RNS Number : 6546Y
Shield Therapeutics PLC
08 September 2022

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

Half-year Report

Business Update and Interim Report for the six months ended 30 June 2022

Accrufer® US total prescriptions quadrupled in H1:2022 compared to H2:2021;
Accrufer® net product revenue increased to US$1.5 million in H1:2022; and
Completion of $10 million shareholder loan on 1 August 2022

London, UK, 8 September, 2022: Shield Therapeutics plc (LSE: STX), a commercial stage specialty pharmaceutical company focused on the commercialization of Accrufer®/Feraccru® (ferric maltol), a novel oral iron therapy differentiated from other conventional irons by its efficacy, well-tolerated formulation, and broad label, reports its unaudited interim results for the first half of 2022 (H1:2022) and provides a business update.

July marked the one-year anniversary of the US launch of Accrufer®. Over the last twelve months, Shield has built a high-performance executive leadership team and launch-savvy commercial organisation. The Company has developed and implemented a new US commercial strategy and launch plan, secured broad reimbursement coverage across Commercial and Medicaid segments, substantially increased prescriber awareness and expanded the global Accrufer® opportunity through a series of new, high-value commercial partnerships.

Accrufer® prescriptions have accelerated in H1:2022, with growth of 87% achieved during Q2:2022 compared to Q1:2022, which follows an equally strong Q1 growth, all achieved with a small but dedicated commercial team. Altogether, prescriptions have increased by approximately 350% during the H1:2022 compared to H2:2021. Shield continues to focus on three main commercial priorities: increasing awareness of Accrufer®, generating clinical experience and expanding payor coverage.

Current Business Update

- Total US Accrufer® prescriptions increased c. 350% to 11,223 in H1:2022 compared to 2,516 in H2:2021:
  - **Women's health practitioners** have written approximately 50% of Accrufer® prescriptions to treat women with underlying diseases leading to iron deficiency and/or iron deficiency anaemia. This segment is growing rapidly.
  - **General practitioners** represent approximately 45% of Accrufer® prescriptions, with demand continuing to grow in this segment as well.
- c.20 million people in the US have anaemia, reflecting a large and continuous unmet medical need.
- Total US net revenue from Accrufer® for H1:2022 increased to US$1.5 million compared to US$0.1 million for H2:2021, which was also the first half year following the launch.
- 1,050 new first time prescribers of Accrufer® during H1:2022, a fivefold increase from January to June 2022, indicating growing awareness and interest by healthcare providers.
- 100 million or ~40% of eligible lives now have coverage for Accrufer® by US payers across Commercial and Medicaid segments, dramatically expanding access for patients.
- c.2,300 Health care providers have been introduced to Accrufer® by participating in Shield-sponsored programmes in H1:2022.
- New digital pharmacy partnership initiated with BLINKRx during Q2:2022 with a goal to provide an innovative and modern prescribing experience for physicians and patients.
- Phase 3 paediatric study in the US and UK progressing with over 75% of sites active.
- New Shield branding logo and updated corporate website introduced.
- Positive data from Accrufer® in patients with Chronic Kidney Disease (AEGIS-CKD) presented at the European Society of Medicine (ESMED) Assembly in early August by Dr Nelson Kopyt, Clinical Professor, Temple University Lewis Katz School of Medicine expanding stakeholder commitment.

- Feraccru® packs sold by commercial partner, Norgine, in Europe increased by 15% in H1:2022 compared with H1:2021 and by 6% compared with H2:2021. The most notable volume increase incurred in the United Kingdom which now makes up c.20% of the total Feraccru® packs sold by Norgine in Europe. Royalty revenue from Norgine amounted to £0.7 million for H1:2022.
- Commercial partner, KYE Pharmaceuticals Inc. ("KYE"), submitted documentation for approval of Accrufer® in the Canadian market in March 2022. Approval is expected mid-2023 and product launch expected by end of 2023.
- US$10 million shareholder loan provides funding through to the end of 2022. The Company also continues to engage with various parties in relation to potential financing opportunities and other strategic partnerships in order to maximise the commercial opportunity for Accrufer® and extend its cash runway.

Greg Madison, CEO of Shield Therapeutics, stated: *"Shield delivered a strong first half of 2022 and executed well across the Company's main commercial priorities. We are increasing awareness, developing new writers, growing prescriptions and expanding payor access, all with a small, motivated commercial footprint in the US. We continue to believe there is tremendous potential to disrupt the iron deficiency market that has lacked innovative new therapies that can offer the efficacy, tolerability and convenience as seen with Accrufer® in our clinical trials to individuals suffering from iron deficiency or iron deficiency anaemia. Based on our interim results and ongoing feedback from target prescribers, we are even more confident today about the potential for Accrufer® to become the oral iron treatment of choice."*

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About Accrufer®/Feraccru®

Accrufer®/Feraccru® (ferric maltol) is a novel, stable, non-salt based oral therapy for adults with iron deficiency, with or without anemia. 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 with a focus on addressing iron deficiency with its lead product Accrufer®/Feraccru® (ferric maltol). The Group has launched Accrufer® in the US and Feraccru® is commercialized in the UK and European Union by Norgine B.V., who also have the 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. in the Republic of Korea, and with KYE Pharmaceuticals Inc. in Canada.
Accrufer®/Feraccru® has patent coverage until the mid-2030s
Accrufer®/Feraccru® are registered trademarks of the Shield Group

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, 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 Group'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 Group disclaims any obligation to update any forward-looking statements contained in this release, even if subsequent events cause our views to change.

Operational Review

Commercialisation of Accrufer® / Feraccru®

USA

Following the US launch of Accrufer® on 1 July 2021, Shield has seen a significant increase in demand during the first six months of 2022 (H1:2022), recording a total of 9,839 prescriptions sold. The average net selling price for an Accrufer® prescription increased c.350% to US$152 in H1:2022 (H2:2021: US$34), reducing the gross-to-net sales price adjustment from 93% to 70%, which is attributable to increased payer coverage from both commercial payers and state-run Medicaid programmes. Overall, Accrufer® now has coverage of more than 100 million lives, significantly increasing access for US patients reported effective 31 December 2021 when coverage included 60 million lives.

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. Additionally, Norgine submitted a reimbursement application in Spain earlier this year.

The number of Feraccru® packs sold by Norgine in Europe increased by 15% in H1:2022 compared with H1:2021 and by 6% compared with H2:2021. The most notable volume increase incurred in the United Kingdom which is now making up 20% of the total Feraccru® packs sold by Norgine in Europe.

Asia

In China, our license partner Beijing Aosaikang Pharmaceutical Co., Ltd. ("ASK Pharm") completed the PK study and is continuing enrollment into the Phase 3 study in 120 Inflammatory Bowel Disease (IBD) patients, which is very similar in design to the study that led to approval by EMA and FDA in Europe and US, respectively.

Korea Pharma Co. Ltd. ("Korea Pharma"), which licensed the development and commercialisation rights for the Republic of Korea in August 2021, continues to negotiate the detailed clinical/regulatory pathway for approval with the Korean regulatory authorities.

Other markets

On 5 January 2022, we announced an exclusive license agreement with KYE Pharmaceuticals Inc. ("KYE") for the development and commercialisation of Accrufer® in Canada. The terms of the agreement include an upfront payment of £0.15 million, a total of £0.85 million in development and sales milestone payments, plus double-digit royalties on net sales of Accrufer®.

KYE submitted the New Drug Submission ("NDS") during H1:2022, which was accepted by Health Canada in July 2022. Upon a successful outcome of the regulatory review, expected by mid-2023, we expect KYE to start marketing Accrufer® in Canada by year end 2023.

Product development

In accordance with regulatory approval for Feraccru®/Accrufer® by the EMA and FDA, respectively, Shield agreed on a Pediatric Investigational Plan (PIP)/Pediatric Development Plan (PDP), both culminating in the conduct of a Phase III study to evaluate the safety, tolerability and efficacy of the product in infants, children and adolescents.

In accordance with these plans, Shield initiated a paediatric clinical study in the US and the UK in H2: 2021. Enrollment is progressing as planned with currently over 75% of sites active.

Outlook

The second half of 2022 will be heavily focused on further increasing the momentum of Accrufer® prescription sales in the US. We plan on doing this by continuing to drive our main focus areas of 1) increasing awareness of Accrufer®, 2) generating clinical experience and 3) expanding payer coverage. Additionally, we will support our

license partners across the globe in their efforts to obtain regulatory approvals for Accrufer®/Feraccru® and in their commercialisation efforts to increase market shares. The Company also continues to engage with various parties in relation to potential financing opportunities and other strategic partnerships in order to maximise the commercial opportunity for Accrufer® and extend its cash runway.

Financial Review

Revenue

Revenue in the first six months of 2022 (H1:2022) amounted to £2.0 million (H1:2021: £0.5 million), of which £1.2 million (H1:2021: £nil) was derived from Accrufer® sales in the US and £0.7 million (H1:2021: £0.5 million) was from royalties for sales of Feraccru® in Europe. Additionally, Shield recorded £0.1 million (H1:2021: £nil) in the form of a license upfront payment from its commercial partner in Canada.

Cost of sales

Cost of sales in H1:2022 amounted to £0.9 million (H1:2021: £0.4 million). The H1:2022 cost of sales comprises manufacturing costs of the prescriptions sold in the US and in Europe, plus the 5% royalty on net sales which is 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 upfront license fees and sales milestones. For the Norgine license agreement, Vitra chose to receive a royalty of 5% of net sales.

Selling, general and administrative expenses

Selling, general and administrative expenses were £11.9 million in H1:2022 (H1:2021:£6.1 million) of which £1.1 million (H1:2021:£1.3 million) represents the amortisation of intangible assets. Excluding amortisation, the underlying costs increased from £4.8 million in H1:2021 to £10.8 million in H1:2022, which is directly attributable to the commencement of commercial activities in the US.

Research and development

In H1:2022, £1.0 million (H1:2021: £1.6 million) development costs were expensed in the statement of profit and loss. In addition, £1.3 million (H1:2021: £nil) of development expenditure were recorded directly to the balance sheet in accordance with the underlying conditions for capitalisation, which are disclosed in the detail in the notes of the Company's annual report. Most of these development costs and expenditure related to the ongoing paediatric study.

Tax

The tax charge of £0.4 million (H1:2021: tax credit of £0.3 million from UK R&D tax credit) represents the tax accrual for income taxes due in the US in connection with the Group's commercial activities and comprises the anticipated UK R&D tax credit in respect of the first half of 2021.

Loss for the period

The loss for H1:2022 was £11.8 million (H1:2021: £7.3 million).

Balance sheet

Intangible assets at 30 June 2022 were £27.1 million (31 December 2021: £26.8 million). The components of this are £15.3 million (31 December 2021: £16.0 million) relating to the acquisition costs of PT20, the phosphate binder product in our development portfolio; £10.5 million (31 December 2021: £9.5 million relating to capitalised Accrufer®/Feraccru® development expenditure), and £1.3 million (31 December 2021: £1.3 million) expenditure on strengthening the Group's intellectual property.

Inventory at 30 June 2022 amounted to £1.4 million (31 December 2021: £1.6 million), which mainly comprises raw materials, with the balance representing finished product.

Trade and other receivables increased to £4.4 million at 30 June 2022 compared with £2.9 million at 31 December 2021. A substantial part of the increase relates to prepaid expenses in the US operation.

The current tax asset of £0.2 million (31 December 2021: £0.6 million) represents anticipated R&D tax credits.

Cash and cash equivalents at 30 June 2022 amounted to £2.4 million (31 December 2021: £12.1 million). Effective 1 August 2022, the Company finalised a convertible loan agreement for US$10 million with an existing shareholder. The loan is secured over the Group's US intellectual property rights associated with Accrufer® and was drawn as a single tranche immediately following the completion of the loan agreement. Interest under the loan will be payable at a rate of 9.1% above the Secured Overnight Financing Rate ("SOFR") and is repayable no later than 31 December 2023. Approximately £2.3 million of this loan was immediately converted into 41,195,246 new ordinary shares in the Company. The Group's unaudited cash balance at 31 August 2022 was £8.2 million.

Trade and other payables at 30 June 2022 were £3.2 million, slightly higher than the £3.1 million at 31 December 2021.

Cash flow

The net cash outflow from operations in H1:2022 was £8.8 million (H1:2021: £8.0 million). The H1:2022 loss for the period was £11.8 million but, after adjusting for non-cash items, the actual cash outflow from this loss was £7.7 million (H1:2021: £5.4 million). Working capital cash outflows amounted to £1.1 million (H1:2021: £2.6 million) caused mainly by prepaid expenses in the US operations.

Further to the capitalised development expenditure of £1.3 million in H1:2022 (H1:2021: nil), the cash outflow for the period was £9.8 million. The cash inflow of £19.6 million in H1:2021 was primarily attributable to the cash raised from the equity placing in March 2021.

Going concern

For the reasons set out in Note 3 below, the Directors believe that it remains appropriate to prepare the financial statements on a going concern basis.

Financial outlook

During the second half of 2022, management will focus on balancing the Company's financial resources with the need to undertake further investments in the US commercial activities through a potential expansion of its field sales force and targeted marketing initiatives. The Company also continues to engage with various parties in relation to potential financing opportunities and other strategic partnerships in order to maximise the commercial opportunity for Accrufer® and extend its cash runway. In the meantime, we expect continued steady growth in revenues from Accrufer® prescription sales, through both increased demand and payer coverage, and from royalties through European product sales through Norgine.

Consolidated statement of profit and loss and other comprehensive income

for the six months ended 30 June 2022

	Note	**Six months ended 30 June 2022 (unaudited) £000**	Six months ended 30 June 2021 (unaudited) £000	Year ended 31 December 2021 (audited) £000
Revenue	4	**2,031**	481	1,519
Cost of sales		**(885)**	(411)	(980)
Gross profit		**1,146**	70	539
Other operating income		**-**	-	111
Operating costs - selling, general and administrative expenses	5	**(11,850)**	(6,121)	(20,023)
Operating loss before research and development expenditure		**(10,704)**	(6,051)	(19,373)
Research and development expenditure		**(1,020)**	(1,592)	(579)
Operating loss		**(11,724)**	(7,643)	(19,952)
Financial income		**296**	63	395
Financial expense		**-**	(3)	(8)
Loss before tax		**(11,428)**	(7,583)	(19,565)
Taxation	6	**(354)**	300	229
Loss for the period		**(11,782)**	(7,283)	(19,336)
Attributable to:				
Equity holders of the parent		**(11,782)**	(7,283)	(19,336)
Other comprehensive loss				
Items that are or may be reclassified subsequently to profit or loss:				
Foreign currency translation differences - foreign operations		**2,513**	58	1,396
Total comprehensive expenditure for the period		**(9,269)**	(7,225)	(17,940)
Attributable to:				
Equity holders of the parent		**(9,269)**	(7,225)	(17,940)
Total comprehensive expenditure for the period		**(9,269)**	(7,225)	(17,940)
Loss per share				
Basic and diluted loss per share	7	**£(0.05)**	£(0.04)	£(0.09)

Group balance sheet

at 30 June 2022

	Note	**30 June 2022 (unaudited) £000**	30 June 2021 (unaudited) £000	31 December 2021 (audited) £000
Non-current assets				
Intangible assets	8	**27,068**	26,016	26,851
Property, plant and equipment		**307**	59	304
		27,375	26,.075	27,155
Current assets				
Inventories	9	**1,423**	1,435	1,635
Trade and other receivables		**4,438**	1,996	2,930
Current tax asset		**184**	300	576
Cash and cash equivalents		**2,404**	22,602	12,117
		8,449	26,333	17,258
Total assets		**35,824**	52,408	44,413
Current liabilities				
Trade and other payables		**(3,157)**	(1,281)	(3,114)
Lease liabilities		**-**	-	(156)
Other liabilities		**(95)**	(113)	(110)
		(3,252)	(1,394)	(3,380)
Total liabilities		**(3,252)**	(1,394)	(3,380)
Net assets		**32,572**	51,014	41,033
Equity				
Share capital	10	**3,243**	3,238	3,238
Share premium		**114,635**	114,583	114,583
Merger reserve		**28,358**	28,358	28,358
Currency translation reserve		**3,962**	111	1,449
Retained earnings		**(117,626)**	(95,276)	(106,595)
Total equity		**32,572**	51,014	41,033

Group statement of changes in equity

for the six months ended 30 June 2022

	Share capital £000	Share premium £000	Merger reserve £000	Currency translation reserve £000	Retained earnings £000	Total £000
Balance at 1 January 2021 (audited)	1,764	88,352	28,358	53	(88,251)	30,276
Loss for the year	-	-	-	-	(19,336)	(19,336)
Other comprehensive income:						
Foreign currency translation differences	-	-	-	1,396	-	1,396
Total comprehensive expense for the year	-	-	-	1,396	(19,336)	(17,940)
Transactions with owners, recorded directly in equity						
Equity placing - new shares issued	1,459	26,220	-	-	-	27,679
Equity-settled share-based payment transactions	15	11	-	-	992	1,018
Balance at 31 December 2021 (audited)	**3,238**	**114,583**	**28,358**	**1,449**	**(106,595)**	**41,033**
Loss for the period	-	-	-	-	(11,782)	(11,782)
Other comprehensive income:						
Foreign currency translation differences	-	-	-	2,513	-	2,513
Total comprehensive expense for the period	-	-	-	2,513	(11,782)	(9,269)
Transactions with owners, recorded directly in equity						
Equity-settled share-based payment transactions	5	52	-	-	751	808
Balance at 30 June 2022 (unaudited)	**3,243**	**114,635**	**28,358**	**3,962**	**(117,626)**	**32,572**

Group statement of cash flows

	Six months ended 30 June 2022 (unaudited) £000	Six months ended 30 June 2021 (unaudited) £000	Year ended 31 December 2021 (audited) £000
Cash flows from operating activities			
Loss for the period	**(11,782)**	(7,283)	(19,336)
Adjustments for:			
Depreciation and amortisation	**1,083**	1,290	2,207
Equity-settled share-based payment expenses	**751**	257	992
Financial income	**(296)**	(63)	(395)
Financial expense	**-**	3	42
Unrealised foreign exchange losses	**2,513**	58	1,396
Income tax	**-**	300	(229)
	(7,731)	(5,438)	(15,323)
(Increase)/decrease in inventories	**212**	(56)	(256)
Increase in trade and other receivables	**(1,116)**	(1,685)	(2,879)
Increase/(decrease) in trade and other payables	**43**	(190)	1,643
Decrease in other liabilities	**(15)**	(640)	(643)
Change in lease assets and liabilities	**(156)**	(28)	128
Income tax received	**-**	-	592
Net cash flows from operating activities	**(8,763)**	(8,037)	(16,738)
Cash flows from investing activities			
Financial income	**235**	2	13
Acquisitions of intangible assets	**-**	(66)	(9)
Acquisition of tangible assets	**(35)**	-	(372)
Capitalised development expenditure	**(1,268)**	-	(1,683)
Net cash flows from investing activities	**(1,068)**	(64)	(2,051)
Cash flows from financing activities			
Cash raised from equity placing	**-**	27,679	27,679
Interest paid	**-**	(3)	(42)
Leases - interest payment	**-**	-	(3)
Proceeds of share options exercised	**57**	26	26
Total cash outflow from leases	**-**	-	(76)
Net cash flows from financing activities	**57**	27,702	27,584
Net increase/(reduction) in cash	**(9,774)**	19,601	8,795
Effect of exchange rate fluctuations on cash held	**61**	61	382
Cash and cash equivalents at beginning of period	**12,117**	2,940	2,940
Cash and cash equivalents at end of period	**2,404**	22,602	12,117

Notes
for the six months ended 30 June 2022

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.

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 financial statements of the Company and its subsidiaries (the "Group") as at and for the year ended 31 December 2021. 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 2021 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; though it did include a reference to a matter to which the auditor drew attention by way of emphasis without qualifying their report in relation to going concern. It does not comply with IAS 34 Interim financial reporting, as is permissible under the rules of AIM.

The interim report was approved by the board of directors on 6 September 2022.

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 2021, as described in those annual financial statements.

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:

Going concern
At 30 June 2022 the Group held £2.4 million of cash. Since that date, Shield secured a US$10 million convertible term loan from an existing shareholder. In addition, the Group is starting to receive cash deposits related to Accrufer® product sales in the US. The Group's unaudited cash balance at 31 August 2022 was £8.2 million.

The Directors have considered the funding requirements of the Group through the preparation of detailed cash flow forecasts for the period to December 2023. Under current business plans, the current cash resources will extend through the end of the year. As a result, additional revenue generating transactions or financing would therefore be needed by that time to allow the business plans to continue.

The Group is currently considering various forms of finance including dilutive and non-dilutive sources, such as debt finance and royalty finance, underpinned by the expected net product revenues generated in the US over the next few years. However, there can be no guarantee that any of these opportunities will be successfully concluded. Based on the status of the various finance considerations, the Directors believe that it remains appropriate to prepare the financial statements on a going concern basis. However, the above matters indicate the existence of a material uncertainty related to events or conditions which may cast significant doubt on the Group's and the Company's ability to continue as a going concern and, therefore, that the Group and Company may be unable to realise their assets and discharge their liabilities in the normal course of business.

The financial statement do not include any adjustments that would result from the basis of preparation being inappropriate.

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 acquired with Phosphate Therapeutics Limited
The valuation of intellectual property acquired with Phosphate Therapeutics Limited in 2016 is based on cash flow forecasts for the underlying product, PT20, and an assumed appropriate cost of capital and other inputs, such as the size of the market in major markets, in order to arrive at a value in use for the asset. The realisation of its value is ultimately dependent on the positive outcome of a PT20 Phase III clinical study followed by regulatory approval and successful commercialisation of the asset. Whilst earlier PT20 clinical studies provide grounds for confidence that the Phase III study would be successful, this cannot be guaranteed. Work on the development of a suitable commercial formulation of the drug product is ongoing. In the event that commercial returns are lower than current expectations this may lead to an impairment.

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 second asset

Operating results which cannot be allocated to an individual segment are recorded as central and unallocated overheads.

	Six months ended 30 June 2022 (unaudited)				Year ended 31 December 2021 (audited)			
	Accrufer®/ Feraccru® £000	**PT20 £000**	**Central and unallocated £000**	**Total £000**	Accrufer®/ Feraccru® £000	PT20 £000	Central and unallocated £000	Total £000
Revenue	**2,031**	**-**	**-**	**2,031**	1,519	-	-	1,519
Operating loss	**(2,610)**	**(44)**	**(9,070)**	**(11,724)**	(18,294)	(159)	(1,499)	(19,952)
Financial income				**296**				395
Financial expense				**-**				(8)
Tax				**(354)**				(229)
Loss for the period				**(11,782)**				(19,336)

The revenue analysis in the table below is based on the country of registration of the fee-paying party. £1.2 million revenue (year ended 31 December 2021: £0.1 million) was derived from Accrufer® sales in the US, £0.7 million (year ended 31 December 2021: £0.9 million) from royalties, and £0.1 million (year ended 31 December 2021: £0.5 million) from license upfront and milestone payments from commercial partners.

	Six months ended 30 June 2022 (unaudited) £000	Six months ended 30 June 2021 (unaudited) £000	Year ended 31 December 2021 (audited) £000
North America	**1,369**	-	61
Europe	**658**	463	908
Asia	**4**	18	550
	2,031	481	1,519

5. Operating costs - selling, general and administrative expenses

Operating costs are comprised of:

	Six months ended 30 June 2022 (unaudited) £000	Six months ended 30 June 2021 (unaudited) £000	Year ended 31 December 2021 (audited) £000
Selling costs	**7,662**	2,245	10,262
General and administrative expenses	**3,105**	2,586	7,554
Depreciation and amortisation	**1,083**	1,290	2,207
	11,850	6,121	20,023

6. Taxation

The Group's tax charge for the 6 months ended 30 June 2022 was £0.4 million (H1:2021: tax credit of £0.3 million), mostly related to the Group's commercial activities in the US.

7. Loss per share

The basic loss per share of £0.05 (H1:2021: £0.04) has been calculated by dividing the loss for the period by the weighted average number of shares of 216,015,815 in issue during the six months ended 30 June 2022 (six months ended 30 June 2021: 182,955,436).

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 2021 (audited)	2,055	9,943	27,070	**39,068**
Additions - externally purchased	9	1,683	-	1,692
Balance at 31 December 2021 (audited)	2,064	11,626	27,070	**40,760**
Additions - externally purchased	-	1,268	-	1,268
Balance at 30 June 2022 (unaudited)	**2,064**	**12,894**	**27,070**	**42,028**
Accumulated amortisation				
Balance at 1 January 2021 (audited)	668	1,509	9,625	**11,802**
Charge for the period	65	588	1,454	2,107
Balance at 31 December 2021 (audited)	733	2,097	11,079	13,909
Charge for the period	43	281	727	1,051
Balance at 30 June 2022 (unaudited)	**776**	**2,378**	**11,806**	**14,960**
Net book values				
30 June 2022 (unaudited)	**1,288**	**10,516**	**15,264**	**27,068**
31 December 2021 (audited)	1,331	9,529	15,991	26,851

9. Inventories

Group	**Six months ended 30 June 2022 (unaudited) £000**	Six months ended 30 June 2021 (unaudited) £000	Year ended 31 December 2021 (audited) £000
Raw materials	**796**	1,079	1,344
Finished goods	**627**	356	291
	1,423	1,435	1,635

10. Share capital

	Six months ended 30 June 2022 Number 000	**Six months ended 30 June 2022 £000**	Year ended 31 December 2021 Number	Year ended 31 December 2021

			000	£000
At beginning of period	**215,885**	**3,238**	117,620	1,764
Exercise of share options	**307**	**5**	985	15
Equity placing	**-**	**-**	97,280	1,459
At end of period	**216,192**	**3,243**	215,885	3,238

307,438 share options were exercised during the 6 months ended 30 June 2022 (6 months ended 30 June 2021: 985,067)

11. Subsequent events

As announced on 30 June 2022 and 1 August 2022, the Company entered into an agreement with an existing shareholder for a US$10 million convertible loan facility. Interest under the loan agreement will be payable at a rate of 9.1% above the Secured Overnight Financing Rate ("SOFR") and the outstanding loan balance will be repayable no later than 31 December 2023.

Immediately following the finalization of the loan agreement, the shareholder converted £2,274,595 (or US$2,764,659) of the loan balance into 41,195,246 shares at a conversion price of 5.5215p per ordinary share.

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