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

Half-year Report
Interim Report for the six months ended 30 June 2020

Profit and cash inflow in first six months of 2020
Continued progress in US commercialisation activities

London, UK, 16 September 2020: Shield Therapeutics plc (LSE: STX), a commercial stage pharmaceutical company with a focus on addressing iron deficiency with its lead product Feraccru®/Accrufer® (ferric maltol), announces its unaudited interim results for the six months ended 30 June 2020.

Operational Highlights

- Licence agreement signed for Feraccru®/Accrufer® with Jiangsu Aosaikang Pharmaceutical Co. Ltd ("ASK Pharm") covering China, Hong Kong, Macau and Taiwan
- Net sales of Feraccru® in Europe for first 6 months of 2020 up 50% over previous 6 months
- Re-analysis of the AEGIS-H2H study data demonstrates that Feraccru®/Accrufer® is a credible alternative to IV iron therapy and offers economic advantages
- Continued progress being made to secure a US commercialisation partner

Financial Highlights

- $11.4 million upfront payment received from ASK Pharm
- Revenues of £8.9 million (H1 2019: £430,000)
- Profit for the period of £3.1 million (H1 2019 loss: £4.2 million)
- Net cash inflow from operating activities of £2.0 million (H1 2019: £1.9 million outflow)
- Cash of £6.5 million (31 December 2019: £4.1 million)

Commenting on the interim results, Tim Watts, CEO of Shield Therapeutics plc, said: *"I am pleased that we have made good operational progress in the first six months of 2020. In January we signed an important licence deal in China with ASK Pharm who have since made excellent progress in agreeing the development plan with the Chinese regulatory authorities as we look to expand the territories in which Feraccru® is marketed.*

"Norgine grew net sales of Feraccru® in Europe by 50% compared with the second half of 2020, and the first half sales in 2020 have matched the sales for the whole of 2019 notwithstanding the ongoing COVID-19 pandemic. Despite the hiatus with the results of the AEGIS-H2H study, the re-analysis of the data has confirmed that Feraccru®/Accrufer® is a credible alternative to IV iron therapy.

"Over the period we have also continued to make progress to secure a commercialisation partner for the important US market which remains our top priority for 2020 and will update the market on this at the appropriate time."

Analyst briefing
A briefing open to analysts will take place remotely via video conference call today, Wednesday 16 September 2020 at 11.00am. If you would like the details of this call please contact Walbrook PR on shield@walbrookpr.com.

Investor briefing
A briefing open to all existing and potential investors will take place remotely today, Wednesday 16 September 2020, at 4.30pm. The briefing will be hosted through the digital platform Investor Meet Company ('IMC'). Investors can sign up to IMC for free and add to meet Shield Therapeutics plc via the following link:
https://www.investormeetcompany.com/shield-therapeutics-plc/register-investor

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About Shield Therapeutics plc

Shield is a de-risked, specialty pharmaceutical company focused on commercialising its lead product, Feraccru®/Accrufer®, a novel, stable, non-salt based oral therapy for adults with iron deficiency with or without anaemia. Feraccru®/Accrufer® has been approved for use in the United States, European Union, UK and Switzerland and has exclusive IP rights until the mid-2030s. Feraccru® is commercialised in the UK and Europe by Norgine B.V. and the Company is currently in the process of selecting a commercialisation partner for the US market. Shield also has an exclusive licence agreement with Beijing Aosaikang Pharmaceutical Co., Ltd., for the development and commercialisation of Feraccru®/Accrufer® in China, Hong Kong, Macau and Taiwan.

For more information, please visit www.shieldtherapeutics.com. Follow Shield on Twitter @ShieldTx

Operational Review

Commercialisation of Feraccru®/Accrufer®

USA

The main priority for the Group during 2020 to date has been to secure a commercialisation partner for Accrufer® in the USA. As well as achieving the right financial terms, we have also been focussed on engaging with potential partners that could exploit Accrufer® across the broad range of therapy areas where iron deficiency is prevalent. We and our advisers have engaged with multiple companies, a number of which have signed confidentiality agreements, several have submitted non-binding offers and more detailed negotiations have been undertaken with a number of parties. We remain confident of securing a partner in 2020 and have recently ordered launch stocks of US packs of Accrufer® which should be available for sale by around the end of 2020.

China

We announced in January 2020 that we had entered into an exclusive licence agreement for Feraccru®/Accrufer® with Jiangsu Aosaikang Pharmaceutical Co. Ltd ("ASK Pharm") covering China, Hong Kong, Macau and Taiwan. We received an upfront payment of US$11.4 million and are eligible to receive a further US$11.4 million upon regulatory approval of Feraccru®/Accrufer® in China. The Chinese regulatory authority (CDE) has recently indicated that, for the New Drug Application, it is likely to require only a short-term Phase III study in Inflammatory Bowel Disease (IBD) patients and will not require a pharmacokinetic study nor a Phase III clinical study in Chronic Kidney Disease (CKD) patients. Assuming this is definitively confirmed by the CDE, successful execution of this study, which could start in early 2021, could lead to an application for marketing approval in H1 2022 and launch in H2 2023. We will also receive royalties of 10% or 15% of net sales of Feraccru®/Accrufer®, depending on the level of net sales, and up to US$40 million in milestone payments upon the achievement of specified cumulative sales targets.

Vitra Pharmaceuticals Ltd was the original owner of the intellectual property underpinning 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 China licence Vitra has elected to receive 10% of the upfront and sales milestones instead of future sales royalties.

Europe, Australia and New Zealand

Norgine, our European commercialisation partner and market authorisation holder, has continued to see growth in sales of Feraccru® in Germany and the UK during the first half of 2020. Despite the impact of COVID-19, aggregate sales volumes in Germany and the UK increased by 50% in H1 2020 compared with H2 2019 and equalled sales for the whole of 2019. Pricing and reimbursement applications in other European countries, which had been suspended while we re-analysed the AEGIS-H2H results, will resume in the next few months based on the re-analysed data.

In Australia, also a Norgine territory, the regulatory approval process is underway and it is possible that Feraccru® could be approved by the end of 2020.

Other markets

Feraccru®/Accrufer® continues to attract interest from companies in other parts of the world and we have commenced discussions in several other markets to investigate potential licensing opportunities in those markets.

AEGIS-H2H (Head-to-Head) study

The AEGIS-H2H study was intended and designed to provide data comparing oral Feraccru®/Accrufer® against intravenous (IV) iron therapy from which health economics data and other analysis could be generated. In March 2020 we announced an update and clarification relating to the original results of the AEGIS-H2H study (published in March 2019) and that the Board had instigated a thorough and complete review into the analysis. In August 2020 we announced the headline results from the review which included:

By week 12 (first phase)

- Of the patients treated with Feraccru®/Accrufer®, 67% of the Intention-To-Treat (ITT) population and 68% of the Per Protocol (PP) population had responded to treatment as defined in the protocol. In the IV arm, 84% of the ITT population and 85% of the PP population had responded. Despite the Feraccru®/Accrufer® results being within 20% of those of IV iron, Feraccru®/Accrufer® did not achieve non-inferiority at 12 weeks in the primary endpoint in either population as the confidence intervals were outside the prespecified 20% margin.
- However the mean increase in Hb levels per patient in the Feraccru®/Accrufer® arm was clinically significant at 2.45 g/dL for the ITT population and 2.57 g/dL in the PP population, compared with 3.04 g/dL and 3.05 g/dL respectively for IV-treated patients.

Long term extension phase (using the ITT results)

- By week 24, 65% Feraccru®/Accrufer® of those patients still being monitored had achieved normal levels of Hb and therefore were non-anaemic, compared with 68% of IV patients.
- At weeks 24, 36 and 52, the mean increases in Hb levels in those patients still being monitored were 2.93 g/dL, 3.16 g/dL and 2.72 g/dL in the Feraccru®/Accrufer® arm compared with 2.84 g/dL, 2.70 g/dL and 2.79 g/dL in the IV arm.

During the first 12-week phase of the study, 82% of IV patients received more than one infusion and collectively 138 days were taken off work in this phase. In the extension phase from week 13 to week 52, 47% of patients who were monitored after the week 12 visit required at least one further infusion. The health economic outcomes from these results, and other more detailed results from the study, are broadly unchanged from the original 2019 analysis and demonstrate that Feraccru®/Accrufer® compares favourably with IV therapy.

We believe that the reanalysis of the AEGIS-H2H study data demonstrates that Feraccru®/Accrufer® is a credible oral alternative to IV therapy and offers economic advantages. Having resolved the anomalies seen in the original analysis the study results can now be used with confidence for further health economics analysis and to support pricing and reimbursement applications in Europe.

Paediatric study

Both the European and US regulatory authorities require a paediatric clinical study to be conducted in children up to 18 years old. For small children and infants, a liquid formulation is required rather than the capsule which is the formulation used in the adult patient population. We have now successfully formulated and manufactured a suitable liquid formulation and the clinical study will start this month. The first stage is a study in 32 healthy adult volunteers to demonstrate therapeutic equivalence between the new liquid formulation and the well-established capsule formulation. Assuming this first stage is successful the main study in children will start during H1 2021.

Supply chain

In our trading update released on 1 May 2020 we stated that our UK manufacturer of bulk ferric maltol was working on a campaign to manufacture around 12.5 metric tonnes of ferric maltol by the end of September 2020. In the event, we decided to complete the manufacture of 4.5 metric tonnes in 2020 and to postpone the manufacture of further bulk product into H1 2021, to preserve shelf-life. The 4.5 tonnes provides sufficient ferric maltol for more than 300,000 packs which we expect to be sufficient at least until the end of 2021.

Intellectual Property (IP)

As previously reported Teva filed oppositions with the European Patent Office (EPO) to the Group's patents, specifically #2 668 175 "Process for preparing an iron hydroxypyrone" and # 3 160 951 "Crystalline forms of ferric maltol". In respect of the Process Patent, on 14 March 2019 the Opposition Division of the European Patent Office (EPO) decided in favour of Shield in respect of the former patent as amended. However, as anticipated, in June 2019 Shield received notice that Teva subsequently filed a notice of appeal to the EPO's decision. We are awaiting the appeal hearing date which has not yet been listed. In respect of the Crystalline Form Patent, the oral proceedings have been listed for 12 March 2021.

Product development – PT20 (phosphate binder)

We continue to believe that PT20 has the potential to be a clinically relevant product in the phosphate binder market. This market continues to grow and, within it, the new iron-based phosphate binders are growing particularly rapidly. PT20, which is iron-based, has characteristics with the potential to give it competitive advantages over existing iron-based products. PT20 has already completed one pivotal clinical study giving us significant confidence in the potential of the product. One further pivotal Phase III study is required to be carried out. Initially we will develop a new formulation of PT20 which will allow the next Phase III study to be carried out and which would be suitable for commercial use. We anticipate that the formulation development work could start in the second half of 2020, subject to finance being available, and should take around 15-18 months, meaning that the Phase III study could potentially start in 2022.

Outlook

Ongoing discussions with potential US partners give us confidence in securing a commercial partner later this year. The results of the AEGIS-H2H study have confirmed that Feraccru®/Accrufer® offers a competitive oral alternative to IV iron therapy from an efficacy perspective and, with the re-analysis completed, our commercialisation partners can move forward with confidence with their market access negotiations and in building compelling health economic arguments for using Feraccru®/Accrufer® which will help build on the growing commercial traction seen in Europe The recent feedback from the Chinese regulators also offers the prospect of launch in China within three years. Accordingly, the strong progress being made across the Group gives the Board considerable confidence in Shield's outlook and prospects.

Financial Review

Note that the comparative financial statements for the six months to 30 June 2019 have been restated to reflect the impact of the requirement to repay Norgine the €2.5 million milestone payment originally received in April 2019 relating to the AEGIS-H2H clinical study. This milestone was subsequently found to be invalid and was excluded from the audited full year financial statements for 2019. The restatement has resulted in revenue and profits for the six months to 30 June 2019 decreasing by £2.2 million.

Revenue

Revenue in the first six months of 2020 (H1 2020) was £8.9 million (H1 2019: £430,000). £8.7 million arose from the upfront payment received from ASK Pharm on entering into the license agreement for the development and commercialisation of Feraccru® in China. The remaining £0.2 million arose from royalties under the Norgine agreement.

Cost of Sales

Cost of sales of £1.0 million (H1 2019: £0.3 million) is comprised primarily of a payment to Vitra Pharmaceuticals Limited (Vitra) of 10% of the licence upfront received from ASK Pharm. Vitra was the original owner of the intellectual property underpinning 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 covering European commercialisation, Vitra chose in 2018 to receive 5% on net sales whereas for the ASK Pharm agreement covering China Vitra has elected to receive 10% of the upfront and sales milestones instead of future sales royalties. H1 2020 cost of sales also includes the cost of finished good supplied to Norgine along with the 5% royalty payable to Vitra on Norgine's net sales.

Selling, general and administrative expenses

Selling, general and administrative expenses were £4.8 million in H1 2020 (H1 2019: £3.6 million) of which £1.3 million (H1 2019 £1.5 million) is the amortisation of intangible assets. A substantial part of the £1.2 million increase in the underlying £3.5 million (H1 2019: £2.0 million) was incurred in adviser costs related to the China licence transaction and on other ongoing corporate projects.

Research and development
In H1 2020, £0.7 million (H1 2019: £1.3 million) development costs have been charged to the income statement The bulk of the H1 2020 costs were incurred on employee and contractor costs, with minimal spend on external development as the planned Feraccru® paediatric study has been delayed due to COVID-19. In H1 2019 a similar amount was incurred on employee and contractors, with a further £0.6 million incurred in support of the US NDA process.

In H1 2019 £1.2 million was capitalised. Most of this was for the AEGIS-H2H study. No development costs have been capitalised in H1 2020.

Tax
The tax credit of £0.4 million (H1 2019: £0.5 million) comprises anticipated R&D tax credits in respect of claims not yet submitted for the 2020 financial year (£0.2 million) and a reduction in the prior-year tax charge for Shield TX (Switzerland) AG as a result of the final tax returns being completed (£0.2 million). In the H1 2019 financial statements the tax credit was an estimated R&D tax credit claim.

Balance sheet
Intangible assets at 30 June 2020 were £28.6 million (31 December 2019: £29.8 million). The components of this are £18.4 million (31 December 2019: £19.5 million) relating to the acquisition costs of PT20, the phosphate binder product in our development portfolio; £8.8 million (31 December 2019: £9.0 million) relating to capitalised Feraccru® development expenditure, and £1.4 million (31 December 2019: £1.5 million) capitalised intellectual property.

Inventory at 30 June 2020 amounted to £1.4 million (31 December 2019: £0.9 million). The increase is due mainly to the production of 4.5 metric tonnes of bulk ferric maltol during H1 2020.

The current tax asset of £1.2 million (31 December 2019: £1.0 million) represents R&D tax credits, £1.0 million of which is expected to be received in H2 2020 in respect of 2019 and an estimate of £0.2 million in respect of H1 2020.

Cash at 30 June 2020 was £6.5 million (31 December 2019: £4.1 million).

Cash flow
The cash inflow during H1 2020 was £2.4 million. The profit for the period was £3.1 million but after adjusting this for non-cash items (in particular depreciation and amortisation £1.3 million, share-based payments £0.2 million, and the £0.4 million tax credits) the cash inflow from the income statement increased to £3.9 million. However inventories increased by £0.4 million, and liabilities and payables decreased by £1.4 million which includes the re-payment to Norgine of the €2.5 million milestone received in 2019 for the outcome of the AEGIS-H2H study, resulting in cash inflow from operating activities amounting to £2.0 million. The cash position at the end of June 2020 also benefited from a £0.4 million currency translation gain arising on cash balances denominated in US$.

Going concern
At the period end the Group held £6.5 million of cash.

The Directors have considered the funding requirements of the Group through the preparation of detailed cash flow forecasts for the period to December 2021. Under current business plans the current cash resources will extend to the first quarter of 2021. As a result, additional revenue generating transactions or additional finance would therefore be needed by the first quarter of 2021 to allow the business plans to continue. The Directors are considering further commercialisation opportunities for Feraccru®/Accrufer®, in the USA and also in other territories. These arrangements would be expected to include upfront payments which, if any one was achieved, would further extend the Group's cash runway. The Directors also believe that other forms of finance, such as debt finance or royalty finance underpinned by the existing European and Chinese out-licensing agreements, are likely to be available to the Group. However, there can be no guarantee that any of these opportunities will be successfully concluded. The Directors do not believe that the ongoing coronavirus pandemic will significantly impact

the revenues included in the cash flow forecasts, nor the ability to complete commercialisation transactions or to raise additional finance.

Based on the above factors the Directors believe that it remains appropriate to prepare the financial statements on a going concern basis. However the above factors give rise to a material uncertainty which may cast significant doubt on the Group's and the Company's ability to continue as a going concern and, therefore, to continue realising its assets and discharging its liabilities in the normal course of business. The financial statements do not include any adjustments that would result from the basis of preparation being inappropriate.

Financial outlook

The Group expects that Feraccru® sales in the UK and Germany will continue to grow during H2 2020 and 2021, and increased royalties will flow from that growth. However, launches in the other major European markets are not expected until late 2021 as pricing and reimbursement negotiations in those countries can take 12 to 18 months. Selling, general and administrative costs will continue at levels seen during 2019 and H1 2020 while R&D expenditure for the year will increase compared with H1 2020 as the paediatric study gets underway. Overall, the Group's cash runway extends into the first quarter of 2021 without including potential upfronts from any out-licensing agreements or other sources of financing as outlined above. In the event that any such agreements are concluded, the Group would expect them to include upfront receipts which would extend the cash runway.

Consolidated statement of profit and loss and other comprehensive income

for the six months ended 30 June 2020

	Note	**Six months ended 30 June 2020 (unaudited) £000**	Six months ended 30 June 2019 (unaudited – restated[1]) £000	Year ended 31 December 2019 (audited) £000
Revenue	4	**8,919**	430	719
Cost of sales		**(1,011)**	(311)	(485)
Gross profit		**7,908**	119	234
Operating costs – selling, general and administrative expenses	5	**(4,834)**	(3,575)	(6,773)
Operating profit/(loss) before research and development expenditure		**3,074**	(3,456)	(6,539)
Research and development expenditure		**(681)**	(1,273)	(2,496)
Operating profit/(loss)		**2,393**	(4,729)	(9,035)
Financial income		**358**	55	18
Financial expense		**(3)**	(8)	(49)
Profit/(loss) before tax		**2,748**	(4,682)	(9,066)
Taxation	6	**376**	500	266
Profit/(loss) for the period		**3,124**	(4,182)	(8,800)
Attributable to:				
Equity holders of the parent		**3,124**	(4,182)	(8,800)
Other comprehensive income				
Items that are or may be reclassified subsequently to profit or loss:				
Foreign currency translation differences – foreign operations		**(29)**	24	**33**
Total comprehensive income/(expenditure) for the period		**3,095**	(4,158)	(8,767)
Attributable to:				
Equity holders of the parent		**3,095**	(4,158)	(8,767)
Total comprehensive income/(expenditure) for the period		**3,095**	(4,158)	(8,767)
Earnings per share				
Basic and diluted profit/(loss) per share	7	**£0.03**	£(0.04)	£(0.08)

(1) see Note 11

Group balance sheet

at 30 June 2020

	Note	**30 June 2020 (unaudited) £000**	30 June 2019 (unaudited - restated[1]) £000	31 December 2019 (audited) £000
Non-current assets				
Intangible assets	8	**28,641**	30,709	**29,898**
Property, plant and equipment		**5**	108	**26**
		28,646	30,817	**29,924**
Current assets				
Inventories	9	**1,385**	453	948
Trade and other receivables		**543**	955	**356**
Current tax asset		**1,152**	2,000	950
Cash and cash equivalents		**6,515**	6,608	**4,141**
		9,595	10,016	**6,395**
Total assets		**38,241**	40,833	**36,319**
Current liabilities				
Trade and other payables		**(2,320)**	(4,057)	**(3,547)**
Lease liabilities		**-**	(102)	(607)
Other liabilities		**(454)**	(118)	**(20)**
		(2,774)	(4,277)	**(4,174)**
Total liabilities		**(2,774)**	(4,277)	**(4,174)**
Net assets		**35,467**	36,556	**32,145**
Equity				
Share capital	10	**1,758**	1,756	**1,758**
Share premium		**88,352**	88,352	**88,352**
Merger reserve		**28,358**	28,358	**28,358**
Currency translation reserve		**40**	60	**69**
Retained earnings		**(83,041)**	(81,970)	**(86,392)**
Total equity		**35,467**	36,556	**32,145**

(1) see Note 11

Group statement of changes in equity

for the six months ended 30 June 2020

	Share capital £000	Share premium £000	Merger reserve £000	Currency translation reserve £000	Retained earnings £000	Total £000
Balance at 1 January 2019 (audited)	1,746	88,338	28,358	36	(78,048)	40,430
Loss for the year	-	-	-	-	(8,800)	(8,800)
Other comprehensive income:						
Foreign currency translation differences	-	-	-	33	-	33
Total comprehensive expense for the year	-	-	-	33	(8,800)	(8,767)
Transactions with owners, recorded directly in equity						
Equity-settled share-based payment transactions	12	14	-	-	456	482
Balance at 31 December 2019 (audited)	1,758	88,352	28,358	69	(86,392)	**32,145**
Profit for the period	-	-	-	-	3,142	3,124
Other comprehensive income:						
Foreign currency translation differences	-	-	-	(29)	-	(29)
Total comprehensive expense for the period	-	-	-	(29)	3,124	3,095
Transactions with owners, recorded directly in equity						
Share options exercised	-	-	-	-	-	-
Equity-settled share-based payment transactions	-	-	-	-	227	227
Balance at 30 June 2020 (unaudited)	**1,758**	**88,352**	**28,358**	**40**	**(83,041)**	**35,467**

Group statement of cash flows

for the six months ended 30 June 2020

	Six months ended 30 June 2020 (unaudited) £000	Six months ended 30 June 2019 (unaudited - restated[1]) £000	Year ended 31 December 2019 (audited) £000
Cash flows from operating activities			
Profit/(loss) for the period	**3,124**	(4,182)	(8,800)
Adjustments for:			
Depreciation and amortisation	**1,281**	1,546	2,621
Equity-settled share-based payment expenses	**227**	260	1,456
Financial income	**(358)**	(55)	(18)
Financial expense	**3**	8	49
Unrealised foreign exchange losses	**(29)**	24	33
Income tax	**(376)**	(500)	(266)
	3,872	(2,899)	(5,925)
(Increase)/decrease in inventories	**(437)**	(344)	(839)
(Increase)/decrease in trade and other receivables	**(14)**	76	681
(Decrease)/increase in trade and other payables	**(1,227)**	1,509	999
(Decrease)/increase in other liabilities	**(153)**	(285)	(286)
Change in lease assets and liabilities	**-**	-	(2)
Income tax (paid)/received	**-**	-	1,306
Net cash flows from operating activities	**2,041**	(1,943)	(4,066)
Cash flows from investing activities			
Financial income	**358**	55	18
Acquisitions of intangible assets	**(2)**	(196)	(34)
Capitalised development expenditure	**-**	(1,007)	(1,350)
Net cash flows from investing activities	**356**	(1,148)	(1,366)
Cash flows from financing activities			
Financial expense	**(3)**	(6)	(49)
Finance leases – interest payment	**-**	(2)	(4)
Proceeds of share options exercise	**-**	24	26
Finance leases – capital payment	**(20)**	(93)	(176)
Net cash flows from financing activities	**(23)**	(77)	(203)
Net increase/(reduction) in cash	**2,374**	(3,168)	(5,635)
Cash and cash equivalents at beginning period	**4,141**	9,776	9,776
Cash and cash equivalents at period end	**6,515**	6,608	4,141

(1) see Note 11

Notes

for the six months ended 30 June 2020

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.

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 2019. 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 2019 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 15 September 2020.

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 2019, 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 the period end the Group held £6.5 million of cash.

The Directors have considered the funding requirements of the Group through the preparation of detailed cash flow forecasts for the period to December 2021. Under current business plans the current cash resources will extend to the first quarter of 2021. As a result, additional revenue generating transactions or additional finance would therefore be needed by the first quarter of 2021 to allow the business plans to continue. The Directors are considering further commercialisation opportunities for Feraccru®/Accrufer®, in the USA and also in other territories. These arrangements would be expected to include upfront payments which, if any one was achieved, would further extend the Group's cash runway. The Directors also believe that other forms of finance, such as debt finance or royalty finance underpinned by the existing European and Chinese out-licensing agreements, are likely to be available to the Group. However, there can be no guarantee that any of these opportunities will be successfully concluded. The Directors do not believe that the ongoing coronavirus pandemic will significantly impact the revenues included in the cash flow forecasts, nor the ability to complete commercialisation transactions or to raise additional finance.

Based on the above factors the Directors believe that it remains appropriate to prepare the financial statements on a going concern basis. However the above factors give rise to a material uncertainty which may cast significant doubt on the Group's and the Company's ability to continue as a going concern and, therefore, to continue realising

its assets and discharging its liabilities in the normal course of business. The financial statements 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 - £18.4 million
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 Feraccru® – £10.2 million
The valuation of intellectual property associated with 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:

- Feraccru® – development and commercialisation of the Group's lead Feraccru® product
- PT20 – development of the Group's secondary asset

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

	Six months ended 30 June 2020 (unaudited)				Year ended 31 December 2019 (audited)			
	Feraccru® £000	**PT20 £000**	**Central and unallocated £000**	**Total £000**	Feraccru® £000	PT20 £000	Central and unallocated £000	Total £000
Revenue	**8,919**	**-**	**-**	**8,919**	719	-	-	719
Operating profit/(loss)	**3,714**	**(40)**	**(1,281)**	**2,393**	(6,421)	(1,908)	(706)	**(9,035)**
Financial income				**358**				18
Financial expense				**(3)**				(49)
Tax				**376**				266
Profit/(Loss) for the period				**3,124**				**(8,800)**

The revenue analysis in the table below is based on the country of registration of the fee paying party. £8.7 million revenue (year ended 31 December 2019: £0.1 million) was derived from licence upfront and milestone payments from commercial partners. The remainder of revenue is derived from the sale of goods.

	Six months ended 30 June 2020 (unaudited) £000	Six months ended 30 June 2019 (unaudited - restated) £000	Year ended 31 December 2019 (audited) £000
UK	**23**	74	**141**
Europe	**204**	356	578
Rest of the World	**8,692**	-	-
	8,919	430	719

Segment assets and liabilities

Six months ended 30 June 2020 (unaudited)	**Feraccru® £000**	**PT20 £000**	**Central and unallocated £000**	**Total £000**
Segment assets	**17,468**	**18,605**	**2,168**	**38,241**
Segment liabilities	**(2,007)**	**(10)**	**(859)**	**(2,877)**
Total net assets	**15,461**	**18,594**	**1,309**	**35,364**
Depreciation, amortisation and impairment	**271**	**1,010**	**-**	**1,281**
Capitalised development costs	**-**	**-**	**-**	**-**

Year ended 31 December 2019 (audited)	Feraccru® £000	PT20 £000	Central and unallocated £000	Total £000
Segment assets	14,802	19,627	1,890	36,319
Segment liabilities	(3,215)	(14)	(945)	**(4,174)**
Total net assets	11,587	19,613	945	32,145
Depreciation, amortisation and impairment	595	2,026	-	2,621
Capital expenditure	-	34	-	34
Capitalised development costs	1,350	-	-	1,350

All material segmental non-current assets are located in the UK.

5. Operating costs – selling, general and administrative expenses

Operating costs are comprised of:

	Six months ended 30 June 2020 (unaudited) £000	Six months ended 30 June 2019 (unaudited) £000	Year ended 31 December 2019 (audited) £000
Selling costs	**137**	125	59
General and administrative expenses	**3,417**	1,904	4,093

Depreciation and amortisation	**1,281**	1,546	2,621
	4,834	3,575	6,773

6. Taxation

The Group's tax credit in the 6 months ended 30 June 2020 was £376,000 (H1 2019: £500,000), comprising anticipated R&D tax credits in respect of claims not yet submitted for the 2020 financial year and a reduction in the prior-year tax charge for Shield TX (Switzerland) AG.

7. Loss per share

The basic profit per share of £0.03 (H1 2019 (restated): loss per share £0.04) has been calculated by dividing the loss for the period by the weighted average number of shares of 177,088,657 in issue during the six months ended 30 June 2020 (six months ended 30 June 2019: 116,782,590).

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	**Patents and trademarks £000**	**Development costs £000**	**Phosphate Therapeutics licences £000**	**Total £000**
Cost				
Balance at 1 January 2019 (audited)	2,021	8,811	27,047	**37,879**
Additions – externally purchased	34	-	-	34
Additions – internally developed	-	1,350	-	1,350
Disposals	-	(218)	-	(218)
Balance at 31 December 2019 (audited)	2,055	9,943	27,047	**39,045**
Additions – externally purchased	-	2	-	2
Additions – internally developed	-	-	-	-
Disposals	-	-	-	-
Balance at 30 June 2020 (unaudited)	**2,055**	**9,945**	**27,047**	**39,047**
Accumulated amortisation				
Balance at 1 January 2019 (audited)	488	869	5,565	**6,922**
Charge for the period	86	331	2,026	2,443
Disposals		(218)	-	(218)
Balance at 31 December 2019 (audited)	574	982	7,591	9,147
Charge for the period	47	202	1,010	1,259
Disposals	-	-	-	-
Balance at 30 June 2020 (unaudited)	**621**	**1,184**	**8,601**	**10,406**
Net book values				
30 June 2020 (unaudited)	**1,434**	**8,761**	**18,446**	**28,641**
31 December 2019 (audited)	1,481	8,961	19,456	29,898

9. Inventories

Group	**Six months ended 30 June 2020 (unaudited) £000**	Six months ended 30 June 2019 (unaudited) £000	Year ended 31 December 2019 (audited) £000
Raw materials	**524**	96	562
Work in progress	**861**	357	366
Finished goods	**-**	-	20
	1,385	453	948

10. Share capital

	Six months ended 30 June 2020 Number 000	**Six months ended 30 June 2020 £000**	Year ended 31 December 2019 Number 000	Year ended 31 December 2019 £000
At beginning of period	**117,189**	**1,758**	116,426	1,746
Exercise of share options	**-**	**-**	763	12
At end of period	**117,189**	**1,758**	117,189	1,758

No share options were exercised during the 6 months ended 30 June 2020 (6 months ended 30 June 2019: 662,806).

11. Restatement of the six months to 30 June 2019

The financial statements for the six months to 30 June 2019 have been restated to reflect the impact of the requirement to repay Norgine the €2.5 million milestone payment originally received in April 2019 relating to the AEGIS-H2H clinical study. This milestone was subsequently found to be invalid and was excluded from the audited full year financial statements for 2019. The restatement has resulted in revenue and profits for the six months to 30 June 2019 decreasing by £2,185,000:

Summary of the prior year accounting impact:

Reduction in revenue and profit	£2,185,000
Increase in other creditors	(£2,185,000)