval of ACCRUFeR® in Korea is anticipated in 2025.
- **ASK Pharma ("ASK") in China**: ASK announced completion of the recruitment of adult patients with IBD and IDA in the Phase 3 confirmatory study, which is the final study required to support the filing of an NDA in China for the commercialisation of ACCRUFeR®/ FeRACCRU®. The Company expects the NDA to be filed with the Chinese National Medical Products Administration (NMPA) in 2025.
- **Pediatric study:** Results from the Phase 3 pediatric clinical trial (FORTIS/ST10-01-305), confirmed the efficacy, safety, and tolerability of the new oral liquid pediatric suspension in children with iron deficiency anemia (IDA). The trial was the final study in the comprehensive pediatric development program that Shield committed to implement with both the European EMA and the US FDA.

2024 Annual Report and Notice of Annual General Meeting

The Annual Report and Accounts and Notice of AGM will be sent to shareholders and in accordance with AIM Rule 26, these documents will also be available to view on the Company's website: Results, Reports & Presentations | Shield Therapeutics plc as of 25 April 2025.

This year the Company's AGM will be held at 2.00 pm (BST) on 22 May 2025 at the offices of Shield Therapeutics plc, Northern Design Centre, Baltic Business Quarter, Gateshead Quays, NE8 3DF. If you wish to attend the AGM in your capacity as a shareholder, please bring proof of shareholding or if shares are held through a nominee account, a letter of representation, to facilitate your entry into the Meeting. The Company will provide a facility for shareholders to join the AGM online and telephonically and there will be an opportunity for shareholders to ask questions. To facilitate the process, the Board would request that shareholders register for the meeting and submit questions in advance, before 2.00 pm (BST) on 20 May 2025.

To register for dial-in details and to submit any questions please contact Investor Relations via email at investorrelations@shiedtx.com or call +44 (0)191 511 8500.

For further information please contact:

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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 anemia (IDA) affect about 20 million people in the US 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. The drug 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 anemia. The Company launched ACCRUFeR® in the U.S. with an exclusive, multi-year collaboration agreement with Viatris Inc. Outside of the U.S., the Company licensed the rights to four specialty pharmaceutical companies. FeRACCRU® is commercialized in the UK and European Union by Norgine B.V., 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 commercialization of ACCRUFeR®/ FeRACCRU® in China, Hong Kong, Macau and Taiwan, with Korea Pharma Co., Ltd. for the Republic of Korea, 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.

Chairman and Chief Executive Officer's joint statement

As we reflect on Shield's performance during 2024, we are very proud of our teams' efforts in making significant progress towards achieving our strategic goal of positive cash flow by the end of 2025.

In 2024 Shield generated a total of $32.2 million in net revenues (excluding Other Income), reflecting 146% growth over 2023 which was mainly driven by sales growth in the US market. The team worked hard to ensure that we strengthened our balance sheet by adding ~$31 million in additional financing in 2024 and shortly post the year end and resetting our operating cost base to put us in the best position to deliver against our core objective of being cash flow positive by end of 2025. In the US, ACCRUFeR® prescriptions nearly doubled while the average net selling price increased to $237 in Q4 2024, compared to $143 in Q4 2023. Additionally, 2024 saw a 153% year-over-year increase in net revenues from ACCRUFeR® reaching $29.3 million.

Our partnership with Viatris in the US has continued to progress steadily and successfully. Both organisations are strategically aligned and the commercialisation of ACCRUFeR® benefits from a strong collaboration and focused execution. Together, we remain steadfast in our commitment to making ACCRUFeR® the oral iron of choice in the US. Outside of the US we were thrilled that in 2024 our partner in Canada, KYE Pharmaceuticals, was able to secure regulatory approval for ACCRUFeR® as a prescription drug for the treatment of adults with iron deficiency anemia (IDA) with Health Canada. This milestone makes Health Canada the fifth regulatory agency in the world, after the FDA (US), EMA (EU), TGA (Australia), and Swiss Medic (Switzerland), addressing a significant unmet need for patients suffering from ID/IDA.

Similarly, our partner Korea Pharma, is working closely with the Korean Ministry of Food and Drug Safety (MFDS) to secure approval of ACCRUFeR® in South Korea, while our partner ASK Pharma has successfully completed recruitment of the Phase III confirmatory study in China in adult patients with inflammatory bowel disease (IBD) and IDA. We are also excited about the prospect of receiving a label expansion from the FDA and EMA for pediatric patients with IDA based on successfully proving highly clinically relevant effectiveness in a pivotal trial in that patient population.

Royalty and milestone revenues accounted for $2.9 million (2023: $1.5 million) including $2.1 million from FeRACCRU® sales in Europe by Norgine, with Germany and United Kingdom accounting for 67% and 21% respectively. Therefore, whilst the US market is the core near-term growth driver, we expect incremental revenues from other territories to become increasingly significant to the Group in the future.

We couldn't be prouder of the dedication, resilience, and performance shown by our team throughout 2024. The milestones we reached in 2024 not only highlight the strength of our team but also the growing demand and receptivity to ACCRUFeR® by patients and physicians across global markets.

Looking Ahead – Our goal is to be a self-sustaining business by the end of 2025. The solid financial foundation we have in place exiting 2024, empowers us to move forward with confidence, fully equipped to execute our strategy. With a stronger balance sheet, effective cost-saving measures, and a thriving presence in the U.S. market, aiming at achieving cash flow positivity by the end of 2025. As we look ahead, our focus is crystal clear:

- Grow ACCRUFeR® net revenues
- Turn cash flow positive by the end of 2025
- Expand Global access to ACCRUFeR®

We are just getting started on our journey to making ACCRUFeR® the oral iron of choice.

Hans Peter Hasler, Chairman
Anders Lundstrom, Chief Executive Officer

Financial Review

Revenue

In 2024, total revenue (excluding other income) reached $32.2 million, up from $13.1 million in 2023. This includes $29.3 million (2023: $11.6 million) in net product revenue from ACCRUFeR® sales in the US, with c.150,000 prescriptions (2023: c.77,000 prescriptions). A significant portion of 2023 and 2024 prescription sales were subsidized through patient assistance programs, resulting in a net average sales price of $184 in 2024 (2023: $137). By the end of Q4 2024, the net average sales price had increased to $237.

Additionally, royalty and milestone revenues accounted for $2.9 million (2023: $1.5 million) including $2.1 million from FeRACCRU® sales in Europe by Norgine, with Germany and United Kingdom accounting for 67% and 21% respectively. Milestone payments accounted for $0.8 million from our Canadian, Korean and prospective Japanese partners.

Cost of sales

The cost of sales for 2024 totaled $17.3 million, compared to $9.0 million in 2023. This includes the manufacturing and shipping costs for prescriptions sold in the US, finished packs supplied to Norgine for sale in Europe, and a 5% royalty on net sales payable to Vitra Pharmaceuticals Limited ("Vitra") who are the original owners of the intellectual property behind ACCRUFeR®/FeRACCRU®.

Selling, general and administrative expenses

Selling, general and administrative expenses were $36.0 million in 2024 (2023: $38.0 million). The decrease was driven primarily due to the restructuring of the ACCRUFeR® sales force announced in Q4 2024. The share-based payment charge to the income statement was $0.9 million in 2023 and 2024.

Research and development

The Group spent $4.3 million (2023: $4.5 million) on research and development. Of that total spend, $2.4 million (2023: $2.7 million) have been capitalised as additions to intangible assets, as management deemed that it is probable that these costs will generate future economic benefits. The balance of $1.9 million (2023: $1.8 million) was expensed in the current year. Research and development expenditure is predominantly related to the ongoing pediatric study.

Financial income

Financial income of $0.3 million was reported in 2024 (2023: $0.5 million). This income was generated primarily through interest received from treasury bank account interest.

Financial expense

Financial expense of $3.9 million was reported in 2024 (2023: $1.6 million). The expense was primarily related to interest charged on the shareholder loan and later the long-term loan with SWK Holdings alongside the AOP milestone financing put in place during 2024.

Balance sheet

As of 31 December 2024, cash stood at $6.5 million, down from $13.9 million on 31 December 2023. As at 31 March 2025 cash and cash equivalents were $10.5 million reflecting the close of the equity financing just post the year end.

Intangible assets increased to $18.2 million as of 31 December 2024, up from $16.9 million in 2023. This includes capitalized development costs for FeRACCRU®, such as the ongoing pediatric pharmacokinetic study, and costs related to FeRACCRU® patents and trademarks, which were incurred to strengthen the Group's intellectual property.

Inventories grew to $5.7 million (31 December 2023: $3.2 million), reflecting the Group's efforts to build inventory in response to growing demand in the US market.

Trade and other receivables as of 31 December 2024 were $25.0 million, up from $13.5 million at 31 December 2023. This increase is due to higher trading volumes in the US, alongside $10.0 million owed by AOP from the equity placing on 29 December 2024, which was paid on 3 January 2025.

The current tax asset stood at $0.3 million at 31 December 2024, down from $0.6 million in 2023. This relates to the expected R&D tax credit claim for the 2024 and 2023 financial years.

Non-current liabilities include a long-term loan from SWK Holdings for $19.8 million and milestone financing from AOP for $6.4 million. Both loans are accounted for using an effective interest rate method in line with IFRS 9.
Trade and other payables were $23.2 million as of 31 December 2024, compared to $12.7 million at 31 December 2023. This increase is primarily due to the growth in trading volumes in the US.

Other liabilities were $9.2 million (2023: $0.8 million) which included $9.0 million (2023: $Nil) of accounts receivable financing with Sallyport Commercial Finance.

Lease liabilities decreased from $0.4 million in 2023 to $0.2 million in 2024.

Cash flow
Net cash outflow in 2024 was $7.5 million, decreasing the cash on hand from $13.9 million at 31 December 2023 to $6.5 million at 31 December 2024. Net cash outflows from operating activities was $6.8 million, comprised of $27.2 million loss for the year, adjusted for non-cash items of $6.6 million (including depreciation and amortisation of $1.4 million, share-based payments of $0.9 million, net financial expense of $3.7 million and income tax of $0.6 million) and a net decrease in the Group's working capital of $13.8 million.

Net cash outflows from investing activities of $2.2 million are the result of capitalised development expenditure of $2.4 million and financial income of $0.3 million.

Net cash inflows from financing activities of $1.4 million are attributable to $5.7 million received in relation to the AOP milestone monetisation agreement, interest paid of $3.9 million, payment of lease liabilities of $0.2 million, proceeds from equity raise of $0.1 million and legal fees paid in relation to the equity raise of $0.2 million.

Going concern
At 31 December 2024, the Group held $6.5 million in cash. The Group's unaudited cash balance at 31 March 2025 was $10.5 million.

Since year end the Group has received $10.0 million from AOP in relation to the pre-year end equity placing.
The forecasts show that the Group's monthly cash flows start to turn positive by the end of 2025 and the Group has sufficient cash to allow the business to continue in operations for at least 12 months from the date of approval of the Financial Statements. The Directors have considered scenarios in which sales revenues fall below base case forecasts. In these circumstances mitigating actions such as reduction of discretionary marketing, general and administrative, and production related expenditure combined with the reliance on the full $15.0 million accounts receivable facility could be taken to preserve cash. The Directors also believe that other forms of finance, such as royalty finance are likely to be available to the Group.

Based on the above factors, the Directors believe that it remains appropriate to prepare the financial statements on a going concern basis.

Recent shifts in U.S. economic policy, including the imposition of tariffs on imported goods such as pharmaceuticals and active pharmaceutical ingredients (APIs), present ongoing risks and uncertainties for our business. These measures may lead to increased costs, supply chain disruptions, and margin pressure, particularly if alternative sourcing options are limited or similarly affected. The evolving nature of U.S. trade policy, including the potential for future tariffs or retaliatory actions by other countries, creates added unpredictability that may impact our operational planning and financial performance. We continue to monitor these developments and evaluate strategies to mitigate potential impacts.

Financial outlook

On the back of significant expansion of ACCRUFeR® in the US in 2024, the Company is poised for a fresh wave of growth in ACCRUFeR® primarily driven by execution of an optimized sales force plan in close collaboration with our partner, Viatris Inc., increasing patient and physician awareness, and enhancing patient access. Globally, we see an oral iron market which has clear needs based on physician and patient feedback for a product that delivers both effectiveness and tolerability.

Contributions from our global partners including continued growth of FeRACCRU® by Norgine in EU, launch of ACCRUFeR® by Kye Pharmaceuticals in Canada, and the progression of the regulatory processes in Korea and China by Korea Pharma and ASK respectively will contribute to revenues through both royalties and milestones. Lastly, our efforts to be hyper focused on return on our investments across the company and strong working capital management are expected to allow us to be cash flow positive by the end of 2025. Despite the weather-related impact on Q1 2025 revenues, on the back of a solid performance in March 2025, we expect to see significant growth in 2025 as we continue to drive the business to become cash flow positive and fully self-sustaining.

Santosh Shanbhag
Chief Financial Officer

Consolidated statement of profit and loss and other comprehensive income
for the year ended 31 December 2024

	2024	2023
	$'000	$'000
Revenue	**32,180**	13,085
Cost of sales	**(17,250)**	(9,058)
Gross profit	**14,930**	4,027
Other operating income	**97**	4,412
Operating costs - selling, general and administrative expenses	**(36,013)**	(37,960)
Research and development expenditure	**(1,887)**	(1,810)
Operating loss	**(22,873)**	(31,331)
Financial income	**266**	518
Financial expense	**(3,949)**	(1,562)
Loss before tax	**(26,556)**	(32,375)
Taxation	**(626)**	(918)
Loss for the year	**(27,182)**	(33,293)
Other comprehensive income		
Items that are or may be reclassified subsequently to profit or loss:		
Foreign currency translation differences - foreign operations	**(646)**	(1,890)
Total comprehensive expense for the year	**(27,828)**	(35,183)
Loss per share		
Basic and diluted loss per share (in cents)	**(3)**	(5)

Group Balance Sheet
for the year ended 31 December 2024

	2024	2023
	$'000	$'000
Non-current assets		
Intangible assets	**18,168**	16,863
Property, plant and equipment	**373**	673
Restricted cash	**1,000**	-
	19,541	**17,536**
Current assets		
Inventories	**5,661**	3,203
Trade and other receivables	**24,968**	13,498
Current tax asset	**286**	614
Restricted cash	**500**	-
Cash and cash equivalents	**6,524**	13,948
	37,939	**31,263**
Total assets	**57,480**	**48,799**
Long-term loan	**(26,174)**	(19,836)
Lease liabilties	**-**	(195)
	(26,174)	(20,031)
Current liabilities		
Trade and other payables	**(23,188)**	(12,721)
Other liabilities	**(9,239)**	(800)
Lease liabilities	**(196)**	(214)
	(32,623)	**(13,735)**
Total liabilities	**(58,797)**	**(33,766)**
Net (liabilities)/assets	**(1,317)**	**15,033**
Equity		
Share capital	**(19,908)**	(15,011)
Share premium	**(203,188)**	(198,759)
Merger reserve	**(43,240)**	(43,240)
Currency translation reserve	**7,806**	8,452
Retained earnings	**259,847**	233,525
Total equity	**1,317**	**(15,033)**

Group statement of changes in equity
for the year ended 31 December 2024

	Issued capital	Deposit for shares	Share premium	Merger reserve	Currency translation reserve	Accumulated deficit	Total
	$'000	$'000	$'000	$'000	$'000	$'000	$'000
Balance at 1 January 2023	5,371	(100)	169,482	43,240	(10,342)	(201,107)	6,544
Loss for the year						(33,293)	(33,293)
Other comprehensive income:							
Foreign currency translation differences					1,890		1,890
Total comprehensive expense for the year					1,890	(33,293)	(31,403)
Transactions with owners, recorded directly in equity							
Equity placing	6,556	100	19,819				26,475
Warrants exercised	98		345				443
Loan conversion	2,986		9,113				12,099
Equity-settled share-based payment transactions						875	875
Balance at 31 December 2023	15,011	0	198,759	43,240	(8,452)	(233,525)	15,033
Loss for the year						(27,182)	(27,182)
Other comprehensive income:							
Foreign currency translation differences					646		646
Total comprehensive expense for the year					646	(27,182)	(26,536)
Transactions with owners, recorded directly in equity							
Equity placing	4,897		4,429				9,326
Equity-settled share-based payment transactions						860	860
Balance at 31 December 2024	**19,908**	**0**	**203,188**	**43,240**	**(7,806)**	**(259,847)**	**(1,317)**

Group statement of cash flows
for the year ended 31 December 2024

	2024	2023
Cash flows from operating activities	**$'000**	$'000
Loss for the year	**(27,182)**	(33,293)
Adjustments for:		
Depreciation and amortisation	**1,425**	1,071
Equity-settled share-based payment expenses	**860**	875
Financial income	**(266)**	(518)
Financial expense	**3,949**	1,562
Income tax	**626**	918
	(20,588)	(29,385)
Increase in inventories	**(2,458)**	(1,446)
Increase in trade and other receivables	**(1,142)**	(7,007)
Increase in restricted cash	**(1,500)**	—
Increase in trade and other payables	**10,467**	1,907
Increase/(decrease) in other liabilities	**9,213**	(478)
Income tax paid	**(762)**	(717)
Net cash flows from operating activities	**(6,770)**	(37,126)
Cash flows from investing activities		
Financial income	**266**	518
Additions to tangible assets	**(35)**	(239)
Capitalised development expenditure	**(2,386)**	(2,709)
Net cash flows from investing activities	**(2,155)**	(2,430)
Cash flows from financing activities		
Interest paid	**(3,949)**	(613)
Proceeds from equity raise	**122**	26,375
Legal fees in relation to equity raise	**(233)**	—
Warrants exercised	**—**	442
Repayment of convertible shareholder loan	**—**	(5,448)
Proceeds from milestone monetisation	**5,700**	—
Proceeds from convertible shareholder loan	**—**	10,000
Proceeds from long-term loan	**—**	19,446
Payment of lease liabilities	**(213)**	(546)
Net cash flows from financing activities	**1,427**	49,656
Net (decrease)/increase in cash	**(7,498)**	10,100
Effect of foreign exchange differences	**74**	446
Cash and cash equivalents at 1 January	**13,948**	3,402
Cash and cash equivalents at 31 December	**6,524**	13,948