

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

Interim results for the six months ended 30 June 2024

More than threefold increase in Total Revenues compared to H1 2023

c. 65,200 ACCRUFeR[®] prescriptions sold, up 161% compared to H1 2023

Net average sales price increase of 33% from H1 2023

London, UK, September 4, 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 anemia) announces its unaudited interim results for the six months ended 30 June 2024, reporting a substantial increase in revenues, ACCRUFeR[®] prescription sales and net average sales price.

Financial Highlights H1 2024

- **Total Revenues:** \$12.1 million, a 3.2x increase over H1 2023 (\$3.7 million)
 - **ACCRUFeR[®] revenue:** \$11.0 million, a 3.5x increase over H1 2023 (\$3.1 million)
 - **Ex-US revenue:** \$1.1 million from global partners for product sales in Europe (H1 2023: \$0.6 million)
- **Operating Loss:** \$15.5 million compared to \$12.6 million in H1 2023 driven primarily by the expansion of US field force supporting the launch of ACCRUFeR[®], partially offset by higher ACCRUFeR[®] revenues
- **Cash and cash equivalents:** \$8.1 million (31 December 2023: \$13.9 million). Post-Period End the Company completed a \$5.7 million monetisation agreement with AOP Health International Management AG (July 2024). Based on our internal assumptions we remain funded to deliver on our growth plans and look forward to further progress in the second half of the year and beyond.

Operational Highlights H1 2024

- **Commercialization of ACCRUFeR[®] in the US:** Continued growth and strong market results with our partner, Viatris Inc.
 - **ACCRUFeR[®] total prescriptions** grew to c.65,200 with an average quarterly growth of 25% following field expansions with Viatris in Q2 2023. The growth was primarily driven in large States such as California, Florida, New York, and Texas.
 - **ACCRUFeR[®] net price per prescription** steadily increased to \$171 per prescription in Q2 2024 driven by successful execution of our market access strategies. H1 2024 was \$158 per prescription, a 33% increase from \$119 per prescription in H1 2023.
- **Global ACCRUFeR[®]/FeRACCRU[®] development programs:** Continued progress in development stage partnerships in Canada, Republic of Korea, and China.
 - **Kye Pharmaceuticals ("Kye") in Canada:** ACCRUFeR[®] recently approved by Health Canada, the only oral iron therapy approved as a prescription drug in Canada. The team at Kye has been preparing for launch in late 2024 pending this approval. In accordance with the collaborative agreement with Kye, Shield is now due to receive a £250,000 milestone payment. 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.
 - **ASK Pharma ("ASK") in China:** Enrolling patients into a Phase 3 study that is similar in design to the previous studies conducted by Shield which led to European Medicines Agency (EMA) and US Food & Drug approval (FDA). The study is targeted to complete enrolment in late 2024.
 - **Paediatric study:** Phase 3 paediatric clinical trial (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 (IDA) expected to be completed in 2024. The trial is

the final study in the comprehensive paediatric development program that Shield committed to implement with both the European EMA and the US FDA.

Anders Lundstrom, Interim CEO of Shield Therapeutics, commented: *“H1 2024 has been another strong period of growth for Shield which is demonstrated through the significant increase in sales figures, net selling price and number of prescriptions for ACCRUFeR® in the US. We continue to focus on building momentum through creating greater awareness of ACCRUFeR® among health care professionals in the US as well as expanding our geographic reach with our international partners.*

We have also continued to manage our cash burn during launch and scale of ACCRUFeR® while strengthening our balance sheet by implementing innovative financing solutions like the working capital financing with Sallyport in April and adding \$5.7 million through the milestone monetization agreement with AOP Health International Management AG post period end. It is a very exciting time for Shield, and we look forward to providing updates for shareholders on our path to making ACCRUFeR® the oral iron of choice for patients with iron deficiency, with or without anemia”

Investor presentation

Interim CEO, Anders Lundstrom, and CFO, Santosh Shanbhag, will be hosting a live online presentation relating to the interim results via the Investor Meet Company platform at 4.30pm (BST) today, Wednesday 4 September 2024.

The presentation is open to all existing and potential investors. Questions can be submitted at any time during the live presentation.

Investors can sign up to Investor Meet Company for free and add to meet Shield Therapeutics plc via:

<https://www.investormeetcompany.com/shield-therapeutics-plc/register-investor>

For further information please contact:

Shield Therapeutics plc

Anders Lundstrom, CEO
Santosh Shanbhag, CFO

www.shieldtherapeutics.com

+44 (0) 191 511 8500

Nominated Adviser and Joint Broker

Peel Hunt LLP

James Steel/Patrick Birkholm

+44 (0)20 7418 8900

Joint Broker

Cavendish Ltd

Geoff Nash/ Rory Sale/Nigel Birks/Harriet Ward

+44 (0)20 7220 0500

Financial PR & IR Advisor

Walbrook PR

Charlotte Edgar / Alice Woodings

+44 (0)20 7933 8780 or shield@walbrookpr.com

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.acrufer.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 has launched ACCRUFer[®] in the U.S. with an exclusive, multi-year collaboration agreement with Viartis. Outside of the U.S., the Company has 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.

Operational Review

Commercialisation of ACCRUFer® in the US

Shield continues to see the positive impact of the successful organisational expansion and launch of **ACCRUFer®** in the US with our partner, Viatrix Inc. Over the first half of 2024, we generated approximately \$11 million in **ACCRUFer®** net revenues which is broadly on par with **ACCRUFer®** net revenues generated in the prior entire financial year (2023: \$11.6 million) and a 3.5x increase compared to H1 2023.

ACCRUFer® net price has steadily increased to \$158 per prescription in H1 2024, a 33% increase on the same period last year (H1 2023: \$119 per prescription), driven by successful execution of our market access strategies. Prescriptions grew to c. 65,200 in the first half of 2024 demonstrating an average quarterly growth of 25% following field expansions with Viatrix in Q2 2023. The growth was primarily driven by large States such as California, New York, and Florida. Following the challenges we experienced with the transition and lack of a Texas State Medicaid Pharmacy Benefit Manager (PBM) during Q1 2024, we continue to see a rebound in the Texas prescription volume.

Overall, our sales team continues to receive very positive feedback on the product from physicians. We continue to believe this provides additional confirmation in two key areas. First, that there is a need from health care professionals (HCPs) and patients for an effective and well tolerated oral iron. Second, ACCRUFer® is highly promotionally sensitive, so the more HCPs we can reach with sales and marketing efforts, the faster we can increase awareness and the opportunity to grow our prescriber base. Awareness about ACCRUFer® as an option to treat iron deficiency, with or without anaemia (ID/IDA) among many of these HCPs remains quite low, and our objective is simple: increase awareness of ACCRUFer®, generate prescriptions from HCPs, and allow patients to experience the benefits we believe ACCRUFer® can provide. While we have made continued progress over the first six months of this year, there is much opportunity still ahead of us to make ACCRUFer® the oral iron of choice for patients with iron ID/IDA.

Global partnerships and development

We have a number of global partnerships, and our objective is to expand this, identifying further opportunities to bring ACCRUFer®/FeRACCRU® to patients with iron deficiency in as many markets as possible. We have a long-standing relationship with Norgine for the distribution of FeRACCRU® in Europe; their efforts are primarily concentrated in those countries where we have positive reimbursement, specifically Germany, UK and the Nordics. During H1 2024, we received \$1.1 million in revenues from our global partners including royalties from Norgine in respect of sales of FeRACCRU® in Europe.

We continue to make excellent progress in our development stage partnerships in Canada, Republic of Korea, and China. Health Canada has recently approved ACCRUFer® (ferric maltol) as a prescription drug for the treatment of adults with iron deficiency anemia (IDA). This development allows Shield's partner, Kye, to launch ACCRUFer® in Canada. In accordance with the collaborative agreement, Shield is now due to receive a £250,000 milestone payment. 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®.

In the Republic of Korea, our partner, Korea Pharma, filed a New Drug Application for ACCRUFer® following the successful completion of a pharmacokinetic (PK) study.

Lastly, our partner in China, ASK Pharma, is enrolling patients into a Phase 3 study that is similar in design to the previous studies conducted by Shield which led to European Medicines Agency (EMA) and US Food & Drug Administration approval (FDA). The study is targeted to complete enrolment in late 2024. Each of these markets represent a growth opportunity with many patients challenged in treating their iron deficiency today. Shield receives various milestones and royalties on net sales across each of these geographies.

Paediatric study

Our paediatric study could lead to an expansion of the indication and uses for ACCRUFer®/FeRACCRU® in both US and EU markets. The study, a requirement of both the FDA and EMA, is enrolling patients with iron deficiency ranging from 12 months to 17 years of age. This is another population where iron deficiency is prevalent and similar challenges to over-the-counter irons exist. As part of this study, Shield is using a new liquid formulation, which, if

approved, may offer an alternative approach for those who can't swallow our current capsule formulation. We expect to complete enrolment of our paediatric study in 2024.

Outlook

The Group continued to execute the expansion and growth of ACCRUFER® in the first half of 2024. We have substantially increased revenues, the net selling price and the number of prescriptions for ACCRUFER® in the US as we continue to build awareness of the product and fine tune our commercial efforts. Based on our internal assumptions we remain funded to deliver on our growth plans. We see an oral iron market which has clear unmet needs, based on physician and patient feedback, for a product that delivers both effectiveness and tolerability. As we move into the second half of 2024 and 2025, Shield and our partner Viartis expect to achieve continued growth in ACCRUFER® prescriptions in the US along with further improvement of other financial metrics. Additionally, we should complete our paediatric study during 2024, increasing expansion opportunities in both the US and EU in future years. Lastly, our ex-US partnerships continue to progress not only making ACCRUFER® /FeRACCRU® available around the globe, but also adding to our revenues through both milestones and royalties.

Financial Review

Revenue

Revenue in the first six months of 2024 (H1 2024) amounted to \$12.1 million (H1 2023: \$3.7 million), of which \$11.0 million (H1 2023: \$3.1 million) was derived from ACCRUFER® sales in the US. The 2023 year-end audit process identified a change in the accounting treatment of commercial rebates resulting in a reduction in both, revenues as well as selling, general and administrative expenses by \$0.6 million compared to the H1 2023 Interim Financials reported in September 2023. There was no impact on the loss for the period, the balance sheet, or the cash flow. The balance of \$1.1 million (H1 2023: \$0.6 million) represents revenues from our global partners including royalties from Norgine in respect of sales of FeRACCRU® in Europe.

Approximately 65,200 prescriptions of ACCRUFER® were sold in the US in H1 2024 and that yielded net revenue of \$11.0 million (H1 2023: \$3.1 million from approximately 25,000 prescriptions). Additionally, the net average sales price per prescription was \$158 in H1 2024 an increase of 33% compared to \$119 per prescription in H1 2023.

In addition, the Group reports \$0.1 million (H1 2023: \$4.3 million) of other operating income. Most of the other operating income in H1 2023 was related to the deferred portion of the upfront payment from Viartis Inc., Shield's co-promote partner in the US, received at the end of 2022.

Cost of sales

Cost of sales in H1 2024 amounted to \$6.7 million (H1 2023: \$2.1 million). The H1 2024 cost of sales comprises manufacturing costs of the prescriptions sold in the US and in Europe, plus the 45% share of the US net product revenues payable to Viartis and 5% royalty on net sales, payable to Vitra Pharmaceuticals Ltd (Vitra).

Selling, general and administrative expenses

Selling, general and administrative expenses were \$18.8 million in H1 2024 (H1 2023: \$17.0 million). The increase is directly attributable to the expansion of the US commercial business in connection with the implementation and commencement of the co-promote partnership with Viartis. As indicated above, H1 2023 expenses reflects a change in the accounting treatment of commercial rebates that were identified during the year end audit process.

Research and development

In H1 2024, \$0.8 million in development costs were expensed in the statement of profit and loss (H1 2023: \$0.4 million). In addition, \$1.5 million (H1 2023: \$1.5 million) of development expenditure was recorded directly to the balance sheet in accordance with the underlying conditions for capitalization (disclosed in the detail in the notes of the Company's 2023 annual report). These development costs and expenditure have been spent in connection with the ongoing pediatric study.

Loss for the period

The loss for H1 2024 was \$15.5 million (H1 2023: \$12.6 million) which includes financial income of \$0.2 million (H1 2023: \$0.3 million), financial expense of \$1.6 million (H1 2023: \$0.6 million) and taxation of \$0.0 million (H1 2023: \$0.8 million).

Balance sheet

Effective 30 April 2024, the Group strengthened its balance sheet through a \$10.0 million accounts receivable financing with Sallyport Commercial Finance (Sallyport). The accounts receivable financing is secured by ACCRUFER® accounts receivables in the US and bears an interest rate of WSJ Prime + 3.0% on funds deployed. Additionally, the Group also amended its existing \$20.0 million debt facility agreement with SWK Funding LLC (SWK), with more favorable loan covenant terms.

Intangible assets on 30 June 2024 were \$17.4 million (31 December 2023: \$16.9 million), comprised of \$16.2 million of capitalized ACCRUFER®/FeRACCRU® development expenditure (31 December 2023: \$15.7 million) and \$1.2 million expenditure related patents and trademarks (31 December 2023: \$1.2 million) to strengthen the Group's intellectual property.

Inventory on 30 June 2024 amounted to \$4.0 million (31 December 2023: \$3.2 million), which comprises work in progress and finished product available for sale.

Trade and other receivables increased to \$15.4 million on 30 June 2024 from \$13.5 million on 31 December 2023. This change is driven by the higher sales volume in the US.

The current tax asset of \$0.3 million (31 December 2023: \$0.6 million) represents anticipated R&D tax credits.

Cash and cash equivalents on 30 June 2024 amounted to \$8.1 million (31 December 2023: \$13.9 million).

Trade and other payables increased from \$12.7 million on 31 December 2023 to \$19.4 million on 30 June 2024. The increase is largely attributed to the revenue share payment due to Viatris on growing ACCRUFER® sales, and the usage of the accounts receivable financing mentioned above.

Cash flow

Net cash outflow from operations in H1 2024 was \$3.6 million (H1 2023: \$19.9 million). The H1 2024 loss for the period was \$15.5 million but, after adjusting for various non-cash items, the actual cash outflow from this loss was \$12.9 million (H1 2023: \$10.8 million). Working capital cash outflows were \$9.1 million in H1 2023 turning to a working capital inflow of \$9.3 million in H1 2024, mainly due to the growing sales of ACCRUFER® in the US, the usage of the accounts receivable financing (see note 11) mentioned above, and the benefit of the R&D tax credits received in the UK.

Net cash outflow from investing activities in H1 2024 was \$0.8 million (H1 2023: \$1.3 million) driven primarily by the capitalized development expenditure of \$1.0 million in H1 2024 (H1 2023: \$1.5 million) partially offset by financial income.

The net cash outflow from financing activities in H1 2024 was \$1.9 million (H1 2023: inflow \$30.1 million) primarily attributable to the interest paid on the Group long-term loan financing. H1 2023 included \$10 million proceeds from convertible shareholder loan and \$20 million cash raised from an equity placing.

Going concern

For the reasons set out in detail under Note 2 of the attached condensed interim financial statements as of and for the six months ended 30 June 2024, the Directors believe that it remains appropriate to prepare the financial statements on a going concern basis.

Consolidated statement of profit and loss and other comprehensive income

for the six months ended 30 June 2024

	Note	Six months ended 30 June 2024 (unaudited) \$000	Six months ended 30 June 2023 (unaudited) \$000	Year ended 31 December 2023 (audited) \$000
Revenue	4	12,132	3,743	13,085
Cost of sales		(6,675)	(2,085)	(9,058)
Gross profit		5,457	1,658	4,027
Other operating income		52	4,298	4,412
Operating costs – selling, general and administrative expenses	5	(18,815)	(17,063)	(37,960)
Operating loss before impairment and research and development expenditure		(13,306)	(11,107)	(29,521)
Impairment of intangible assets		-	-	-
Research and development expenditure		(752)	(434)	(1,810)
Operating loss		(14,058)	(11,541)	(31,331)
Financial income		203	326	518
Financial expense		(1,625)	(578)	(1,562)
Loss before tax		(15,480)	(11,793)	(32,375)
Taxation		2	(812)	(918)
Loss for the period		(15,478)	(12,605)	(33,293)

Other comprehensive income

Items that are or may be reclassified subsequently to profit or loss:

Foreign currency translation differences – foreign operations		(402)	894	(1,890)
Total comprehensive expenditure for the period		(15,880)	(11,711)	(35,183)

Loss per share

Basic and diluted loss per share (in US cents)	7	\$(0.02)	\$(0.02)	\$(0.05)
--	---	-----------------	----------	----------

Group balance sheet

at 30 June 2024

	Note	30 June 2024 (unaudited) \$000	30 June 2023 (unaudited) \$000	31 December 2023 (audited) \$000
Non-current assets				
Intangible assets	7	17,401	15,239	16,863
Property, plant and equipment		524	327	673
Restricted cash	8	1,000	-	-
		18,925	15,566	17,536
Current assets				
Inventories	9	4,035	2,695	3,203
Trade and other receivables		15,406	9,262	13,498
Current tax asset		296	550	614
Cash and cash equivalents		8,099	13,594	13,948
		27,836	26,101	31,263
Total assets		46,761	41,667	48,799
Non-current liabilities				
Convertible shareholder loan		-	(5,705)	-
Long-term loan		(19,679)	-	(19,836)
Lease liabilities		-	-	(195)
Fair value of loan conversion feature		-	-	-
		(19,679)	(5,705)	(20,031)
Current liabilities				
Trade and other payables	10	(19,364)	(8,080)	(12,721)
Lease liabilities		(292)	(67)	(214)
Other liabilities	11	(6,885)	(713)	(800)
		(26,541)	(8,860)	(13,735)
Total liabilities		(46,220)	(14,565)	(33,766)
Net assets		541	27,102	15,033
Equity				
Share capital	12	(15,011)	(13,734)	(15,011)
Share premium		(198,759)	(173,087)	(198,759)
Merger reserve		(43,240)	(42,966)	(43,240)
Currency translation reserve		8,050	(10,603)	(8,452)
Deposit for shares		-	-	-
Accumulated deficit		248,419	213,288	233,525
Total equity		(541)	(27,102)	(15,033)

Group statement of changes in equity

for the six months ended 30 June 2024

	Share capital \$000	Deposit For shares \$000	Share premium \$000	Merger reserve \$000	Currency translation reserve \$000	Retained earnings \$000	Total \$000
Balance at 1 January 2023 (audited)	5,371	(100)	169,482	43,240	(10,342)	(201,107)	6,544
Loss for the year	-	-	-	-	-	(33,293)	(33,293)
<i>Other comprehensive income:</i>							
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 (audited)	15,011	-	198,759	43,240	(8,452)	(233,525)	15,033
Loss for the period	-	-	-	-	-	(15,478)	(15,478)
<i>Other comprehensive income:</i>							
Foreign currency translation differences	-	-	-	-	402	-	402
Total comprehensive expense for the period	-	-	-	-	402	(15,478)	(15,076)
Transactions with owners, recorded directly in equity							
Equity placing	-	-	-	-	-	-	-
Loan conversion	-	-	-	-	-	-	-
Equity-settled share-based payment transactions	-	-	-	-	-	584	584
Balance at 30 June 2024 (unaudited)	15,011	-	198,759	43,240	(8,050)	(248,419)	541

Group statement of cash flows

for the six months ended 30 June 2024

	Six months ended 30 June 2024 (unaudited) \$000	Six months ended 30 June 2023 (unaudited) \$000	Year ended 31 December 2023 (audited) \$000
Cash flows from operating activities			
Loss for the period	(15,478)	(12,605)	(33,293)
<i>Adjustments for:</i>			
Depreciation and amortization	601	524	1,071
Equity-settled share-based payment expenses	584	176	875
Financial income	(203)	(326)	(518)
Financial expense	1,625	578	1,562
Impairment of intangible assets	-	-	-
Income tax	-	813	918
	(12,871)	(10,840)	(29,385)
Increase in inventories	(832)	(938)	(1,446)
Increase in trade and other receivables	(1,908)	(3,612)	(7,007)
Increase in restricted cash	(1,000)	-	-
Increase/(decrease) in trade and other payables	6,643	(3,364)	1,907
Increase/(decrease) in other liabilities	5,212	(1,142)	(478)
Income tax received/(paid)	1,191	-	(717)
Net cash flows from operating activities	(3,565)	(19,896)	(37,126)
Cash flows from investing activities			
Financial income	203	326	518
Acquisition of tangible assets	(34)	(178)	(239)
Capitalised development expenditure	(978)	(1,466)	(2,709)
Net cash flows from investing activities	(809)	(1,318)	(2,430)
Cash flows from financing activities			
Cash raised from equity placing	-	20,170	26,375
Interest paid	(1,782)	-	(613)
Warrants exercised	-	-	442
Proceeds from convertible shareholder loan	-	10,000	10,000
Proceeds from long-term loan	-	-	19,446
Total cash outflow from leases	(117)	(40)	(546)
Net cash flows from financing activities	(1,899)	30,130	49,656
Net increase/(reduction) in cash	(6,273)	8,916	10,100
Effect of exchange rate fluctuations on cash held	424	1,276	446
Cash and cash equivalents at beginning period	13,948	3,402	3,402
Cash and cash equivalents at period end	8,099	13,594	13,948

Notes

for the six months ended 30 June 2024

1. General information

Shield Therapeutics plc (the "Company") is incorporated in England and Wales as a public limited company. The Company trades on the London Stock Exchange's AIM market, having been admitted on 26 February 2016.

The Company is domiciled in England and the registered office of the Company is at Northern Design Centre, Baltic Business Quarter, Gateshead Quays NE8 3DF.

The financial statements in this interim report comprise the Company and its subsidiaries (together referred to as the 'Group'). The Group is engaged in the late-stage development and commercialization of clinical stage pharmaceuticals to treat unmet medical needs.

This interim report, which is not audited, has been prepared in accordance with the measurement and recognition criteria of EU Adopted International Financial Reporting Standards. It does not include all the information required for full annual financial statements and should be read in conjunction with the consolidated financial statements of the Group as at and for the year ended 31 December 2023. This financial information does not constitute statutory financial statements as defined in Section 435 of the Companies Act 2006. The comparative figures for the year ended 31 December 2023 are not the Company's statutory accounts for that financial year. Those accounts have been reported on by the Company's auditor and delivered to the Registrar of Companies. The report of the auditors was unqualified. The auditor has reported on those accounts; their report was unqualified and did not contain a statement under Section 498 (2) or (3) of the Companies Act 2006.

The interim report was approved by the board of directors on 4 September 2024.

2. Accounting policies

The accounting policies applied in these interim financial statements are consistent with those of the annual financial statements for the year ended 31 December 2023, as described in those annual financial statements.

Going concern

At 30 June 2024, the Group held \$8.1 million in cash. On 3 July 2024, the Group announced a \$5.7 million milestone monetization agreement with AOP.

The Directors have considered the funding requirements of the Group through the preparation of detailed cash flow forecasts for the period to December 2025, including the prospective ACCRUFer[®] sales revenues and the related commercial operating costs. These forecasts show that the Group's monthly cash flows start to turn positive in H2 2025 and that the funding detailed above should provide sufficient cash to allow the business to continue in operations for at least twelve months from the date of this report. The Directors have considered scenarios in which sales revenues fall below forecasts. In these circumstances mitigating actions such as reduction of discretionary selling and marketing expenditure could be taken to preserve cash. The Directors also believe that other forms of finance, such as debt finance or 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.

3. Critical accounting judgments and key sources of estimation uncertainty

In the application of the Group's accounting policies, management is required to make judgments, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources.

The significant judgments made in relation to the financial statements are:

Development expenditure

Development expenditure is capitalized when the conditions referred to in Note 2 of the Company's annual report are met.

Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period or in the period of the revision and future periods if the revision affects both current and future periods. The significant estimates which may lead to material adjustment in the next accounting period are:

Valuation of intellectual property associated with ACCRUFer[®]/FeRACCRU[®]

The valuation of intellectual property associated with ACCRUFer[®]/FeRACCRU[®] (including patents, development costs and the Company's investment in Shield TX (Switzerland) AG) is based on cash flow forecasts for the underlying business and an assumed appropriate cost of capital and other inputs in order to arrive at a fair value for the asset. The realization of its value is ultimately dependent on the successful commercialization of the asset. In the event that commercial returns are lower than current expectations this may lead to an impairment. No impairment has been recognized to date.

Deferred tax assets

Estimates of future profitability are required for the decision whether to create a deferred tax asset. To date no deferred tax assets have been recognized.

4. Segmental reporting

The following analysis by segment is presented in accordance with IFRS 8 on the basis of those segments whose operating results are regularly reviewed by the Chief Operating Decision Maker (considered to be the Board of Directors) to assess performance and make strategic decisions about the allocation of resources. Segmental results are calculated on an IFRS basis.

A brief description of the segments of the business is as follows:

- ACCRUFer®/FeRACCRU® – development and commercialization of the Group’s lead ACCRUFer®/FeRACCRU® product
 - PT20 – development of the Group’s secondary asset (all related assets were written off effective 31 December 2022)
- Operating results which cannot be allocated to an individual segment are recorded as central and unallocated overheads.

	Six months ended 30 June 2024 (unaudited)				Six months ended 30 June 2023 (unaudited)			
	ACCRUFer®/ FeRACCRU® \$000	PT20 \$000	Central and unallocated \$000	Total \$000	ACCRUFer®/ FeRACCRU® \$000	PT20 \$000	Central and unallocated \$000	Total \$000
Revenue	12,132	-	-	12,132	3,743	-	-	3,743
Operating loss	(12,412)	-	(1,652)	(14,058)	(865)	-	(10,676)	(11,541)
Financial income				203			326	326
Financial expense				(1,625)			(578)	(578)
Tax				2				(812)
Loss for the period				(15,478)				(12,605)

	Year ended 31 December 2023 (audited)			
	ACCRUFer®/ FeRACCRU® \$000	PT20 \$000	Central and unallocated \$000	Total \$000
Revenue	13,085	-	-	13,085
Operating loss	(26,649)	858	(5,540)	(31,331)
Financial income			518	518
Financial expense			(1,562)	(1,562)
Tax				(918)
Loss for the period				(33,293)

The revenue analysis in the table below is based on the country of registration of the fee-paying party. \$11.0 million revenue (H1 2023: \$3.1 million) was derived from ACCRUFer® sales in the US and \$1.1 million (H1 2023: \$0.6 million).

	Six months ended 30 June 2024 (unaudited) \$000	Six months ended 30 June 2023 (unaudited) \$000	Year ended 31 December 2023 (audited) \$000
USA	10,955	3,151	11,570
The Netherlands	1,067	592	1,495
Canada	-	-	-
South Korea	110	-	20
	12,132	3,743	13,085

5. Operating costs – selling, general and administrative expenses

Operating costs are comprised of:

	Six months ended 30 June 2024 (unaudited) \$000	Six months ended 30 June 2023 (unaudited) \$000	Year ended 31 December 2022 (audited) \$000
Selling costs	12,341	11,202	21,717
General and administrative expenses	5,703	5,366	15,172
Depreciation and amortization	771	495	1,071
	18,815	17,063	37,960

6. Loss per share

The basic loss per share of \$0.02 (H1 2023: \$0.02) has been calculated by dividing the loss for the period by the weighted average number of shares of 782,056,367 in issue during the six months ended 30 June 2024 (six months ended 30 June 2023: 702,902,306).

Although there are potentially dilutive ordinary shares these would not serve to increase or reduce the loss per ordinary share, as the Group is loss-making. There is therefore no difference between the loss per ordinary share and the diluted loss per ordinary share.

7. Intangible assets

	ACCRUFeR®/ FeRACCRU® patents and trademarks \$000	ACCRUFeR®/ FeRACCRU® development costs \$000	Total \$000
Cost			
Balance at 1 January 2023 (audited)	2,284	16,245	18,529
Additions – externally purchased		2,709	2,709
Effect of change in foreign currency	126	878	1,004
Balance at 31 December 2023 (audited)	2,410	19,832	22,242
Additions – externally purchased	-	1,466	1,466
Effect of change in foreign currency	(29)	(203)	(232)
Balance at 30 June 2024 (unaudited)	2,381	20,607	22,988
Accumulated amortization			
Balance at 1 January 2023 (audited)	1,054	3,267	4,321
Charge for the period	121	705	826
Effect of change in foreign currency	52	180	232
Balance at 31 December 2023 (audited)	1,227	4,152	5,379
Charge for the period	47	388	435
Effect of change in foreign currency	(26)	(184)	(210)
Balance at 30 June 2024 (unaudited)	1,262	4,325	5,587
Net book values			
30 June 2024 (unaudited)	1,119	16,282	17,401
31 December 2023 (audited)	1,183	15,680	16,863

8. Restricted cash

The Group has \$1.0 million (H1 2023: \$Nil) of restricted cash held within an escrow account in relation to the accounts receivable financing with Sallyport Commercial Finance, LLC.

9. Inventories

	Six months ended 30 June 2024 (unaudited) \$000	Six months ended 30 June 2023 (unaudited) \$000	Year ended 31 December 2023 (audited) \$000
Work in progress	1,284	-	1,098
Finished goods	2,751	2,695	2,105
	4,035	2,695	3,203

10. Trade and other payables

	Six months ended 30 June 2024 (unaudited) \$000	Six months ended 30 June 2023 (unaudited) \$000	Year ended 31 December 2023 (audited) \$000
Taxation payables	3,674	2,835	4,049
Accruals	15,690	5,245	8,672
	19,364	8,080	12,721

11. Other liabilities

	Six months ended 30 June 2024 (unaudited) \$000	Six months ended 30 June 2023 (unaudited) \$000	Year ended 31 December 2023 (audited) \$000
Taxation and social security	33	63	96
Accounts receivable financing	6,835	-	-
Other payables	17	650	704
	6,885	713	800

12. Share capital

	Six months ended 30 June 2024 Number 000	Six months ended 30 June 2024 \$000	Six months ended 30 June 2023 Number 000	Six months ended 30 June 2023 \$000	Year ended 31 December 2023 Number 000	Year ended 31 December 2023 \$000
At beginning of period	782,056	15,011	259,388	5,371	259,388	5,371
Exercise of share options	-	-	-	-	-	-
Conversion of loan	-	-	158,805	2,941	158,805	2,986
Warrants exercised	-	-	-	-	5148	98
Equity placing	-	-	294,844	5,422	358,715	6,556
Total shares authorized and in issue at end of period – fully paid	782,056	15,011	713,037	13,734	782,056	15,011

No share options were exercised during the six months ended 30 June 2024 (six months ended 30 June 2023: Nil)

13. Subsequent events

On 3 July 2024 the Group announced a \$5.7 million milestone monetization agreement with AOP. Under the terms of the Agreement, AOP provided Shield with \$5.7 million in cash, in exchange for the right to receive the \$11.4 million China approval milestone payment that may be paid to Shield by Jiangsu Aosaikang Pharmaceutical Co., Ltd. ASK Pharma continues to enroll patients into a Phase 3 study and enrollment is expected to complete late in 2024. Subject to the Phase 3 reading out successfully and regulatory approval by the Chinese regulator Shield believes the Approval Milestone may be payable by the year ending 2026. Under the terms of the Agreement, if the Approval Milestone falls due Shield is required to pay its full value to AOP 30 days after the Approval Milestone has been achieved. Further, if the Approval Milestone has not been triggered by 31 December 2026, or in the event the Agreement is terminated, including at Shield's election or due to a breach by Shield of its terms, the Advance plus accrued interest and fees at the 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. The Advance will be secured inter alia by AOP's right to receive the ASK Approval Milestone.