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

Half-year Report
Interim Report for the six months ended 30 June 2019

London, UK, 7 August 2019: Shield Therapeutics plc (LSE: STX), a commercial stage, pharmaceutical company with an initial focus on addressing iron deficiency, announces its unaudited interim results for the six months ended 30 June 2019.

Operational Highlights

- Norgine commenced promotion of Feraccru® in the UK and Germany with early signs of the positive impact of a larger commercial operation, and have started pricing and reimbursement activities in other European markets
- Positive results in AEGIS-H2H non-inferiority study, triggering €2.5 million development milestone from Norgine
- Positive results achieved in long-term follow-up of patients enrolled in AEGIS-CKD clinical study
- Feraccru® granted extension of approved indication in Switzerland to include treatment of all adults with iron deficiency

Financial Highlights

- Revenues of £2.6 million (H1 2018: £0.5 million)
- Loss for the period of £2.0 million (H1 2018: £8.0 million)
- Cash of £6.6 million (31 December 2018: £9.8 million)

Post-period Feraccru® Highlights

- FDA approves Accrufer® (as Feraccru® is to be marketed in the US) on 25 July 2019 with a broad label of treating iron deficiency in adults

Commenting on the interim results, Carl Sterritt, CEO of Shield Therapeutics plc, said: *"The Board and I are delighted with the progress the business has made through the first half of 2019. Feraccru® sales in Germany and the UK are beginning to increase significantly on the back of Norgine's enhanced promotional activities, and we have continued to deliver strong clinical data from the CKD and H2H studies. Since the period end, we have achieved the value-enhancing milestone of securing US FDA approval of Accrufer®, the fundamental step towards being able to exploit the world's largest prescription pharmaceuticals market. The Board and I have great confidence in the future of Shield and we look forward to updating the market on progress with ongoing discussions relating to both potential US and Chinese commercialisation partners."*

Analyst briefing

A briefing for analysts will take place at 9.30am on Wednesday 7 August 2019 at the Brand Exchange, 3 Birchin Lane, London, EC3V 9BW. A recording of this briefing will be made available on the Company's website https://www.shieldtherapeutics.com/

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About Shield Therapeutics plc
Shield is a de-risked, commercial stage, specialty pharmaceutical company delivering innovative pharmaceuticals to address patients' unmet medical needs. The Company's clear purpose is to help its patients become people again, by enabling them to enjoy the things that make the difference in their everyday lives. The Group has a marketed product, Feraccru®/Accrufer®, for the treatment of iron deficiency in adults which has exclusive IP rights until the mid-2030s. Feraccru®/Accrufer® is approved by the FDA, EMA and Swiss Medic for the treatment of iron deficiency in adults and is commercialised in the European Union by Norgine BV, with a US commercialisation partner currently being selected. For more information please visit www.shieldtherapeutics.com.

About Feraccru®/Accrufer®
Feraccru®/Accrufer® is a novel, stable, non-salt based oral treatment for adults with iron deficiency with or without anaemia that has been shown to be an efficacious and well-tolerated therapy in a range of controlled phase 3 trials. Following the recently announced positive results of the Phase IIIb AEGIS-H2H study in which Feraccru® demonstrated it was non-inferior to intravenously-administered Ferinject® at delivering improvements in haemoglobin levels without requiring hospital-based administration, Feraccru®/Accrufer® offers a compelling alternative to IV Iron for those patients that cannot tolerate salt-based oral iron therapies and wish to avoid the complexities of infusion-based therapies.

When salt-based oral iron therapies are ingested they can cause a range of mild-to-severe gastrointestinal tract (GI) adverse events, including nausea, bloating and constipation. These lead to poor tolerability, reduced patient compliance and ultimately treatment failure. Feraccru®/Accrufer® is not an iron salt; iron can be absorbed from the ferric maltol molecule and, as a result, it does not routinely cause the same treatment-limiting intolerance issues.

Prior to Feraccru®/Accrufer®, IV iron therapies were the only realistic alternative treatment option for patients intolerant of or unwilling to take salt-based oral iron therapies. However, use of such an invasive, costly, inconvenient and complex to administer treatment option, which is associated with potentially life-threatening and spontaneous hypersensitivity reactions, means there remains a clear unmet medical need for patients with iron deficiency to have access to an effective therapy like Feraccru®/Accrufer® that is well tolerated, convenient and does not require hospital-based administration.

About Iron Deficiency
The WHO state that iron deficiency is the most common and widespread nutritional disorder in the world. As well as affecting a large number of children and women in non-industrialized countries, it is the only nutrient deficiency which is also significantly prevalent in virtually all industrialised nations. There are no current global figures for iron deficiency, but using anaemia as an indirect indicator it can be estimated that most preschool children and pregnant women in non-industrialized countries, and at least 30-40% in industrialized countries, are iron deficient.

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 Feraccru®/Accrufer®. 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

European commercialisation progress

Norgine

Our key commercialisation partner in Europe is Norgine BV ('Norgine'). We chose them as our commercial partner for Feraccru® in Europe as we believed it would be a material product for them and, with such an attractive market available to it, Feraccru® would provide Norgine with an engine for growth over the coming years. The licence agreement was concluded in September 2018 and this was immediately followed by a necessary period of transfer to Norgine of knowledge, technical information and the Marketing Authorisation (MA), as well as a full suite of educational and marketing materials. During this period Norgine's own sales representatives were also trained on the product, resulting in commercial activities in Germany and England commencing in earnest in the first quarter of 2019.

In Europe products are often commercialised first in these two markets as companies are able to set the selling prices and Feraccru® has been able to achieve attractive pricing levels in both markets. In most other European markets, and in particular the large markets of France, Italy and Spain, as well as the remaining countries in the UK, it is necessary to submit pricing and reimbursement applications to the relevant authorities and for these to be agreed before the product receives reimbursement and therefore can be commercialised effectively. With the successful non-inferiority outcome of the AEGIS-H2H study comparing Feraccru® with Ferinject®, the market leading IV iron therapy, these pricing applications are now being prepared and filed as quickly as possible by Norgine using the AEGIS-H2H results to support the applications for reimbursement of Feraccru® as a treatment for iron deficiency ('ID'). These pricing and reimbursement processes do take time however, so we do not expect launches to occur in these markets before late 2020.

In both Germany and England, in order to establish the product before broadening promotion to other indications, the initial promotional focus by Norgine has been on iron deficiency anaemia (IDA) in Inflammatory Bowel Disease (IBD), targeting gastroenterology specialists working in hospitals and office clinics. Norgine has a significant number of sales representatives and key account managers promoting Feraccru® in Germany and England and these teams are supported by medical and reimbursement specialists. Progress to date has been encouraging with combined in-market pack sales in these two markets in the second quarter of 2019 already being almost 60% higher than in the last quarter of 2018.

As is usual with prescription pharmaceutical commercialisation in Europe, early growth in Germany has been stronger than that in England as Feraccru® benefits from nationwide reimbursement in Germany, whereas in England each of the nearly 200 Clinical Commissioning Groups (CCGs) has its own formulary, with each requiring new products to be reviewed before reimbursement is approved. This involves the submission of formulary applications for approval by each CCG, inevitably slowing down the initial uptake of a product across England. To date around one-quarter of the CCGs in England have approved reimbursement of Feraccru® for the treatment of IDA in IBD patients.

Making progress on (a) widening the indication for treatment and reimbursement to match the product's label of treatment of iron deficiency in adults and (b) increasing the number of CCGs that provide reimbursement are primary aims of Norgine's ongoing activities in England. Scotland, Wales and Northern Ireland have their own procedures and, with the AEGIS-H2H data to hand, Norgine is in the process of submitting applications for Feraccru® to be prescribed and reimbursed in all three regions.

Switzerland

In April 2019 the Swiss Agency for Therapeutic Products (Swissmedic) approved a major extension of the approved indication for Feraccru® to include treatment of all adults with ID with or without anaemia, effectively aligning the label with that in the European Union and expanding the commercial opportunity for Feraccru®. This extension triggered the payment to Shield of a one-off £0.1 million milestone from our Swiss commercialisation partner, Ewopharma AG (EWO). Taking advantage of the AEGIS-H2H study results, EWO are currently negotiating pricing and reimbursement with the Swiss authorities.

US approval

On 25 July 2019 we received notification from the FDA that they had completed their review of our New Drug Application (NDA) for Accrufer® (as Feraccru® is to be known in the US) in the United States and that Accrufer® is now approved for the treatment of iron deficiency in adults. We are delighted that the product has been approved and has been given the same broad label as in Europe. This is the outcome of many years of hard work in which we have delivered the pivotal clinical studies used in the NDA (in Inflammatory Bowel Disease and Chronic Kidney Disease (CKD)) and worked closely with the FDA to ensure that their requirements were met.

As with all new drugs approved in the US, under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), we are obliged to develop a suitable paediatric formulation and confirm the safety and efficacy of the drug in the paediatric population. The planned Phase III paediatric study addresses the efficacy and safety data required under PREA, and paediatric formulation development is already under way. In addition, we have agreed to perform a Phase I study to investigate any food effect associated with the absorption of the paediatric formulation. As an additional post-marketing requirement, we have committed to conducting an in vitro drug binding study to evaluate the potential for ferric maltol to bind commonly used concomitant oral medications.

With this broad label approval Accrufer® has taken a significant step towards exploiting the very large commercial opportunity in the USA, the world's largest and most attractively reimbursed pharmaceutical market. Research suggests that the prescription market for iron replacement therapy in the USA is worth over $1.0bn annually. There are between 8 million and 9 million patients in the USA who suffer from iron deficiency anaemia and management estimate potentially two to three times this number require treatment for iron deficiency. Accrufer®'s confirmed efficacy, together with its good tolerability and novel features, which include the body only absorbing as much iron from Accrufer® as it needs and not releasing highly reactive free iron into the gut (which is believed to be the primary cause of the well documented and treatment limiting spectrum of adverse events seen with existing oral therapies) means that the product could be the ideal choice for iron deficient patients who cannot tolerate the existing oral products. When combined with the non-inferiority results from the AEGIS-H2H study announced in March 2019, treatment with Accrufer® might remove the need for patients to progress to expensive intravenous therapy, leading to a change in the current paradigm for the treatment of iron deficiency, with or without anaemia, as Accrufer® offers a simple to administer, well tolerated and efficacious oral treatment alternative, without the need for hospital-based administration.

US partnering process

In the second quarter we started a process to identify a commercialisation partner for Accrufer® in the US market. Having appointed a sector-specific adviser to assist with the process, we started identifying and contacting a long list of potential partners who might be considered appropriate for the commercialisation of Accrufer® in the USA. This list is being reduced to a shorter list of companies whom we believe have the capabilities required to successfully commercialise Accrufer® in the USA and who have also high levels of interest in the Accrufer® opportunity. We are focused on completing this process prior to the end of 2019 if possible, although choosing the correct partner with attractive commercial terms is more important than meeting an arbitrary deadline.

China partnering process

We have also been running a partnering process for China for a number of months and have narrowed the potential partners to a shortlist. In China we expect that a further clinical study in Chinese patients will be required before Feraccru® can be approved and the intention is that a Chinese partner would both fund and run the required study. We remain optimistic that an out-licensing agreement may also be concluded before the end of 2019.

Product development - Feraccru®

In January 2019 we announced positive results for the long-term phase of the AEGIS-CKD study. For the patients initially treated for 16 weeks with Feraccru®, haemoglobin levels were maintained over the 36-week follow-up period and the treatment continued to be well tolerated. Those subjects who were initially treated for 16 weeks with placebo and who switched to Feraccru® for the follow-up period demonstrated a similar rise in haemoglobin over their first 16 weeks of Feraccru® treatment when compared to those initially treated with Feraccru®, and subsequently maintained the improvement over the follow-up period.

We were delighted in March 2019 that the AEGIS-H2H study results demonstrated that Feraccru® is non-inferior to Ferinject®, the leading intravenous (IV) iron therapy. This is a very significant outcome as it means that, in Feraccru®, there is now a highly credible oral alternative to IV iron.

We are continuing to plan for a Phase III paediatric study. We have designed the study protocol and selected a Clinical Research Organisation to conduct the study on our behalf. We are currently working on the development of a liquid formulation which should be more suitable for young children than capsules, the form in which the product is currently presented commercially. This formulation work is progressing well and we are aiming to be in a position to start the clinical study by early 2020. The study is likely to last two to three years and, if successful, children and young adults suffering from iron deficiency will be able to benefit from Feraccru® along with adults for whom it is currently approved.

Publications

We have also been active in the first six months of 2019 in publishing the results of clinical studies. In June 2019, a poster was presented at the British Society of Gastroenterology Annual Meeting summarising the results of a microbiome study conducted by scientists at the University of Liverpool. Their key conclusion was that Feraccru®, unlike ferrous sulphate, does not adversely affect the intestinal microbiome. Also in June 2019, a poster summarising the results of Shield's paediatric pharmacokinetics study, which was completed in 2018, was presented at the World Summit on Paediatrics. This study concluded that all three different doses of ferric maltol that were administered to patients enrolled in the study increased iron uptake and had a favourable tolerability profile. Finally, an abstract on the AEGIS-H2H study has been accepted for oral presentation and publication at the United European Gastroenterology Week in October 2019. Publication of these results is significant as it will allow Norgine to use the non-inferiority results in their promotional activities for the first time.

Product development – PT20 (phosphate binder)

Although we were not able to prioritise PT20 for development during 2018, we have now re-started this programme. We continue to believe that PT20 has the potential to be a significant 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 which could 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 are developing 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 have identified a shortlist of Contract Manufacturing Organisations who could carry out this development work for us, and manufacture for the Phase III study, and expect to make the appointment in due course. We anticipate that the formulation work should take around 15-18 months, meaning that the Phase III study could potentially start in 2021, subject to finance being available.

Intellectual Property (IP)

We continue to work on strengthening our intellectual property, including patents. During 2019, both the US and Japanese patent offices have allowed a "treatment use" patent protecting Feraccru® until January 2035. This application (entitled "Dosage regimen of ferric trimaltol") allowed claims relating to the administration of Feraccru® twice-daily on an empty stomach, where the percentage of ferric trimaltol is at least 60% of the combined weight of ferric trimaltol and excipients.

We also continue to defend our patents robustly. As previously reported Teva has raised objections with the European Patent Office (EPO) to the Group's patents (#2 668 175 and # 3 160 951) which cover "Process for preparing an iron hydroxypyrone" and "Crystalline forms of ferric maltol" respectively. On 14 March 2019 the Opposition Division of the European Patent Office (EPO) decided in favour of Shield in respect of the former patent. However, as anticipated, in June 2019 Shield received notice that Teva has filed a notice of appeal to the EPO's decision. Currently we do not know the basis for their appeal and no date has been set for the appeal hearing. The EPO has set a date of 23 June 2020 for the oral hearing in respect of patent # 3 160 951.

Outlook

Having secured FDA approval of Accrufer® and with Feraccru® sales in Germany and the UK beginning to increase significantly on the back of Norgine's enhanced promotional activities, the Board has great confidence in the future for Shield. We are optimistic that by the end of 2019 we may have completed out-licensing transactions in both the USA and China. We expect that both of these transactions will have upfront receipts associated with them, which would further strengthen our balance sheet and provide additional funding for the Group's activities including the continued development of PT20. The positive results of the AEGIS-H2H comparator study combined with the broad iron deficiency labels in the US and Europe mean that Feraccru®/Accrufer® is a highly competitive product in two very large markets, which should drive Shield's royalty and sales milestone income for many years.

Financial Review

Revenue
Revenue in the first six months of 2019 (H1 2019) was £2.6 million (H1 2018: £0.5 million). £2.2 million arose from the milestone payment received from Norgine on the successful outcome from the AEGIS-H2H clinical study and a further £0.1 million was received from Ewopharma AG (EWO) as a consequence of the broadening of the Feraccru® label in Switzerland. The remaining £0.3 million arose from royalties under the Norgine agreement. The revenue in H1 2018 is not readily comparable with H1 2019 as it mainly comprised sales made directly by Shield as the Norgine agreement was not signed until September 2018.

Cost of Sales
Cost of sales of £0.3 million (H1 2018: £0.1 million) is comprised primarily of the cost of finished goods supplied to Norgine, but it also includes the 5% royalty payable on Norgine's net sales to Vitra Limited, the original owner of the intellectual property underpinning Feraccru®.

Selling, general and administrative expenses
Selling, general and administrative expenses were £3.6 million in H1 2019, substantially below the £6.3 million in the equivalent period of 2018. The largest reduction was in selling costs, where the £2.6 million incurred in H1 2018 was reduced to £0.1 million in H1 2019 following the decision taken in February 2018 to adopt an out-licensing strategy for commercialisation rather than the self-commercialisation strategy employed until then. General and administrative expenses also reduced, from £2.3 million in H1 2018 to £1.9 million in H1 2019, as a consequence of the change in commercialisation strategy which led to a reduction of support and administration costs as well as selling costs. The remaining £1.5 million in H1 2019 (H1 2018: £1.4 million) was attributable to depreciation and amortisation, of which £1.4 million (H1 2018: £1.2 million) was amortisation of intangible assets with the balance in each year being depreciation, primarily on leasehold premises.

Research and development
Research and development costs charged to the income statement needs to be considered in aggregation with capitalised development costs. In H1 2019, £1.3 million (H1 2018: £2.1 million) development costs have been charged to the income statement and a further £1.2 million (H1 2018: £2.7 million) has been capitalised.

The £1.3 million charged in 2019 has been reduced by the write-back of £0.2 million into inventory of batches produced in prior periods for manufacturing validation purposes, the cost of which was written off at the time it was incurred as development expenditure. These batches are now available for commercial sale and will be charged to cost of sales as incurred. The underlying development expense of £1.5 million primarily comprised £0.7 million employee and contractor costs, £0.6 million in support of the US NDA process, with the balance spent on publication of clinical studies and preparation of the formulation required for the planned paediatric study.

The £1.2 million of capitalised development costs comprised £1.0 million (H1 2018 £2.6 million) in respect of the AEGIS-H2H study and £0.2 million (H1 2018: £0.1 million) for developing and improving our IP protection.

Tax
The tax credit of £0.5 million (H1 2018: £NIL) is an accrual for the expected R&D tax credit receivable for H1 2019. In the H1 2018 financial statements we took a more prudent approach and did not make any such provision for H1 2018, pending the actual cash receipt of the 2017 tax credit claim.

Balance sheet
Intangible assets at 30 June 2019 were £30.7 million (31 December 2018: £31.0 million). The components of this are £20.5 million (31 December 2018: £21.5 million) relating to the acquisition costs of PT20, the phosphate binder product in our development portfolio; £8.5 million (31 December 2018: £7.9 million) relating to capitalised Feraccru® development expenditure, in particular the AEGIS-H2H study and the Paediatric Pharmacokinetic study, and £1.7 million (31 December 2018: £1.5 million) expenditure on strengthening the Group's intellectual property. During H1 2019, amortisation of £1.5 million exceeded new expenditure being capitalised amounting to £1.2 million.

Property, plant and equipment has been restated under IFRS 16 (Leases) as this has impacted the accounting treatment of our leasehold premises (See Note 2). As a consequence, at 30 June 2019 the balance was £0.1 million (31 December 2018: £0.2 million, restated).

Inventory at 30 June 2019 amounted to £0.5 million (31 December 2018: £0.1 million). The increase is due partly to the £0.2 million write-back of inventory production costs which had previously been expensed as the relevant inventory production was part of the validation process of the manufacturing process and therefore treated as development costs in prior periods.

The current tax asset of £2.0 million (31 December 2018: £1.5 million) represents £1.5 million R&D Tax Credit expected to be received in respect of 2018 and £0.5 million receivable for H1 2019.

Cash at 30 June 2019 was £6.6 million (31 December 2018: £9.8 million).

Lease liabilities of £0.1 million at 30 June 2019 (31 December 2018: £0.1 million) have arisen as a result of the IFRS 16 restatement referred to under Property, Plant and Equipment above.

Cash flow

The cash outflow during H1 2019 was £3.2 million. The loss for the period was £2.0 million but after adjusting this for non-cash items (depreciation and amortisation £1.5 million, share-based payments £0.3 million, and the accrual for the R&D tax credit £0.5 million), the cash outflow from the income statement was reduced to £0.7 million. However the movements in working capital, in particular the increase in inventories (£0.4 million) and decrease in liabilities and payables (£1.0 million), increased the cash outflow from operating activities to £1.9 million. In addition, the £1.2 million expenditure on capitalised development costs and IP improvements and the £0.1 million capital payments on finance leases increased the overall cash outflow to £3.2 million.

Going concern

At the period end the Group held £6.6 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 2020. Under current business plans the current cash resources will extend to the third quarter of 2020. Based on this, additional funding is expected to be required by the third quarter of 2020 in order to support the Group's going concern status. In the light of the FDA's approval of Accrufer® for commercialisation in the US the Directors are confident that a partnership out-licence transaction which would include an up-front receipt can be completed by the end of 2019 . They are also confident that an out-licence transaction for China can be achieved in a similar timescale. These arrangements would further extend the Group's cash runway (being the period for which the Group's cash resources are expected to last). The Directors also believe that other forms of finance, such as royalty finance underpinned by the existing European out-licensing agreement with Norgine, are likely to be available to the Group. However, there can be no guarantee that any of these opportunities will be successfully concluded.

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

Financial outlook

The Group expects that Feraccru® sales in the UK and Germany will continue to grow during the second six months of 2019, and increased royalties will flow from that growth. However launches in the other major European markets will not happen in 2019 as Norgine will need to negotiate pricing and reimbursement in those countries. Selling, General and Administrative costs in H2 2019 will continue at levels seen during H1 2019 while total R&D expenditure (i.e. both the amount charged to the statement of profit and loss and any amounts capitalised) for the year will be broadly in line with the amount charged to the statement of profit and loss in 2018 not including the amount capitalised. Overall, the Group's cash runway extends into the third quarter of 2020 without including potential upfronts from further out-licensing agreements. In the event that out-licensing transactions are

concluded in either the USA or China, the Group would expect those agreements to include substantial upfront receipts which would extend the cash runway significantly.

Consolidated statement of profit and loss and other comprehensive income

for the six months ended 30 June 2019

	Note	**Six months ended 30 June 2019 (unaudited) £000**	Six months ended 30 June 2018 (unaudited - restated) £000	Year ended 31 December 2018 (audited - restated) £000
Revenue	4	**2,615**	495	11,881
Cost of sales		**(311)**	(131)	(311)
Gross profit		**2,304**	364	11,570
Operating costs – selling, general and administrative expenses	5	**(3,575)**	(6,295)	(12,429)
Operating loss before research and development expenditure		**(1,271)**	(5,931)	(859)
Research and development expenditure		**(1,273)**	(2,146)	(4,300)
Operating loss		**(2,544)**	(8,077)	(5,159)
Financial income		**55**	58	50
Financial expense		**(8)**	(17)	(42)
Loss before tax		**(2,497)**	(8,036)	(5,151)
Taxation	6	**500**	(8)	3,359
Loss for the period		**(1,997)**	(8,044)	(1,792)
Attributable to:				
Equity holders of the parent		**(1,997)**	(8,044)	(1,792)
Other comprehensive income				
Items that are or may be reclassified subsequently to profit or loss:				
Foreign currency translation differences – foreign operations		**24**	1	4
Total comprehensive expenditure for the period		**(1,973)**	(8,043)	(1,788)
Attributable to:				
Equity holders of the parent		**(1,973)**	(8,043)	(1,788)
Total comprehensive expenditure for the period		**(1,973)**	(8,043)	(1,788)
Earnings per share				
Basic and diluted loss per share	7	**£(0.02)**	£(0.07)	£(0.02)

Group balance sheet

at 30 June 2019

	Note	**30 June 2019 (unaudited) £000**	30 June 2018 (unaudited - restated) £000	31 December 2018 (audited – restated) £000
Non-current assets				
Intangible assets	8	**30,709**	31,511	30,957
Property, plant and equipment		**108**	148	155
		30,817	31,659	31,112
Current assets				
Inventories		**453**	151	109
Trade and other receivables		**955**	1,256	1,031
Current tax asset		**2,000**	-	1,500
Cash and cash equivalents		**6,608**	3,508	9,776
		10,016	4,915	12,416
Total assets		**40,833**	36,574	43,528
Current liabilities				
Trade and other payables		**(1,872)**	(2,720)	(2,548)
Lease liabilities		**(102)**	(138)	(147)
Other liabilities		**(118)**	(194)	(403)
		(2,092)	(3,052)	(3,098)
Total liabilities		**(2,092)**	(3,052)	(3,098)
Net assets		**38,741**	33,522	40,430
Equity				
Share capital	9	**1,756**	1,746	1,746
Share premium		**88,352**	88,338	88,338
Merger reserve		**28,358**	28,358	28,358
Currency translation reserve		**60**	33	36
Retained earnings		**(79,785)**	(84,953)	(78,048)
Total equity		**38,741**	33,522	40,430

Group statement of changes in equity

for the six months ended 30 June 2019

	Share capital £000	Share premium £000	Merger reserve £000	Currency translation reserve £000	Retained earnings £000	Total £000
Balance at 1 January 2018 (audited – as previously stated)	1,746	88,338	28,358	32	(77,267)	41,207
Prior period adjustment – adoption of IFRS 16 Leases	-	-	-	-	(2)	(2)
Balance at 1 January 2018 (audited - as restated)	1,746	88,338	28,358	32	(77,269)	41,205
Loss for the year (as restated)	-	-	-	-	(1,792)	(1,792)
Other comprehensive income:						
Foreign currency translation differences	-	-	-	4	-	4
Total comprehensive expense for the year	-	-	-	4	(1,792)	(1,788)
Transactions with owners, recorded directly in equity						
Equity-settled share-based payment transactions	-	-	-	-	1,013	1,013
Balance at 31 December 2018 (audited – as restated)	1,746	88,338	28,358	36	(78,048)	40,430
Loss for the period	-	-	-	-	(1,997)	(1,997)
Other comprehensive income:						
Foreign currency translation differences	-	-	-	24	-	24
Total comprehensive expense for the period	-	-	-	24	(1,997)	(1,973)
Transactions with owners, recorded directly in equity						
Share options exercised	10	14	-	-	-	24
Equity-settled share-based payment transactions	-	-	-	-	260	260
Balance at 30 June 2019 (unaudited)	**1,756**	**88,352**	**28,358**	**60**	**(79,785)**	**38,741**

Group statement of cash flows

for the six months ended 30 June 2019

	Six months ended 30 June 2019 (unaudited) £000	Six months ended 30 June 2018 (unaudited - restated) £000	Year ended 31 December 2018 (audited - restated) £000
Cash flows from operating activities			
Loss for the period	**(1,997)**	(8,044)	(1,792)
Adjustments for:			
Depreciation and amortisation	**1,546**	1,380	2,690
Equity-settled share-based payment expenses	**260**	421	1,013
Financial income	**(55)**	(4)	(50)
Financial expense	**8**	17	42
Unrealised foreign exchange losses	**24**	1	4
Income tax	**(500)**	8	(3,359)
	(714)	(6,221)	(1,452)
(Increase)/decrease in inventories	**(344)**	(26)	16
Decrease in trade and other receivables	**76**	320	541
Decrease in trade and other payables	**(676)**	(786)	(953)
(Decrease)/increase in other liabilities	**(285)**	(130)	141
Change in lease assets and liabilities	**-**	(1)	(2)
Financial income	**55**	4	50
Financial expense	**(6)**	(12)	(35)
Finance leases – interest payment	**(2)**	(5)	(7)
Income tax (paid)/received	**-**	(8)	1,859
Net cash flows from operating activities	**(1,896)**	(6,865)	158
Cash flows from investing activities			
Acquisitions of intangible assets	**(196)**	(118)	(346)
Capitalised development expenditure	**(1,007)**	(2,589)	(2,999)
Net cash flows from investing activities	**(1,203)**	(2,707)	(3,345)
Cash flows from financing activities			
Proceeds of share options exercise	**24**	-	-
Finance leases – capital payment	**(93)**	(219)	(336)
Net cash flows from financing activities	**(69)**	(219)	(336)
Net reduction in cash	**(3,168)**	(9,791)	(3,523)
Cash and cash equivalents at beginning period	**9,776**	13,299	13,299
Cash and cash equivalents at period end	**6,608**	3,508	9,776

Notes

for the six months ended 30 June 2019

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 2018. 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 2018 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 August 2019.

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 2018, as described in those annual financial statements, except as explained in Accounting Developments below.

Accounting developments – IFRS 16 Leases

The Group has applied IFRS 16 with a date of initial application of 1 January 2019. As a result, the Group has changed its accounting policy for lease contracts as detailed below.

As a lessee, the Group previously classified leases as operating or finance leases based on its assessment of whether the lease transferred significantly all of the risks and rewards incidental to ownership of the underlying asset to the Group. Under IFRS 16, the Group recognises right of use assets and lease liabilities for most leases, i.e. these leases are on-balance sheet. The Group decided to apply the recognition exemptions to short-term leases of IT equipment. For leases of other assets, which were classified as operating under IAS 17, the Group recognised right of use assets and lease liabilities. The Group has applied IFRS 16 using the retrospective approach. The weighted average incremental borrowing rate applied to the lease liabilities at 1 January 2019 was 2.25%.

The following tables summarise the impact of adopting IFRS 16 on the Group's financial information. Comparative information for the year ended 31 December 2018 is audited, with the exception of restated balances.

Group balance sheet – at 30 June 2018	As previously reported £000	Adjustments £000	As restated £000
Property, plant and equipment	10	138	148
Lease liabilities	-	(138)	(138)
Net assets	33,522	-	33,522

Group balance sheet – at 31 December 2018

	As previously reported £000	Adjustments £000	As restated £000
Property, plant and equipment	8	147	155
Lease liabilities	-	(147)	(147)
Net assets	40,430	-	40,430

Consolidated statement of profit and loss and other comprehensive income – for the six months ended 30 June 2018	As previously reported £000	Adjustments £000	As restated £000
Operating costs – selling general and administrative expenses	(6,301)	6	(6,295)
Financial expense	(12)	(5)	(17)
Loss for the period	(8,045)	1	(8,044)

Consolidated statement of profit and loss and other comprehensive income – for the year ended 31 December 2018	As previously reported £000	Adjustments £000	As restated £000
Operating costs – selling general and administrative expenses	(12,438)	9	(12,429)
Financial expense	(35)	(7)	(42)
Loss for the year	(1,794)	2	(1,792)

Group statement of cash flows – for the six months ended 30 June 2018	As previously reported £000	Adjustments £000	As restated £000
Loss for the period	(8,045)	1	(8,044)
Depreciation and amortisation	1,161	219	1,380
Financial expense	12	5	17
Change in lease assets and liabilities	-	(1)	(1)
Finance leases – interest payment	-	(5)	(5)
Finance leases – capital payment	-	(219)	(219)
Net reduction in cash	(9,791)	-	(9,791)

Group statement of cash flows – for the year ended 31 December 2018	As previously reported £000	Adjustments £000	As restated £000
Loss for the period	(1,794)	2	(1,792)
Depreciation and amortisation	2,354	336	2,690
Financial expense	35	7	42
Change in lease assets and liabilities	-	(2)	(2)
Finance leases – interest payment	-	(7)	(7)
Finance leases – capital payment	-	(336)	(336)
Net reduction in cash	(3,523)	-	(3,523)

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 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 judgments and estimates which may lead to material adjustment in the next accounting period are:

Going concern

At the period end the Group held £6.6 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 2020. Under current business plans the current cash resources will extend to the third quarter of 2020. Based on this, additional funding is expected to be required by the third quarter of 2020 in order to support the Group's going concern status. In the light of the FDA's approval of Accrufer® for commercialisation in the US the Directors are confident that a partnership out-licence transaction which would include an up-front receipt can be completed by the end of 2019 . They are also confident that an out-licence transaction for China can be achieved in a similar timescale. These arrangements would further extend the Group's cash runway (being the period for which the Group's cash resources are expected to last). The Directors also believe that other forms of finance, such as royalty finance underpinned by the

existing European out-licensing agreement with Norgine, are likely to be available to the Group. However, there can be no guarantee that any of these opportunities will be successfully concluded.

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

Valuation of intellectual property acquired with Phosphate Therapeutics Limited - £20.5 million
The valuation of intellectual property acquired with Phosphate Therapeutics Limited in 2016 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 value in use for the asset. The realisation of its value is ultimately dependent on regulatory approval and successful commercialisation of the asset. 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.

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

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. An agreement was reached during the prior year with a strategic commercial partner for the asset in Europe. An upfront payment of £11.0 million was received as part of the agreement and a further milestone payment of £2.2 million in 2019, with the potential for significant additional milestone payments and royalties to follow. In the event that commercial returns are lower than current expectations or partner or alternative funding is not available 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 supply 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.

	Six months ended 30 June 2019 (unaudited)				Year ended 31 December 2018 (audited - restated)			
	Feraccru® £000	**PT20 £000**	**Central and unallocated £000**	**Total £000**	Feraccru® £000	PT20 £000	Central and unallocated £000	Total £000
Revenue	**2,615**	**-**	**-**	**2,615**	11,881	-	-	11,881
Operating loss	**(791)**	**(1,027)**	**(726)**	**(2,544)**	2,009	(1,904)	(5,264)	(5,159)
Financial income				**50**				50
Financial expense				**(3)**				(42)
Tax				**500**				3,359
Loss for the period				**(1,997)**				(1,792)

The revenue analysis in the table below is based on the country of registration of the fee paying party. £Nil of revenue (year ended 31 December 2018: £11.1 million) was derived from milestone payments from commercial partners. The remainder of revenue is derived from the sale of goods.

	Six months ended 30 June 2019 (unaudited) £000	Six months ended 30 June 2018 (unaudited) £000	Year ended 31 December 2018 (audited) £000
UK	**-**	107	171
Europe	**2,615**	388	11,710
	2,615	495	11,881

Segment assets and liabilities

Six months ended 30 June 2019 (unaudited)	Feraccru® £000	PT20 £000	Central and unallocated £000	Total £000
Segment assets	**15,631**	**20,627**	**4,575**	**40,833**
Segment liabilities	**(1,435)**	**(22)**	**(635)**	**(2,092)**
Total net assets	**14,196**	**20,605**	**3,940**	**38,741**
Depreciation, amortisation and impairment	**505**	**1,041**	**-**	**1,546**
Capitalised development costs	**1,007**	**-**	**-**	**1,007**

Year ended 31 December 2018 (audited - restated)	Feraccru® £000	PT20 £000	Central and unallocated £000	Total £000
Segment assets	12,643	21,627	9,258	43,528
Segment liabilities	(2,068)	(57)	(973)	(3,098)
Total net assets	10,575	21,570	8,285	40,430
Depreciation, amortisation and impairment	435	1,919	336	2,690
Capitalised development costs	2,999	-	-	2,999

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 2019 (unaudited) £000	Six months ended 30 June 2018 (unaudited - restated) £000	Year ended 31 December 2018 (audited - restated) £000
Selling costs	**125**	2,575	3,495
General and administrative expenses	**1,904**	2,340	6,244
Depreciation and amortisation	**1,546**	1,380	2,690
	3,575	6,295	12,429

6. Taxation

The Group's tax credit in the 6 months ended 30 June 2019 was £0.5 million (year ended 31 December 2018: £3.4 million). The current period tax credit relates to anticipated R&D tax credits in respect of claims not yet submitted for the 2019 financial year.

7. Loss per share

The basic loss per share of £0.02 (H1 2018: £0.07) has been calculated by dividing the loss for the period by the weighted average number of shares of 116,782,590 in issue during the six months ended 30 June 2019 (six months ended 30 June 2018: 116,425,851).

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 2018 (audited)	1,675	5,812	27,047	34,534
Additions – externally purchased	346	-	-	346
Additions – internally developed	-	2,999	-	2,999
Balance at 31 December 2018 (audited)	2,021	8,811	27,047	37,879
Additions – externally purchased	196	-	-	196
Additions – internally developed	-	1,007	-	1,007
Disposals	-	(218)	-	(218)
Balance at 30 June 2019 (unaudited)	**2,217**	**9,600**	**27,047**	**38,864**
Accumulated amortisation				
Balance at 1 January 2018 (audited)	417	442	3,714	4,573
Charge for the period	71	427	1,851	2,349
Balance at 31 December 2018 (audited)	488	869	5,565	6,922
Charge for the period	46	401	1,004	1,451
Disposals	-	(218)	-	(218)
Balance at 30 June 2019 (unaudited)	**534**	**1,052**	**6,569**	**8,155**
Net book values				
30 June 2019 (unaudited)	**1,683**	**8,548**	**20,478**	**30,709**
31 December 2018 (audited)	1,533	7,942	21,482	30,957

9. Share capital

	Six months ended 30 June 2019 Number 000	Six months ended 30 June 2019 £000	Year ended 31 December 2018 Number 000	Year ended 31 December 2018 £000
At beginning of period	**116,426**	**1,746**	116,426	1,746
Exercise of share options	**663**	**10**	-	-
At end of period	**117,089**	**1,756**	116,426	1,746

662,806 of share options were exercised during the 6 months ended 30 June 2019 (6 months ended 30 June 2018: Nil).