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

Interim results update and business update

Shield reports strong H1 2023 prescription growth momentum for Accrufer®

Accelerating prescription growth, with expectations for 80% increase in Q3 2023

KPI performance and new market access expansion puts Shield on track to grow 2023 Accrufer® prescriptions to 100,000-130,000

Total H1 2023 revenue and other income of $8.6 million

New $20 million Term Loan and equity financing to accelerate growth and expand working capital, fortifying plans to reach cash flow break-even by end of 2024

London, UK, 28 September, 2023: 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) today provides a business update, covering recent operational and financing progress, and reported interim financial results including 50% sequential Q2 2023 US Accrufer® growth and expectations for 80% sequential growth in Q3 2023.

Shield reported strong, consistent, sequential Accrufer® prescription momentum for H1 2023, powered by expanded sales and marketing resources from the commercial partnership with Viatris Inc. (Viatris), supported by continuous acceleration across the Company's key performance indicators/KPIs, the refreshed branding campaign and significantly expanded market access. Total prescriptions for H1 2023 increased 59% compared to H2 2022, totaling over 26,200 for the first six months of 2023. The average net selling price per prescription was $119 during H1 2023.

Early indications suggest Accrufer's® growth trajectory will continue to rise in Q3 2023, exceeding 28,400 prescriptions, representing an ~80% sequential increase vs Q2. The prescriptions in Q3 2023 are on track to exceed the total for the entire first six months of the year. Excellent initial results following the commercial expansion put Shield on track to reach a major corporate milestone for 2023, with line of sight to total Accrufer® prescriptions of 100,000 to 130,000. Since the completion of the sales force expansion in May, Accrufer® has grown an average of 26% month over month through to the end of August.

Current Business Updates

New market access expansion for Accrufer® increases total covered lives to 123 million

- **Recent addition of the two largest Medicaid programs in California and New York**
- **Market access lives expanded by ~ 20% heading into Q4 2023**

KPIs underscore U.S. Accrufer® growth momentum (all quarters refer to 2023):

- **Total prescriptions** – 15,808, increased 51% Q2 vs Q1
- **First time writers** -- increased 157% Q2 vs Q1
- **New prescriptions** -- increased 63% Q2 vs Q1
- **Repeat writers** – 73% of writers who wrote a prescription in Q1 also wrote one in Q2

Key drivers highlight effective Shield-Viatris partnership and growth strategy: Shield continues to make excellent progress on its mission of making Accrufer® the oral iron treatment of choice in the US and beyond, evidenced by continued execution across key commercial drivers including:

- **Fully-deployed Shield/Viatris commercial team poised for continued growth** – The Shield/Viatris commercial team, fully operational since May, is well poised to target the 12,000+ highest prescribers. Early results, marked by strong Accrufer® growth, indicate the partnership is working extremely well.

- **Refreshed branding campaign resonating in the field** – Shield's campaign to take "irony out of oral iron" was launched for patients and prescribers along with the new commercial team, with accompanying new patient and HCP websites.
- **New Chief Commercial Officer adds to the Shield C-Suite**: Addition of Andy Hurley, hired in April, provides dedicated leadership and expertise to lead the Accrufer® brand and marketing campaign.

Shield Chief Executive Officer Greg Madison commented: *"I am pleased to report that Shield has had an excellent first half of 2023. We successfully initiated the Accrufer® commercial partnership with Viatris, completed the build out of the combined team and effectively implemented our new commercial growth strategy and marketing campaign. Our strong performance, following completion of the commercial expansion in May, is evidenced by the momentum achieved across each of our KPIs and consistent, significant prescription growth. These results reflect the unwavering dedication and deep experience of our outstanding team and our commitment to make Accrufer® the oral iron of choice.*

We believe our standout H1 2023 results, KPI achievements and expectations for continued Q3 2023 growth put us on track to reach total 2023 Accrufer® prescriptions of 100,000 to 130,000. This is a major corporate milestone for Shield and forms the foundation for future growth. Looking ahead, we have defined additional initiatives to improve our gross-to-net, continue the growth in Accrufer® prescriptions and market adoption and expand market access. Our commercial results provide validation of our strategic plan and give us access to important growth capital. The new $20 million term loan announced today and an equity financing of up to $7.4 million will put us on a steady path to reach our guidance of cash flow breakeven, expected by year-end 2024.

As we enter the fourth quarter of 2023, I am optimistic about the growth prospects for Accrufer® and Shield. The combination of our high-performance team, the high-value Viatris partnership, well-crafted growth strategy and strong balance sheet set the Company up to maximize potential future growth and value creation opportunities for our investors and key stakeholders."

Global Partners and Pipeline Update

- **Norgine (EU+ rights)** – Data received from Norgine indicate that in H1 2023, the number of Feraccru® sales packs sold in Europe increased by 19% vs H2 2022 and 11% vs H1 2022.
- **KYE Pharmaceuticals (Canada)** – KYE filed a New Drug Submission for Accrufer™ with Health Canada in Q1 2022, and decision is expected by year end 2023.
- **Korea Pharma (Republic of Korea)** – Korea Pharma is currently enrolling patients in the pharmacokinetic study, which is the only study required to support approval.
- **Beijing Aosaikang Pharmaceutical Co. Ltd. (China, ASK Pharma)** – Patients are currently being enrolled in the pivotal Phase 3 study. While the pace of enrolment in the Phase 3 program was impacted by COVID-19, these challenges are now resolved.

Cash and Balance Sheet Items

- Cash on hand of $13.6 million (unaudited) at 30 June 2023, excluding receipt of selling cost and payment of net revenue shares for Q2 2023 from commercial partner Viatris
- New financing transactions announced today of a new $20 million term loan and an equity financing of up to $7.4 million.

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 anemia (IDA) affect about 20 million people in the US and represent a $2.3 billion 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 anemia. The Company has launched Accrufer® in the US with an exclusive, multi-year commercial agreement with Viatris. Outside of the US, the Company has licensed the rights to four specialty pharmaceutical companies. Feraccru® is commercialized 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 commercialization 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.

Operational Review

Commercialisation of Accrufer® / Feraccru®

USA

Following the completion of the co-commercialization agreement with Viatris in late December 2022, we successfully recruited, hired and trained a new 50-person sales team along with six regional managers, all of whom are employees of Shield. This effort ran in parallel with our new partner Viatris, having a designated 50-person sales team on their own, and together, we held a National Sales Meeting in mid-May as the final training for the combined 100-person field sales force. That team is tasked to call on approximately 12,000 high prescribing HCP's

In the first half of 2023, we generated 26,284 prescriptions for Accrufer® with the second quarter recording a volume increase of 50% versus the first quarter, a strong early indication of the potential of this expanded commercial team and high sensitivity of promotional efforts. The number of prescriptions generated during the first half of 2023 exceeds the total for all prescriptions written in 2022. The average net selling price in the first half of 2023 declined slightly relative to H2 2022 at $119 per prescription (H2: 2022 $124), and we are planning to undertake a variety of initiatives to increase this net price during H2 2023 and into 2024.

Europe

Feraccru® is commercialised in Europe by our license partner Norgine BV. The product is currently sold in Germany, the United Kingdom and the Nordics.

The number of Feraccru® packs sold by Norgine in Europe increased by 11% in H1 2023 compared with H1 2022 and by 19% compared with H2 2022. The most notable volume increase incurred in the United Kingdom and Germany with 19% and 16% increases, respectively, now representing 88% of the total Feraccru® packs sold in Europe. Maybe to include the new initiative to shift targeting beyond GI giving additional sales potential as shown in the US.

Asia and Canada

In China, our license partner Beijing Aosaikang Pharmaceutical Co., Ltd. ("ASK Pharm") is currently enrolling patients in the pivotal Phase 3 study (required by regulatory authority). There were delays in recruiting primarily due to COVID related challenges within China.

Korea Pharma Co. Ltd. ("Korea Pharma") is currently enrolling patients in the PK study, which is the only study required prior to submission for approval. This study is targeted to complete enrolment by year end.

KYE submitted a New Drug Submission ("NDS") during the first half of 2022, which was accepted by Health Canada in July 2022. The submission is currently under review by Health Canada and decision is expected in the H2 2023.

Product development

Shield has agreed a Feraccru®/Accrufer® Paediatric Investigational Plan (PIP)/Pediatric Development Plan (PDP) with the EMA/FDA, respectively, both culminating in the conduct of a study to evaluate the safety, tolerability and efficacy of the product in infants, children and adolescents. This study is currently enrolling patients across its sites.

Outlook

During the second half of 2023, we are planning to continue the momentum on prescription growth we started to achieve in our US business during the second quarter. At the same time, we will focus on improving the profitability

by reducing the gross-to-net discount with the goal of increasing the average net selling price. In addition, we will continue to support our license partners across the globe in their efforts to obtain regulatory approvals for Accrufer®/Feraccru® and their commercialisation efforts to increase market shares.

Financial Review

As announced on 6 September 2023, the Company decided to change its presentational currency from Pounds Sterling to US Dollars (or dollars), as most of its revenues and operating expenses are denominated in dollars due to the continuing focus on its US-based commercial operations. As a result, the interim results for the six months ending 30 June 2023 have been published in dollars, and the comparative prior year figures have been restated to the same currency.

Revenue
Revenue in the first six months of 2023 (H1 2023) amounted to $4.3 million (H1 2022: $2.6 million), of which $3.7 million (H1 2022: $1.7 million) was derived from Accrufer® sales in the US. The balance of $0.6 million (H1 2022: $0.7 million) represents royalties from Norgine in respect of sales of Feraccru® in Europe. In addition, the Group reports $4.3 million (H1 2022: nil) of other operating income, representing the previous deferred portion of the upfront payment from Viatris Inc., Shield's co-promote partner in the US, received at the end of 2022 and now recognized in H1 2023.

Cost of sales
Cost of sales in H1 2023 amounted to $2.1 million (H1 2022: $1.1 million). The H1 2022 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 Viatris and 5% royalty on net sales, payable to Vitra Pharmaceuticals Ltd (Vitra) under the 2010 Asset Purchase Agreement.

Vitra was the original owner of the intellectual property underpinning Accrufer® / Feraccru® and, under the terms of the 2010 Asset Purchase Agreement, is entitled to receive either a 5% royalty on net sales or 10% of any licence upfront and sales milestones. For the Norgine licence agreement Vitra chose to receive a royalty of 5% of net sales; for the ASK Pharm agreement Vitra opted to receive 10% of the upfront receipt and any subsequent milestones.

Selling, general and administrative expenses
Selling, general and administrative expenses were $17.7 million in H1 2023 (H1 2022: $15.2 million) of which $0.5 million (H1 2022: $1.3 million) represents the amortization of intangible assets. Excluding amortization, the underlying costs increased by 24% from $13.9 million in H1 2022 to $17.2 million in H1 2023, which is directly attributable to the expansion of the US commercial business in connection with the implementation and commencement of the co-promote partnership with Viatris.

Research and development
In H1 2023, $0.4 million (H1 2022: $1.3 million) development costs were expensed in the statement of profit and loss. In addition, $1.5 million (H1 2022: $1.5 million) of development expenditure were recorded directly to the balance sheet in accordance with the underlying conditions for capitalization, which are disclosed in the detail in the notes of the Company's annual report. These development costs and expenditure have been spent in connection with the ongoing pediatric study.

Tax
The tax charge of $0.8 million (H1 2022: $0.5 million) represents the tax accrual for income taxes due in the US in connection with the Group's commercial activities.

Loss for the period
The loss for H1 2023 was $12.6 million (H1 2022: $15.1 million).

Balance sheet
Intangible assets at 30 June 2023 were $15.2 million (31 December 2022: $14.2 million), comprised of $14.1 million (31 December 2022: $1.2 million) of capitalised Accrufer®/Feraccru® development expenditure and $1.2 million (31

December 2022: $1.2 million) expenditure for related patents and trademarks to strengthen the Group's intellectual property.

Inventory at 30 June 2023 amounted to $2.7 million (31 December 2022: $1.8 million), which comprises finished product available for sale.

Trade and other receivables increased to $9.3 million at 30 June 2023 from $6.5 million at 31 December 2022. This increase can be directly attributable to the higher sales volume in the US.

The current tax asset of $0.6 million (31 December 2022: $0.5 million) represents anticipated R&D tax credits.

Cash and cash equivalents at 30 June 2023 amounted to $13.6 million (31 December 2022: $3.4 million). Effective 28 September 2023, the Company finalized a credit agreement for $20 million with SWK Holdings. The facility has a five-year term and is secured over the Group's US intellectual property rights associated with Accrufer®. Interest will be payable at a rate of 9.25% above the Secured Overnight Financing Rate ("SOFR"). The first eight quarters from the effective date are interest only periods; thereafter, the loan will be amortized at a fixed amount of $1 million per quarter. The proceeds from this loan facility will be used 1) to repay the remaining balance of $5.7 million (31 December 2022: $7.2 million) on the AOP shareholder loan, 2) on commercial programs and initiatives to accelerate the launch curve and increase the average net selling price, and 3) on further investment in working capital to pre-finance inventory and trade receivable build-up.

Trade and other payables decreased from $11.4 million at 31 December 2022 to $8.1 million at 30 June 2023. This difference is largely due to the deferred portion of the Viatris upfront payment in the amount of $4.3 million, which was included in the year-end payables balance and recognized as other operating income in the first half of 2023.

Cash flow

The net cash outflow from operations in H1 2023 was $19.9 million (H1 2022: $14.3 million). The H1 2023 loss for the period was $12.6 million but, after adjusting for various non-cash items, the actual cash outflow from this loss was $10.8 million (H1 2022: $13.2 million). Working capital cash outflows increased from $1.1 million in H1 2022 to $9.1 million in H1 2023, mainly due to the underlying volume increase of the US commercial business.

Capitalised development expenditure of $1.5 million in H1 2023 (H1 2022: $1.5 million) was the main driver of the net cash outflow from investing activities of $1.3 million (H1 2022: $1.3 million).

The cash inflow from financing activities of $30.1 million (H1 2022: $0.1 million) is primarily attributable to the net proceeds from the equity placing in the amount of $20.2 million (H1 2022: nil) and the proceeds from the convertible shareholder loan from AOP in the amount of $10 million (H1 2022: nil), both of which were completed in January 2023.

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 2023, the Directors believe that it remains appropriate to prepare the financial statements on a going concern basis.

Financial outlook

During the second half of 2023, management expects a further increase in net product revenue from Accrufer® sales in the US. That increase will be driven by a continuing increase in prescription volume, plus a modest increase in the net selling price through several initiatives specifically targeted to reduce the gross-to-net discount. Whereas several of these initiatives will be implemented during 2023, it is expected that an acceleration in the improvement in gross-to-net discounts will be achieved through 2024 with an average net sales price of between $220 and $240 being targeted by 2025. In addition, we expect a continuing steady increase in royalties from product sales by our European license partner Norgine.

Consolidated statement of profit and loss and other comprehensive income

for the six months ended 30 June 2023

	Note	**Six months ended 30 June 2023 (unaudited) $000**	Six months ended 30 June 2022 (unaudited) $000	Year ended 31 December 2022 (audited) $000
Revenue	4	**4,334**	2,614	5,492
Cost of sales		**(2,085)**	(1,139)	(3,038)
Gross profit		**2,249**	1,475	2,454
Other operating income		**4,298**	-	859
Operating costs – selling, general and administrative expenses	5	**(17,654)**	(15,205)	(33,611)
Operating loss before impairment and research and development expenditure		**(11,107)**	(13,730)	(30,298)
Impairment of intangible assets		**-**	-	(17,748)
Research and development expenditure		**(434)**	(1,313)	(1,315)
Operating loss	4	**(11,541)**	(15,043)	(49,361)
Financial income	4	**326**	381	811
Financial expense	4	**(578)**	-	(403)
Loss before tax		**(11,793)**	(14,662)	(48,953)
Taxation	4,6	**(812)**	(456)	(447)
Loss for the period		**(12,605)**	(15,118)	(49,400)
Other comprehensive income				
Items that are or may be reclassified subsequently to profit or loss:				
Foreign currency translation differences – foreign operations		**894**	2,583	1,441
Total comprehensive expenditure for the period		**(11,711)**	(12,535)	(47,959)
Loss per share				
Basic and diluted loss per share (in US cents)	7	**$(0.02)**	$(0.07)	$(0.21)

Group balance sheet

at 30 June 2023

	Note	**30 June 2023 (unaudited) $000**	30 June 2022 (unaudited) $000	31 December 2022 (audited) $000
Non-current assets				
Intangible assets	8	**15,239**	32,912	14,208
Property, plant and equipment		**327**	373	238
		15,566	33,285	14,446
Current assets				
Inventories	9	**2,695**	1,730	1,757
Trade and other receivables		**9,262**	5,449	6,487
Current tax asset		**550**	224	526
Cash and cash equivalents		**13,594**	2,934	3,402
		26,101	10,337	12,172
Total assets		**41,667**	43,622	26,618
Non-current liabilities				
Convertible shareholder loan		**(5,705)**	-	(6,683)
Fair value of loan conversion feature		**-**	-	(562)
		(5,705)	-	(7,245)
Current liabilities				
Trade and other payables		**(8,080)**	(3,839)	(11,443)
Lease liabilities		**(67)**	-	(107)
Other liabilities		**(713)**	(117)	(1.278)
		(8,860)	(3,956)	(12,828)
Total liabilities		**(14,565)**	(3,956)	(20,073)
Net assets		**27,102**	39,666	6,545
Equity				
Share capital	10	**(13,734)**	(4,017)	(5,371)
Share premium		**(173,087)**	(147,927)	(149,458)
Merger reserve		**(42,966)**	(42,966)	(42,966)
Currency translation reserve		**(10,603)**	(10,851)	(9,709)
Deposit for shares		**-**	-	100
Accumulated deficit		**213,288**	166,095	200,859
Total equity		**(27,102)**	(39,666)	(6,545)

Group statement of changes in equity

for the six months ended 30 June 2023

	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 2022 (audited)	4,574	-	147,927	42,966	8,268	(152,371)	51,364
Loss for the year	-	-	-	-	-	(49,400)	(49,400)
Other comprehensive income:							
Foreign currency translation differences	-	-	-	-	1,441	-	1,441
Total comprehensive expense for the year	-	-	-	-	1,441	(49,400)	(47,959)
Transactions with owners, recorded directly in equity							
Share options exercised	42	-	62	-	-		104
Prepaid shares for equity placing		(100)					(100)
Loan conversion	755		1,469	-	-	-	2,224
Equity-settled share-based payment transactions	-	-	-	-	-	912	912
Balance at 31 December 2022 (audited)	**5,371**	**(100)**	**149,458**	**42,966**	**9,709**	**(200,859)**	**6,545**
Loss for the period	-		-	-	-	(12,605)	(12,605)
Other comprehensive income:							
Foreign currency translation differences	-		-	-	894	-	894
Total comprehensive expense for the period	-	-	-	-	894	(12,605)	(11,711)
Transactions with owners, recorded directly in equity							
Equity placing	5,422	100	14,648	-	-	-	20,170
Loan conversion	2,941		8,981	-	-	-	11,922
Equity-settled share-based payment transactions	-		-	-	-	176	176
Balance at 30 June 2023 (unaudited)	**13,734**	**-**	**173,087**	**42,966**	**10,603**	**(213,288)**	**27,102**

Group statement of cash flows

for the six months ended 30 June 2023

	Six months ended 30 June 2023 (unaudited) $000	Six months ended 30 June 2022 (unaudited) $000	Year ended 31 December 2022 (audited) $£000
Cash flows from operating activities			
Loss for the period	**(12,605)**	(15,118)	(49,400)
Adjustments for:			
Depreciation and amortisation	**524**	1,318	2,848
Equity-settled share-based payment expenses	**176**	967	912
Financial income	**(326)**	(381)	(869)
Financial expense	**578**	-	469
Impairment of intangible assets	**-**	-	17,735
Income tax	**813**	-	437
	(10,840)	(13,214)	(27,868)
(Increase)/decrease in inventories	**(938)**	258	215
Increase in trade and other receivables	**(3,612)**	(1,410)	(2,787)
Increase/(decrease) in trade and other payables	**(3,364)**	52	7,271
Decrease in other liabilities	**(1,142)**	(19)	1,262
Income tax (paid)/received	**-**	-	(427)
Fair value conversion option	**-**	-	843
Net cash flows from operating activities	**(19,896)**	(14,333)	(21,491)
Cash flows from investing activities			
Financial income	**326**	320	36
Acquisitions of intangible assets	**-**	-	-
Acquisition of tangible assets	**(178)**	(43)	(64)
Capitalised development expenditure	**(1,466)**	(1,542)	(2,221)
Net cash flows from investing activities	**(1,318)**	(1,265)	(2,249)
Cash flows from financing activities			
Cash raised from equity placing	**20,170**	-	-
Interest paid	**-**	-	(403)
Leases – interest payment	**-**	-	(5)
Proceeds from convertible shareholder loan	**10,000**	-	10,000
Deposit for shares	**-**	-	(100)
Proceeds of share options exercised	**-**	69	105
Change in lease assets and liabilities (new leased assets)	**-**	-	(76)
Total cash outflow from leases	**(40)**	(190)	(152)
Net cash flows from financing activities	**30,130**	(121)	9,369
Net increase/(reduction) in cash	**8,916**	(15,719)	(14,371)
Effect of exchange rate fluctuations on cash held	**1,276**	2,252	1,372
Cash and cash equivalents at beginning period	**3,402**	16,401	16,401
Cash and cash equivalents at period end	**13,594**	2,934	3,402

Notes

for the six months ended 30 June 2023

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 2022. 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 2022 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 27 September 2023.

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 2022, as described in those annual financial statements, except for the change in the Company's presentation currency which is further described below.

Change in reporting currency

The Company's presentation currency has changed from Pound Sterling ('Sterling' or '£') to US Dollars ('$' or 'US$') effective 1 January 2023. This is on the basis that an increasing proportion of the Company transactions are denominated in US Dollars. We consider that this change will give investors and other key stakeholders a clearer understanding of the Company's performance over time.

Following this change in accounting policy the impact was applied retrospectively and thus the comparatives in the consolidated financial statements were restated in US Dollars, as required by IAS 8. The procedures used for this restatement were formed based on the requirements of IAS 21 and were as follows:

- Share capital, share premiums and other reserves are translated at historic rates prevailing at the dates of transactions.
- Other assets and liabilities are translated into US Dollars at closing rates of exchange.
- Trading results are translated into US Dollars at the average rate for the financial period.
- For differences resulting from the assets and the results for the period have been presented in the foreign exchange reserve, a component within shareholders' equity.
- Cumulative currency translation adjustments are presented as if the Group had used US Dollars as the presentation currency of its consolidated financial statements since that date.

Going concern

At 30 June 2023, the Group held $13.6 million in cash. On 28 September 2023, the Company announced a new credit facility in the amount of $20 million from SWK Holdings. The Company further announced an equity fundraise of up to $7.4 million before expenses.

The Group is planning to use these funds to repay the remaining balance of the existing convertible shareholder loan from AOP Health International Management AG, undertake further investments in the commercial business to accelerate the launch curve and help increase the net sales price, and invest in the working capital needs of the Group.

The Directors have considered the funding requirements of the Group through the preparation of detailed cash flow forecasts for the period to December 2024, 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 by the end of 2024 and that the fundraise detailed above should provide sufficient cash to allow the business to continue in operations for at least twelve months from the balance sheet date. The Directors have considered scenarios in which sales revenues fall below base case 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 capitalised 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 recognised 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 realisation of its value is ultimately dependent on the successful commercialisation of the asset. In the event that commercial returns are lower than current expectations this may lead to an impairment. No impairment has been recognised to date.

Deferred tax assets

Estimates of future profitability are required for the decision whether or not to create a deferred tax asset. To date no deferred tax assets have been recognised.

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 commercialisation 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 2023 (unaudited)				Year ended 31 December 2022 (audited)			
	Accrufer®/ Feraccru® $000	**PT20 $000**	**Central and unallocated $000**	**Total $000**	Accrufer®/ Feraccru® $000	PT20 $000	Central and unallocated $000	Total $000
Revenue	**4,334**	**-**	**-**	**4,334**	5,492	-	-	5,429
Operating loss	**(865)**	**-**	**(10,676)**	**(11,541)**	(27,635)	(18,625)	(3,101)	(49,361)
Financial income				**326**				811
Financial expense				**(578)**				(403)
Tax				**(812)**				(447)
Loss for the period				**(12,605)**				(49,400)

The revenue analysis in the table below is based on the country of registration of the fee-paying party. $3.7 million revenue (year ended 31 December 2022: $3.5 million) was derived from Accrufer® sales in the US, $0.6 million (year ended 31 December 2022: $1.8 million) from royalties, and $Nil (year ended 31 December 2022: $0.2 million) from license upfront and milestone payments from commercial partners.

	Six months ended 30 June 2023 (unaudited) $000	Six months ended 30 June 2022 (unaudited) $000	Year ended 31 December 2022 (audited) $£000
USA	**3,742**	1,664	3,539
The Netherlands	**592**	752	1,766
Canada	**-**	193	181
South Korea	**-**	5	6
	4,334	2,614	5,492

5. Operating costs – selling, general and administrative expenses

Operating costs are comprised of:

	Six months ended 30 June 2023 (unaudited) $000	Six months ended 30 June 2022 (unaudited) $000	Year ended 31 December 2022 (audited) $000
Selling costs	**11,793**	9,855	19,964
General and administrative expenses	**5,366**	4,006	10,743
Depreciation and amortization	**495**	1,344	2,904
	17,654	15,205	33,611

6. Taxation

The Group's tax charge for the six months ended 30 June 2023 was $0.8 million (H1 2022: $0.5 million), mostly related to the Group's commercial activities in the US.

7. Loss per share

The basic loss per share of $0.02 (H1 2022: $0.07) has been calculated by dividing the loss for the period by the weighted average number of shares of 702,902,306 in issue during the six months ended 30 June 2023 (six months ended 30 June 2022: 216,015,815).

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.

8. Intangible assets

Group	**Accrufer®/ Feraccru® patents and trademarks $000**	**Accrufer®/ Feraccru® development costs $000**	**Phosphate Therapeutics licences $000**	**Total $000**
Cost				
Balance at 1 January 2022 (audited)	2,490	14,023	32,651	**49,164**
Additions – externally purchased	-	2,222	-	**2,222**
Impairment of intangible assets	(212)	-	(32,651)	**(32,863)**
Balance at 31 December 2022 (audited)	2,278	16,245	-	**18,523**
Additions – externally purchased	-	1,466	-	**1,466**
Balance at 30 June 2023 (unaudited)	**2,278**	**17,711**	**-**	**19,989**
Accumulated amortisation				
Balance at 1 January 2022 (audited)	884	2,529	13,363	**16,776**
Charge for the period	164	738	1,754	**2,656**
Impairment of intangible assets	-	-	(15,117)	**(15,117)**
Balance at 31 December 2022 (audited)	1,048	3,267	-	**4,315**
Charge for the period	47	388	-	**435**
Balance at 30 June 2023 (unaudited)	**1,095**	**3,655**	**-**	**4,750**
Net book values				
30 June 2023 (unaudited)	**1,183**	**14,056**	**-**	**15,239**
31 December 2022 (audited)	1,230	12,978	-	14,208

9. Inventories

Group	**Six months ended 30 June 2023 (unaudited) $000**	Six months ended 30 June 2022 (unaudited) $000	Year ended 31 December 2022 (audited) $000
Finished goods	**2,695**	1,730	1,757
	2,695	1,730	1,757

10. Share capital

	Six months ended 30 June 2023 Number 000	**Six months ended 30 June 2023 $000**	Year ended 31 December 2022 Number 000	Year ended 31 December 2022 $000
At beginning of period	**259,388**	**5,371**	215,885	4,574
Exercise of share options	**-**	**-**	2,348	35
Conversion of loan	**158,805**	**2,941**	41,155	762
Equity placing	**294,844**	**5,422**	-	-
Total shares authorised and in issue at end of period – fully paid	**713,037**	**13,734**	259,388	5,371

No share options were exercised during the six months ended 30 June 2023 (six months ended 30 June 2022: 307,438)

11. Subsequent events

On 28 September 2023, the Company announced a new credit facility in the amount of $20 million from SWK Holdings. The facility has a five-year term and is secured over the Group's US intellectual property rights associated with Accrufer®. Interest will be payable at a rate of 9.25% above the Secured Overnight Financing Rate ("SOFR"). The first eight quarters from the effective date are interest only periods; thereafter, the loan will amortize at a fixed amount of $1 million per quarter. The credit agreement with SWK Holdings includes financial covenants in respect to minimal liquidity and minimum revenue targets.

The Company further announced on 28 September 2023, an equity fundraise of up to $7.4 million before expenses.