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

Preliminary Results for the Year Ended 31 December 2019

London, UK, 21 May 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 preliminary Group results for the year ended 31 December 2019.

Operational highlights

- FDA approved Accrufer® with a broad label for treating iron deficiency in adults
- Positive long term data from AEGIS-H2H (head-to-head) clinical study comparing Feraccru®/Accrufer® to IV iron although the study did not meet its primary end point at 12 weeks
- The H2H study demonstrated that Feraccru®/Accrufer® offers a simple, well tolerated and efficacious oral treatment alternative to IV iron therapy, without the need for hospital-based administration
- Long term phase of AEGIS-CKD study shows haemoglobin levels increased and maintained across 52 weeks of Feraccru® therapy in patients with chronic iron deficiency anaemia (IDA)
- Swissmedic approved Feraccru® to treat iron deficiency with or without anaemia in adults

Financial highlights

- Revenues of £0.7 million (2018: £11.9 million)
- Loss for the year of £8.8 million (2018: £1.8 million)
- Net cash of £4.1 million (2018: £9.8 million)

Post-period highlights

- Exclusive licence agreement with Beijing Aosaikang Pharmaceutical Co. Ltd ("ASK Pharm") for the development and commercialisation of Feraccru®/Accrufer® in China
- Deal highlights:
    - US$11.4 million upfront licence payment to Shield
    - Up to US$51.4 million in development and sales milestones
    - Ongoing tiered double-digit royalties on net sales payable to Shield
    - ASK Pharm to be responsible for, and cover costs of, all development and regulatory activity
- Agreed to repay €2.5 million milestone to Norgine, originally received in respect of AEGIS-H2H clinical study in the first half of 2019

Commenting on the preliminary results, Tim Watts, CEO of Shield Therapeutics plc, said: *"I am honoured to have been appointed as CEO at this important time for Shield. 2019 was a very successful year for Shield with the approval of Accrufer® by the FDA for marketing in the USA and the positive long-term results from the AEGIS-H2H clinical study, and the conclusion in January 2020 of the licence agreement with ASK Pharm in China. Our top priority is now to conclude a partnering agreement in the USA during 2020."*

For further information please contact:

Shield Therapeutics plc www.shieldtherapeutics.com
Tim Watts, Chief Executive Officer +44 (0)20 7186 8500

Nominated Adviser and Joint Broker
Peel Hunt LLP
James Steel/Dr Christopher Golden +44 (0)20 7418 8900

Joint Broker

finnCap Ltd +44 (0)20 7220 0500
Geoff Nash/Matt Radley/Alice Lane

Financial PR & IR Advisor
Walbrook PR +44 (0)20 7933 8780 or shield@walbrookpr.com
Paul McManus/Lianne Cawthorne +44 (0)7980 541 893 / +44 (0)7584 391 303

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 develop products that help patients become people again, enabling them to enjoy the things that make a difference in their everyday lives. The Group's lead product, Feraccru®/ Accrufer® has exclusive IP rights until the mid-2030s and is approved for the treatment of iron deficiency with or without anaemia in adults in the European Union, the United States and Switzerland. In Europe it is marketed as Feraccru® with commercialisation led by Norgine BV and in the USA the product will be marketed as Accrufer® with Shield currently in the process of selecting a commercialisation partner. 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

About Feraccru®/Accrufer®
Feraccru®/Accrufer® is a novel, stable, non-salt based oral therapy 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, including positive results from the Phase IIIb AEGIS-H2H study in which Feraccru®/Accrufer® demonstrated it was non-inferior in delivering improvements in haemoglobin levels compared to intravenously-administered (IV) Ferinject®/Injectafer® (ferric carboxymaltose). Feraccru®/Accrufer® therefore offers a compelling alternative to IV iron for those patients unable to tolerate salt-based oral iron therapies and wish to avoid the complexities of infusion-based iron 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 through the release and subsequent reactivity of free iron in the GI tract, leading to poor tolerability, reduced patient compliance and ultimately treatment failure. Feraccru®/Accrufer® is not an iron salt and, as a result, it does not routinely cause the same treatment-limiting intolerance issues of salt-based iron therapies, whilst the iron from the ferric maltol molecule can be readily absorbed.

Prior to Feraccru®/Accrufer®, IV iron therapies were the only realistic alternative treatment option for iron deficient patients with or without anaemia intolerant of or unwilling to be treated 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 these patients to have access to an effective therapy that is well tolerated, convenient and does not require hospital-based administration. Feraccru®/Accrufer® meets those requirements.

About Iron Deficiency
The WHO states that iron deficiency is the most common and widespread nutritional disorder in the world. As well as affecting a large number of women and children 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-industrialised countries, together with 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.

Chairman's statement

I am delighted to report in my second statement as Chairman that 2019 has been a successful year for Shield Therapeutics during which we have started to repay the faith investors have shown in the Group and its lead product.

2018 was a challenging year but, by the end of that year, the Group was poised for success. Feraccru had been out-licensed in September 2018 to Norgine for commercialisation in Europe and the £11 million upfront license payment received from that deal gave the Group the cash runway needed for the next phase of the business development. Also by the end of 2018, the FDA had accepted the filing of Feraccru®/Accrufer® for marketing approval in the United States.

The most significant achievement in 2019 was the approval of Accrufer® in July by the USA's FDA. The marketing approval in the USA is for the broad label for the treatment of iron deficiency in adults, the same as in Europe, and this opens up the potential for Accrufer® to access a substantial patient population in the world's most valuable pharmaceutical market. We also received the results of the AEGIS-H2H (head-to-head) clinical study in which we compared Feraccru®/Accrufer® with the leading IV iron therapy. Although the study did not, as originally thought, statistically demonstrate non-inferiority at twelve weeks and, as a result we have agreed to repay the €2.5 million milestone received from Norgine, it did generate substantial data that should be very helpful in support of pricing and reimbursement initiatives.

I explained in my statement in the 2018 Annual Report how the Group's commercialisation strategy had been changed to focus on out-licensing the product. This was first demonstrated by the Norgine license announced in 2018. During 2019 the Group has continued to follow that strategy and we were delighted to announce in early January 2020 that we have out-licensed Feraccru® in China to Beijing Aosaikang Pharmaceutical Co. Ltd ("ASK Pharm"). ASK Pharm has an excellent track record of product development and commercialisation in China and they will be an ideal partner to secure the marketing approval of Feraccru® in China and then to exploit it. Having secured the approval of Accrufer® in the USA, the Company is in the process of identifying a suitable licence partner capable of optimising the commercial prospects for the product in that market.

Commercialisation in Europe is still in its early stages as, in the major European markets, the product is still only marketed in Germany and England with pricing and reimbursement applications currently being prepared for France, Italy and Spain, and the other countries in the UK. However, Norgine's sales progress in these two markets is good with 2019 sales volumes almost 70% greater than those in 2018.

The achievements over the last eighteen months have been a vindication of the Group's strategy. The identification of Feraccru®'s potential over ten years' ago, followed by the clinical study programme in challenging patient populations in inflammatory bowel disease, chronic kidney disease and the head-to-head study have resulted in an effective product with a good side-effect profile for use in a broad range of patients, which is now approved in Europe, where it is already marketed, the USA and with excellent prospects of approval in China and elsewhere.

Based on current cash flow forecasts, the Board believes the cash runway extends into the first quarter of 2021 and there is therefore a material uncertainty which may cast significant doubt on the Group's ability to continue as a going concern. However we are confident that further financing will be secured, either from future out-licensing opportunities in the US and elsewhere or from other forms of finance such as royalty financing.

None of this can happen without the commitment and expertise of the Group's employees. As I write this, the world is struggling with the coronavirus emergency. Although Shield has not been affected as badly as many businesses, the lockdown in the UK has inevitably made life more difficult for our employees and I thank them sincerely for their willing perseverance and continuing contribution to the Group's activities and objectives.

In April 2020 Carl Sterritt announced his decision to resign as Chief Executive Officer. I would like to reiterate my thanks to Mr Sterritt for the substantial contributions that he made to Shield since he founded the Company and I

wish him and his family all the best for the future. I am very pleased that Tim Watts, formerly Chief Financial Officer, has been appointed as the new CEO and I wish him every success in the role.

Finally, I have notified the Board that I will be standing down from the Board and not seeking re-election as a Director at the 2020 Annual General Meeting. I am proud to have been able to work with the Company over the last four years during a time when it has been transformed from a development company into a full commercial company with Feraccru®/Accrufer® approved in both Europe and the United States. I wish the Company every success in the future.

James Karis, Non-Executive Chairman

Chief Executive Officer's statement and financial review

This is my first statement as Shield's CEO and I am pleased to report that 2019 was a very successful year for the Group and its potential has begun to be realised. The most significant event during the year was the approval of Accrufer® by the US FDA for marketing in the USA but we also received positive long term results from the head-to-head clinical study which compared Feraccru®/Accrufer® with the leading intravenous (IV) iron therapy.

By the end of 2018 we had laid the foundations for success in 2019. In Europe, the European Medicines Agency had expanded the label for Feraccru® to encompass the treatment of iron deficiency in adults, with or without anaemia, and we subsequently out-licensed Feraccru® to Norgine for commercialisation in Europe, Australia and New Zealand. In the USA, towards the end of the year the FDA had accepted our filing of the US New Drug Application (NDA) for the marketing approval of Accrufer® (the brand name in the USA).

Regulatory and clinical studies

In the first half of 2019 much of our efforts were targeted at supporting the NDA process and responding as necessary to questions arising from the FDA. We were delighted in July 2019 when we received confirmation from the FDA that it had approved Accrufer® with the same broad label as in Europe, namely the treatment of iron deficiency in adults. With the approval of this broad label Accrufer® has taken a big step towards exploiting the very large commercial opportunity in the USA, the world's largest and most attractively reimbursed pharmaceutical market. Market research suggests that the prescription market for iron replacement therapy in the USA is worth over $1.0bn annually. There are between 9 million and 10 million patients in the USA who suffer from iron deficiency anaemia and we estimate that potentially two to three times this number require treatment for iron deficiency.

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). EWO are currently negotiating pricing and reimbursement with the Swiss authorities.

During 2019 the results of the AEGIS-H2H clinical study became available although the Group announced in March 2020 that it had initiated a review of the analysis of the data which is currently ongoing. This study compared Feraccru® to Ferinject®, the market-leading intravenously-delivered iron replacement therapy. The AEGIS-H2H study was a multi-national Phase IIIb randomised, active-controlled trial in inflammatory bowel disease (IBD) patients with iron deficiency anaemia (IDA) and whose haemoglobin (Hb) measurements were as low as 8.0g/dL. The objective of the study was to assess whether the effect of Feraccru® on Hb response (defined by the protocol as normalisation of Hb or a >2g/dL rise in Hb from baseline) was comparable to the effect seen with IV treatment at 12 weeks. This was followed by a 40-week extension phase, during which eligible subjects continued treatment with Feraccru® or received IV therapy in line with clinical need. The key findings of the study were:

- The study did not meet its overall primary end point of non-inferiority at twelve weeks because this was clearly not achieved in the "intention to treat" (ITT) population, although there was a high response rate;
- IDA re-occurred at least once in approximately 39% (49) of the subjects in the IV arm of the study following the initial treatment with IV therapy, requiring a total of 69 additional IV iron infusions to be administered; and
- Feraccru®/Accrufer® was effective and generally well tolerated over 52 weeks of treatment with a side effect profile consistent to that seen in previous placebo-controlled studies.

The positive long term data provides further evidence to support results of earlier clinical studies that Feraccru® is effective and well tolerated over 52 weeks, even in patients who have been unable to tolerate oral iron salts previously. It also shows that Feraccru® is a real oral alternative to IV iron for patients with IDA and it can prevent the need for repeated IV infusions. The outcome of this study is therefore very helpful for health economics evaluations and will also be beneficial in pricing and reimbursement negotiations in countries around the world as

it will help to justify attractive pricing. The results of the ongoing review of the data analysis will be announced when completed.

Early in 2019 we announced positive results from the from the open-label extension phase of the AEGIS-CKD (chronic kidney disease) clinical study of Feraccru®. The AEGIS-CKD study was a pivotal phase III randomized, placebo-controlled, double-blind trial in CKD patients with IDA, which demonstrated superiority of Feraccru® when the change in haemoglobin (Hb) from baseline after 16 weeks of treatment with oral Feraccru® (30mg twice daily) was compared to placebo. This was followed by a 36-week open-label extension phase during which all subjects were treated with Feraccru®. For those patients initially treated with Feraccru®, Hb levels were maintained over this 36-week follow-up period and the treatment continued to be well tolerated. In addition, subjects who switched to Feraccru® for the open-label phase showed a similar mean rise in Hb over their first 16 weeks of Feraccru® treatment when compared to those initially treated with Feraccru® (0.79g/dl v 0.57g/dl). These data further support our hypotheses that Feraccru® is consistently well absorbed and that chronic treatment with Feraccru® can maintain Hb levels. As previously shown in patients with IDA associated with IBD, this study in CKD patients demonstrates that Feraccru® is also well tolerated in a group of patients whose IDA is caused by a very different primary disease.

Both the European and US regulatory authorities require that the Group conduct a paediatric clinical study 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. A crucial first step is therefore to formulate a suitable liquid formulation and then to prove its equivalence to the capsule. We have been working on developing this formulation during 2019 but the process has taken somewhat longer than we originally envisaged. However, we now have a formulation and, subject to the coronavirus pandemic situation, the equivalence study will be conducted towards the end of 2020.

Commercialisation

In Europe we licensed Feraccru® to Norgine for commercialisation in September 2018. The first few months after this were taken up with the 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 positive long term results from the AEGIS-H2H study comparing Feraccru® with Ferinject®, the market leading IV iron therapy, these pricing applications are now being prepared for filing with the authorities in France, Italy and Spain by Norgine using the AEGIS-H2H results to support the applications for reimbursement. These pricing and reimbursement processes do take time however, so we do not expect launches to occur in these markets before 2021.

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 IDA in 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 2019 already being almost 70% higher than 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-third of the hospital trusts in England have approved reimbursement of Feraccru®. Norgine is

continuing to work on persuading the remaining hospital trusts to place Feraccru® on their formularies. Scotland, Wales and Northern Ireland have their own procedures and, with the AEGIS-H2H data available, Norgine is in the process of submitting applications to these authorities.

Norgine has also begun the regulatory approval process in Australia where the product could be approved towards the end of 2020.

During 2019 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 by identifying and contacting a long list of potential partners who might be considered appropriate for the commercialisation of Accrufer® in the USA. We have had considerable interest in Accrufer® from a range of US-based companies, ranging from relatively small companies which focus on single therapeutic areas to larger organisations which span several of the therapeutic areas in which Accrufer® is relevant. We are continuing to work hard to identify the optimal combination of partner, from a capability perspective, and financial terms. I look forward to being able to update the market in the coming months.

Also during 2019 we were working on finding a partner for China and were able to announce in early January 2020 that we have has entered into an exclusive licence agreement for Feraccru®/Accrufer® with Beijing Aosaikang Pharmaceutical Co. Ltd ("ASK Pharm") in China, Hong Kong, Macau and Taiwan. Shield received an upfront payment of US$11.4 million and is eligible to receive a further US$11.4 million upon regulatory approval of Feraccru®/Accrufer® in China. It is probable that a further clinical study in Chinese patients will be required before the authorities approve the product. ASK Pharm will be responsible for the design, conduct and costs of this study. Once the product is on the market Shield will receive tiered ongoing royalties of 10% or 15% of net sales and up to US$40 million in milestone payments upon the achievement of specified cumulative sales targets. ASK Pharm will be responsible for the costs of manufacturing and distribution.

Based in Nanjing, Jiangsu Province, ASK Pharm was founded in 2003 and is listed on the Shenzhen stock exchange. ASK Pharm is an integrated pharmaceutical enterprise that focuses on the GI and oncology therapeutic areas, being one of China's leading manufacturers of proton pump inhibitor and oncology medications. With a market capitalisation of approximately CNY15 billion (US$2.2 billion), 2018 sales revenues in China equivalent to more than US$560 million and over 1,000 sales representatives, ASK Pharm is both well-resourced and very well positioned to capitalise on the Feraccru®/Accrufer® opportunity in China, one of the world's largest and fastest growing prescription pharmaceutical markets. I am delighted that we have been able to partner with ASK Pharm in China. It is an ambitious and successful pharmaceutical company with an excellent track record of product development and commercial success. Its established product development and commercial infrastructure and expertise in China should speed the regulatory approval and drive subsequent sales of Feraccru®/Accrufer®. The market in China for novel prescription pharmaceuticals continues to grow rapidly and this agreement will mean more patients with iron deficiency will benefit from Feraccru®/Accrufer® therapy. We very much look forward to working with ASK Pharm and supporting them as it advances the Feraccru®/Accrufer® franchise in China.

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. More recently, in April 2020, the Chinese Patent Office has allowed our composition of matter patent.

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 as amended. However, as anticipated, in June 2019 Shield received notice that Teva has filed a notice of appeal to the EPO's decision. Currently no date has been set for the appeal hearing. The EPO had set a date of 23 June 2020

for the oral hearing in respect of patent # 3 160 951951 but this has now been postponed due to the coronavirus pandemic.

Pipeline – PT20 (phosphate binder)

Although we were not able to prioritise PT20 for development during 2018 and 2019, we plan to re-start 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 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 and manufacturing clinical study material could start in the second half of 2020 and should take around 15-18 months, meaning that the Phase III study could potentially start in 2022, subject to finance being available.

Brexit

After the 2016 Brexit referendum result we decided to de-risk the Feraccru® supply chain by outsourcing the manufacture of the finished packs to Patheon in France. The bulk drug/active ingredient is manufactured in the UK but it has a long shelf life and we are able to store sufficient quantities in France to avoid any risk of running out of bulk drug needed during finished goods production as a result of potential supply chain disruption at the UK or French borders.

In the event that WTO tariffs are imposed, we do not believe that this would have a material impact as such tariffs would only apply to the export of our bulk drug from the UK to France.

Coronavirus

The business has continued to operate effectively since the introduction of the lockdown in the UK. Whilst we have closed both our London and Newcastle offices, all of our employees are able to continue working from home successfully. Generally, we are finding that the businesses with which we have close relationships are also operating effectively and so we have seen minimal disruption to our commercial progress.

Outlook

Having secured FDA approval of Accrufer®, and with Feraccru® sales in Germany and the UK beginning to increase significantly, and the China licence secured, I have great confidence in the future for Shield. Having received $11.4 million from ASK Pharm we have a cash runway extending into the first quarter of 2021 which gives us the flexibility to negotiate the best possible commercialisation arrangement in the US. 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, which should drive Shield's royalty and sales milestone income for many years.

Financial review

Revenue
Revenue in 2019 was £0.7 million (2018: £11.9 million). In 2018 £11.0 million revenue was received from Norgine as the up-front payment on signing of the licence agreement whereas in 2019 only £0.1 million of milestone revenue was received, from our Swiss partner EWO, triggered by the broadening of the Feraccru® label by the Swiss authorities. The remaining £0.6 million revenue in 2019 came almost entirely from Norgine based on sales-related activity.

Cost of sales
Cost of sales of £0.5 million (2018: £0.3 million) is comprised primarily of the cost of finished goods supplied to Norgine, but it also includes the 5% royalty payable to Vitra Limited, the original owner of the intellectual property underpinning Feraccru®, due on Norgine's net sales.

Selling, general and administrative expenses
Selling, general and administrative expenses were £6.8 million in 2019 (2018: £12.4 million). £3.4 million of this reduction is attributable to the reduction in selling costs from £3.5 million in 2018 to £0.1 million 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 £6.6 million in 2018 to £4.1 million in 2019, as a consequence of the change in commercialisation strategy which led to restructuring costs in 2018 which have not recurred in 2019 and a broader reduction of support and administration costs. The remaining £2.6 million of the 2019 costs arose on depreciation and amortisation, compared with £2.4 million in 2018, the increase being due largely to the increase in capitalised development costs.

Research and development
The total cost of research and development was £3.9 million including both the amount charged to the income statement and capitalised development costs. In 2019, £2.5 million (2018: £4.3 million) development costs have been charged to the income statement and a further £1.4 million (2018: £3.3 million) has been capitalised.

The £1.4 million of capitalised development costs is predominantly due to the AEGIS-H2H study.

Tax
The tax credit of £0.3 million (2018: £3.4 million) is an accrual for the expected R&D tax credit receivable in respect of 2019, £1.0 million, offset by £0.5 million tax payable by Shield TX (Switzerland) AG arising under the 2016 purchase of rights to Feraccru® by Shield TX (UK) Ltd, and an adjustment of £0.2 million relating to prior years. The 2019 financial statements included £1.9 million actual cash received during 2018 in respect of 2017 and £1.5 million accrued in respect of 2018.

Balance sheet
Intangible assets at 31 December 2019 were £29.9 million (31 December 2018: £31.0 million). The components of this are £19.5 million (31 December 2018: £21.5 million) relating to the acquisition costs of PT20, the phosphate binder product in our development portfolio; £9.0 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 £1.5 million (31 December 2018: £1.5 million) expenditure on strengthening the Group's intellectual property.

Property, plant and equipment has been restated under IFRS 16 (Leases) as this has impacted the accounting treatment of our leasehold premises. At 31 December 2019 the balance was £26,000 (31 December 2018: £0.2 million, restated).

Inventory at 31 December 2019 amounted to £0.9 million (31 December 2018: £0.1 million). The increase is due to the increase in manufacturing activity as a consequence of supplying Norgine.

The current tax asset of £1.0 million (31 December 2018: £1.5 million) represents £1.0 million R&D Tax Credit expected to be received in respect of 2019.

Cash at 31 December 2019 was £4.1 million (31 December 2018: £9.8 million).

Trade and other payables of £3.5 million (31 December 2018: ££2.5 million) include the €2.5 million milestone repayable to Norgine in respect of the AEGIS-H2H study which was found not to have met its primary endpoint.

Lease liabilities of £20,000 at 31 December 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 2019 was £5.6 million. The loss for the period was £8.8 million but after adjusting this for non-cash items (depreciation and amortisation £2.6 million, share-based payments £0.5 million, and the income tax credit £0.3 million), the cash outflow from the income statement was reduced to £5.9 million. Movements in working capital reduced this further by £0.6 million. £1.3 million was received in respect of the 2018 R&D tax credit, and £1.4 million was incurred on capitalised development expenditure.

Going concern

At the year end the Group held £4.1 million of cash. Since the year end, the Group has secured an exclusive licence agreement with Beijing Aosaikang Pharmaceutical Co. Ltd (ASK Pharm) for the development and commercialisation of Feraccru®/Accrufer® in China. This has resulted in $11.4 million being received as an upfront payment during January 2020. The Group's unaudited cash balance at 30 April was £10.4 million.

The Directors have considered the funding requirements of the Group through the preparation of detailed cash flow forecasts for the period to December 2021 including the repayment of the €2.5 million milestone to Norgine. Under current business plans the current cash resources will extend into 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 out-licensing 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 coronavirus pandemic will significantly impact the revenues included in the cash flow forecasts, nor the ability to complete commercialisation out-licensing 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 2020, and increased royalties will flow from that growth. However launches in the other major European markets are not expected until 2021 as pricing and reimbursement negotiations in those countries can take 12 to 18 months. Selling, general and administrative costs in 2020 will continue at levels seen during 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 amounts incurred in 2019. Overall, the Group's cash runway extends into the first quarter of 2021 without including any potential upfront from an out-licensing agreement in the USA or other regions. In the event that such agreements are concluded, the Group would expect them to include upfront receipts which would extend the cash runway.

Tim Watts, Chief Executive Officer

Consolidated statement of profit and loss and other comprehensive income
for the year ended 31 December

	Notes	2019 £000	2018 (restated See Note 4) £000
Revenue	5	**719**	11,881
Cost of sales		**(485)**	(311)
Gross profit		**234**	11,570
Operating costs – selling, general and administrative expenses	6	**(6,773)**	(12,429)
Operating loss before research and development expenditure		**(6,539)**	(859)
Research and development expenditure		**(2,496)**	(4,300)
Operating loss		**(9,035)**	(5,159)
Financial income		**18**	50
Financial expense		**(49)**	(42)
Loss before tax		**(9,066)**	(5,151)
Taxation	7	**266**	3,359
Loss for the year		**(8,800)**	(1,792)
Attributable to			
Equity holders of the parent		**(8,800)**	(1,792)
Other comprehensive income			
Items that are or may be reclassified subsequently to profit or loss:			
Foreign currency translation differences – foreign operations		**33**	4
Total comprehensive expenditure for the year		**(8,767)**	(1,788)
Attributable to			
Equity holders of the parent		**(8,767)**	(1,788)
Total comprehensive expenditure for the year		**(8,767)**	(1,788)
Earnings per share			
Basic and diluted loss per share	8	**£(0.08)**	£(0.02)

Group balance sheet
at 31 December

	Notes	2019 £000	2018 (restated See Note 4) £000
Non-current assets			
Intangible assets	9	**29,898**	30,957
Property, plant and equipment		**26**	155
		29,924	31,112
Current assets			
Inventories	10	**948**	109
Trade and other receivables		**356**	1,031
Current tax asset		**950**	1,500
Cash and cash equivalents		**4,141**	9,776
		6,395	12,416
Total assets		**36,319**	43,528
Current liabilities			
Trade and other payables		**(3,547)**	(2,548)
Other liabilities		**(607)**	(403)
Lease liabilities		**(20)**	(147)
		(4,174)	(3,098)
Total liabilities		**(4,174)**	(3,098)
Net assets		**32,145**	40,430
Equity			
Share capital	11	**1,758**	1,746
Share premium		**88,352**	88,338
Merger reserve		**28,358**	28,358
Currency translation reserve		**69**	36
Retained earnings		**(86,392)**	(78,048)
Total equity		**32,145**	40,430

These financial statements were approved by the Board of Directors on 20 May 2020 and were signed on its behalf by:

Tim Watts

Director

Company registered number: 09761509

Group statement of changes in equity
for the year ended 31 December

	Issued capital £000	Share premium £000	Merger reserve £000	Currency translation reserve £000	Retained earnings £000	Total £000
Balance at 1 January 2018 (as previously stated)	1,746	88,338	28,358	32	(77,267)	41,207
Prior period adjustment (see Note 4)					(2)	(2)
Balance at 1 January 2018 (as restated)	1,746	88,338	28,358	32	(77,269)	41,205
Loss for the year	—	—	—	—	(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	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	**1,758**	**88,352**	**28,358**	**69**	**(86,392)**	**32,145**

Group statement of cash flows
for the year ended 31 December

	2019	2018 (restated See Note 4)
	£000	£000
Cash flows from operating activities		
Loss for the year	**(8,800)**	(1,792)
Adjustments for:		
Depreciation and amortisation	**2,621**	2,690
Equity-settled share-based payment expenses	**456**	1,013
Financial income	**(18)**	(50)
Financial expense	**49**	43
Unrealised foreign exchange losses	**33**	4
Income tax	**(266)**	(3,359)
	(5,925)	(1,451)
(Increase)/decrease in inventories	**(839)**	16
Decrease in trade and other receivables	**681**	541
Decrease in trade and other payables	**999**	(953)
(Decrease)/increase in other liabilities	**(286)**	141
Change in lease assets and liabilities	**(2)**	(2)
Income tax received	**1,306**	1,859
Net cash flows from operating activities	**(4,066)**	151
Cash flows from investing activities		
Financial income	**18**	50
Acquisitions of intangible assets	**(34)**	(346)
Capitalised development expenditure	**(1,350)**	(2,999)
Net cash flows from investing activities	**(1,366)**	(3,295)
Cash flows from financing activities		
Interest paid	**(49)**	(35)
Finance leases – interest payment	**(4)**	(8)
Proceeds of share options exercised	**26**	—
Total cash outflow for leases	**(176)**	(336)
Net cash flows from financing activities	**(203)**	(379)
Net decrease in cash	**(5,635)**	(3,523)
Cash and cash equivalents at 1 January	**9,776**	13,299
Cash and cash equivalents at 31 December	**4,141**	9,776

Notes
for the year ended 31 December

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, 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.

Shield Therapeutics plc is the parent entity that holds investments in a number of subsidiaries. Its trading subsidiaries are engaged in the late-stage development and commercialisation of clinical stage pharmaceuticals to treat unmet medical needs.

2. Accounting policies
The consolidated and parent company financial statements have been prepared and approved by the Directors in accordance with International Financial Reporting Standards as adopted by the EU ("Adopted IFRSs").

The accounting policies set out below have, with the exception of the introduction of IFRS 16 Leases which has impacted leases and property, plant and equipment, been applied consistently to all periods presented in these financial statements (see Note 4). The financial statements are prepared on the historical cost basis. The functional currency of the Company is GBP. The consolidated financial statements are presented in GBP and all values are rounded to the nearest thousand (£000), except as otherwise indicated.

The financial information set out above does not constitute the company's statutory accounts for the years ended 31 December 2019 or 2018 but is derived from those accounts. Statutory accounts for 2018 have been delivered to the registrar of companies, and those for 2019 will be delivered in due course. The auditor has reported on those accounts; their reports were (i) unqualified and (ii) did not contain a statement under section 498 (2) or (3) of the Companies Act 2006; though in both years 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.

Company income statement
As permitted by Section 408 of the Companies Act 2006, the Company has not presented its own income statement. The loss for the financial year per the accounts of the Company was £0.3 million. The total comprehensive expenditure for the year comprises the net loss and is wholly attributable to the equity holders of Shield Therapeutics plc; therefore, no statement of comprehensive income has been disclosed.

Basis of preparation
Going concern
At the year end the Group held £4.1 million of cash. Since the year end, the Group has secured an exclusive licence agreement with Beijing Aosaikang Pharmaceutical Co. Ltd (ASK Pharm) for the development and commercialisation of Feraccru®/Accrufer® in China. This has resulted in $11.4 million being received as an upfront payment during January 2020. The Group's unaudited cash balance at 30 April was £10.4 million.

The Directors have considered the funding requirements of the Group through the preparation of detailed cash flow forecasts for the period to December 2021 including the repayment of the €2.5 million milestone to Norgine. Under current business plans the current cash resources will extend into 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 out-licensing 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 coronavirus pandemic will significantly impact the revenues included in the cash flow forecasts, nor the ability to complete commercialisation out-licensing 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.

Basis of consolidation

The consolidated financial statements comprise the financial statements of the Group and its subsidiaries as at 31 December 2019.

Subsidiaries are fully consolidated from the date of acquisition, being the date on which the Group obtains control, and continue to be consolidated until the date when such control ceases. The financial statements of the subsidiaries are prepared for the same reporting period as the parent company, using consistent accounting policies. All intra-group balances and transactions, unrealised gains and losses resulting from intra-group transactions and dividends are eliminated in full.

A change in the ownership interest of a subsidiary, without a loss of control, is accounted for as an equity transaction.

Foreign currency

Transactions in foreign currencies are translated into Sterling at the rate of exchange ruling at the transaction date. Assets and liabilities in foreign currencies are retranslated into Sterling at the rates of exchange ruling at the balance sheet date. Differences arising due to exchange rate fluctuations are taken to the statement of comprehensive income in the period in which they arise.

Revenue

Revenue arises primarily from product licensing arrangements with third parties. Typically such arrangements will include upfront payments at the time of entering the agreement, development milestones contingent on successful further product development, sales royalties based on annual sales of the product and sales milestones when specified sales targets are achieved. Revenue also arises when inventory is transferred to licence partners. Revenue is recognised in the consolidated statement of profit and loss and other comprehensive income in accordance with IFRS 15 Revenue from contracts with customers. Under IFRS 15 revenue from upfront payments, development and sales milestones, and the transfer of inventory to customers is recognised when a performance obligation is satisfied by transferring a good or service to a customer. Sales-related royalties are recognised when the underlying sale by the licence partner occurs.

The Norgine licence agreement was assessed in 2018 as a right-to-use licence on the grounds that the Group's activities after the agreement was signed in September 2018 were not expected to significantly enhance the value of the asset to Norgine, and the agreement contained three types of performance obligation:

- Execution of the licence – revenue was recognised at the time the agreement was signed;
- Event-based milestones such as completion of the paediatric clinical study and the achievement of sales thresholds – these comprise variable consideration and, as such, revenue is only recognised when it is highly probable that such revenue will not be reversed in future. No revenue has been recognised in respect of these performance obligations in either 2018 or 2019; and
- Sales-based royalties – these are attributable to the licence and revenue is recognised when sales occur.

Cost of sales
Cost of sales comprise the costs of manufacturing product which is transferred to licence partners and royalties or other payments due to Vitra Pharmaceuticals Limited ("Vitra") under the 2010 Asset Purchase Agreement (APA).

The cost of manufacturing product is the cost incurred with contract manufacturing organisations who manufacture the product on behalf of the Group. Under the APA, Vitra has the right to receive a mid-single digit royalty in respect of products falling within the scope of the acquired intellectual property.

Research and development
Research expenditure is charged to the statement of comprehensive income in the period in which it is incurred. Expenditure incurred on development projects is recognised as an intangible asset when it is probable that the project will generate future economic benefits, considering factors including its commercial and technological feasibility, status of regulatory approval, and the ability to measure costs reliably. Development expenditure which has been capitalised and has a finite useful life is amortised from the commencement of the commercial production of the product on a straight-line basis over the period of its expected benefit. Other development expenditure is recognised as an expense when incurred.

Employee benefit costs
Employee benefit costs, including holiday pay and contributions to the Group's defined contribution pension plan, are charged to the statement of comprehensive income on an accruals basis. The assets of the pension scheme are held separately from those of the Group in independently administered funds. The Group does not offer any other post-retirement benefits.

Share-based payments
The Group's employee share option schemes allow Group employees to acquire shares of the Company subject to certain criteria. The fair value of options granted is recognised as an expense of employment in the statement of comprehensive income with a corresponding increase in equity. The fair value is measured at the date of grant and spread over the period during which the employees become unconditionally entitled to the options. The fair value of options granted under the share option schemes is measured using a Black-Scholes model or, for grants where vesting is contingent on performance conditions, a Monte Carlo model taking into account the performance conditions under which such options were granted. At each financial year end, the Group revises its estimate of the number of options that are expected to become exercisable based on forfeiture such that at the end of the vesting period the cumulative charge reflects the actual options that have vested, with no charge for those options which were forfeit prior to vesting. When share options are exercised the proceeds received are credited to equity.

Finance income and costs
Finance income and costs comprise interest income and interest payable during the year,

Taxation
Tax on the profit or loss for the year comprises current and deferred tax. Tax is recognised in the statement of profit and loss except to the extent that it relates to items recognised directly in equity, in which case it is recognised in equity.

Current tax is the expected tax payable or receivable on the taxable income or loss for the year, using tax rates enacted or substantively enacted at the balance sheet date, and any adjustment to tax payable in respect of previous years.

A deferred tax asset is recognised only to the extent that it is probable that future taxable profits will be available against which the temporary difference can be utilised.

Intangible assets
Intellectual property and in-process research and development acquired through business combinations are recognised as intangible assets at fair value. Other acquired intangible assets are initially recognised at cost.

Expenditure incurred on development projects is recognised as an intangible asset when it is probable that the project will generate future economic benefits, considering factors including its commercial and technological feasibility, status of regulatory approval, and the ability to measure costs reliably.

Expenditure in relation to patent registration is capitalised and recorded as an intangible asset.

Amortisation is charged to the statement of profit and loss on the straight-line basis. Amortisation commences when patents are issued or, in the case of other capitalised development expenditure, once intangible assets are available for use, being also the point at which revenue is being generated from products. Amortisation is charged as follows:

Patents, trademarks and development costs	– over the term of the patents (currently until 2029–2035)
Chemistry, manufacturing and controls costs development costs	– over the assumed five-year life associated with the process
Intellectual property purchase costs	– over the term of the patents

Impairment of intangible assets
An impairment review is carried out annually for intangible assets. The recoverable amount is the higher of an asset's fair value less costs to sell and its value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows.

Property, plant and equipment
Purchased property, plant and equipment is stated at historical cost less depreciation. The cost of property, plant and equipment includes the purchase price and any costs directly attributable to bringing it into working order. Leased property is accounted for as a "right-of-use" asset under IFRS 16 Leases. The initial value of a right-of-use asset is determined by the value of the lease liability.

Depreciation on purchased property, plant and equipment is calculated to allocate the cost to the residual values over the estimated useful lives, as follows:

Furniture, fittings and equipment	– 25% reducing balance basis
Computer equipment	– 33.33% straight-line basis

Depreciation on leased property is charged over the life of the lease.

The assets' residual values and useful lives are reviewed, and adjusted if appropriate, at the end of each reporting period.

An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount.

Investments in subsidiaries

Investments are carried at cost less any provision made for impairment. Options over the Company's shares have been awarded to employees of subsidiary companies. In accordance with IFRS 2, the Company treats the value of these awards as a capital contribution to the subsidiaries, resulting in an increase in the cost of investment. Investments in subsidiary undertakings, including shares and loans, are carried at cost less any impairment provision. Such investments are subject to review, and any impairment is charged to the statement of comprehensive income. At each year end the carrying value of the Company's investment in subsidiaries is reviewed. Where the review performed concludes that there is a material shortfall in the carrying value compared to its recoverable amount, the carrying value of the Company's investments in subsidiaries is adjusted.

Inventories
Inventories are stated at the lower of cost and net realisable value. The cost of finished goods comprises raw materials and the costs charged by third party contract manufacturers. Net realisable value is the estimated selling

price in the ordinary course of business, less applicable variable selling expenses. In arriving at net realisable value, provision is made for any obsolete or damaged inventories.

Financial assets and liabilities

Other investments held by the Group are classified as fair value through profit and loss.

Cash and cash equivalents include cash in hand, bank deposits repayable on demand, and other short term highly liquid investments with original maturities of three months or less.

Trade receivables are recognised initially at the transaction price as these assets do not have significant financing components and are subsequently measured at amortised cost. The Group recognises loss allowances for trade receivables under the expected credit loss model as established by evidence that the Group will not be able to collect all amounts due according to the original terms of the receivables.

Trade payables are recognised initially at fair value and subsequently measured at amortised cost using the effective interest method. Trade payables are classified as current liabilities if payment is due within one year or less. If not, they are presented as non-current liabilities.

Lease liabilities are recognised under IFRS 16 by reference to the future payments due under the lease contract.

3. Critical accounting judgments and key sources of estimation uncertainty

In the application of the Group's accounting policies, which are described in Note 2, management is required to make judgements, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources.

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

Going concern

The Board has formed a judgement that it is appropriate to adopt the going concern basis of preparation for the Group and parent company. This judgement is based on an evaluation of the Group's cash flow forecasts and risks to its business model and how those risks might affect the Group's and Company's financial resources or ability to continue operations over a period of at least twelve months from the date of approval of the financial statements. The Directors consider it appropriate to adopt the going concern basis of accounting in preparing the financial statements for the reasons set out in Note1 and note that these reasons 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.

Development expenditure

Development expenditure is capitalised when the conditions described in Note 2 are met.

Expenditure on the Feraccru® AEGIS-H2H study have been capitalised as Feraccru® had received marketing approval in Europe by the time the study started and it was judged probable that the project would generate future economic benefits. Other development expenditure in 2019, such as the development of a formulation for the paediatric clinical study, have not been capitalised as there is considerable technical uncertainty as to whether the formulation and the paediatric study will lead to approval of the product for use in children.

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

Valuation of intellectual property acquired with Phosphate Therapeutics Limited – £19.5 million; investments in Company balance sheet of £26.8 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 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. See Note 9 for sensitivity analysis of key assumptions in this valuation.

Valuation of intellectual property associated with Feraccru® – intangible assets of £9.0 million; investments in Company balance sheet of £77.2 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. See Note 9 for sensitivity analysis of key assumptions in this valuation.

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. New standards and interpretations

The Group has adopted the following standards, amendments and interpretations in these financial statements for the first time. The adoption of these pronouncements has not had a material impact on the Group's accounting policies, financial position or performance.

The Group has applied IFRS 16 Leases with a date of initial application of 1 January 2019. As a result, the Group has changed its accounting policy for lease contracts. 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, principally the leases of the Group's office accommodation in London and Newcastle which were classified as operating leases under IAS 17, the Group has 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 impact of the retrospective application to the 2018 financial statements was

- To increase depreciation of property, plant and equipment in 2018 by £336,000 and to decrease lease expenses charged in 2018 by £345,000, leading to a £9,000 reduction in selling, general and administrative expenses
- To increase financial expense by £7,000 relating to the interest payment on finance leases
- to increase the net book value of property, plant and equipment at 31 December 2018 by £147,000 and lease liabilities by the same amount.

5. 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.

	Feraccru® 2019 £000	**PT20 2019 £000**	**Central and unallocated 2019 £000**	**Total 2019 £000**	Feraccru® 2018 £000	PT20 2018 £000	Central and unallocated 2018 £000	Total 2018 £000
Revenue	**719**	**—**	**—**	**719**	11,881	—	—	11,881
Operating (loss)/profit	**(6,421)**	**(1,908)**	**(706)**	**(9,035)**	2,009	(1,904)	(5,264)	(5,159)
Financial income				**18**				50
Financial expense				**(49)**				(42)
Tax				**266**				3,359
Loss for the year				**(8,800)**				(1,792)

The revenue analysis in the table below is based on the country of registration of the fee-paying party. £0.1 million (2018: £11.1 million) of revenue is derived from milestone payments from commercial partners. The remainder of revenue is derived from royalties and the sale of goods.

	Year ended 31 December 2019 £000	Year ended 31 December 2018 £000
UK	**141**	171
Europe	**578**	11,710
	719	11,881

An analysis of revenue by customer is set out in the table below.

	Year ended 31 December 2019 £000	Year ended 31 December 2018 £000
Customer A	**592**	11,025
Customer B	**83**	516
Customer C	**28**	126
Other customers	**16**	214
	719	11,881

As at 31 December 2019	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**

As at 31 December 2018	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	—	2,354
Capital expenditure	—	—	—	—
Capitalised development costs	2,999	—	—	2,999

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

6. Operating costs – selling, general and administrative expenses

Operating costs are comprised of:

	Year ended 31 December 2019 £000	Year ended 31 December 2018 £000
Selling costs	**59**	3,495
General administrative expenses	**4,093**	6,552
Depreciation and amortisation	**2,621**	2,382
	6,773	12,429

7. Taxation

Recognised in the income statement:

	Year ended 31 December 2019 £000	Year ended 31 December 2018 £000
Current income tax	**460**	1,500
Current income tax – adjustments in respect of prior years	**(194)**	1,859
Deferred tax	**—**	—
Total tax credit	**266**	3,359

8. Loss per share

	2019			2018		
	Loss £000	**Weighted shares 000**	**Loss per share £**	Loss £000	Weighted shares 000	Loss per share £
Basic and diluted	**(8,800)**	**116,987**	**(0.08)**	(1,792)	116,426	(0.02)

Basic EPS is calculated by dividing the profit or loss for the year attributable to ordinary equity holders of the parent by the weighted average number of Ordinary Shares outstanding during the year.

Diluted EPS is calculated by dividing the profit or loss attributable to ordinary equity holders of the parent by the weighted average number of Ordinary Shares outstanding during the year plus the weighted average number of Ordinary Shares that would be issued on conversion of all the dilutive potential Ordinary Shares into Ordinary Shares.

The diluted loss per share is identical to the basic loss per share in both years, as potential dilutive shares are not treated as dilutive since they would reduce the loss per share. At the date of approval of the report 4,205,154 of share options were in issue under the Company's share option plans (see Note 23). These are considered non-dilutive and potentially provide 4,176,932 additional Ordinary Shares (approximately 3.6% of the current share capital).

Included within property, plant and equipment are £20,000 net book value of assets recognised as leases under IFRS 16. Further details of these leases are disclosed in Note 24.

9. Intangible assets

Group	Patents and trademarks £000	Feraccru® development costs £000	Phosphate Therapeutics licences £000	Total £000
Cost				
Balance at 1 January 2018	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	**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	**2,055**	**9,943**	**27,047**	**39,045**
Accumulated amortisation				
Balance at 1 January 2018	417	442	3,714	4,573
Charge for the period	71	427	1,851	2,349
Balance at 31 December 2018	**488**	**869**	**5,565**	**6,922**
Charge for the period	86	331	2,026	2,443
Disposals	—	(218)	—	(218)
Balance at 31 December 2019	**574**	**982**	**7,591**	**9,147**
Net book value				
31 December 2019	**1,481**	**8,961**	**19,456**	**29,898**
31 December 2018	1,533	7,942	21,482	30,957

At the year end management reviewed the carrying value of the intangible assets for impairment. The intangible assets relate to two cash-generating units, being the Feraccru® business and the Phosphate Therapeutics Limited business. The recoverable amount has been determined based on value-in-use calculations, using pre-tax cash flow

projections for the period of the patents. Management has considered the potential impact of the coronavirus pandemic but does not believe it will materially adversely affect the prospects for either Feraccru® or PT20 due to the ongoing worldwide patient need for treatment for iron deficiency and hyperphosphatemia respectively and the long patent lives of both products. The following key assumptions have been included in the value-in-use calculations:

Feraccru®

The value in use has been calculated based on income forecast to arise from the commercialisation licence agreements with Norgine BV covering Europe, Australia and New Zealand and with Beijing Aosaikang Pharmaceutical Co. Ltd covering China, Taiwan, Hong Kong and Macau, and also potential income from the US market once a commercial partner has been secured. Sales forecasts in each territory have been derived from discussions with partners and potential partners, and from other third party market projections. Discount rates of 10% have been applied to Europe, recognising the product is already marketed and 15% for the USA and China reflecting the fact that the product is not yet marketed in these territories.

Phosphate Therapeutics Limited

The value in use of PT20, Phosphate Therapeutics Limited's main asset, has been based on cash flow forecasts of out-licensing income which could be derived from the product PT20 until 2034, being the current patent life of the asset with an additional five years supplementary patent protection. Sales forecasts have been derived from third party market projections for the phosphate binder global market with the assumed market share of PT20 cross-referenced to sales of existing comparable products. Commercialisation of PT20 is contingent on the successful outcome of a Phase III clinical study, which cannot be guaranteed, and subsequent regulatory approval. Once the product is approved, the value in use is further dependent on successfully out-licensing the asset to a commercialisation partner and the generation of sufficient sales over the patent life with product launch assumed in 2024. A discount factor of 15% has been applied, reflecting the inherent uncertainty attached to obtaining marketing authorisation for the drug and its subsequent commercial success under an anticipated out-licensing business model.

The carrying amount of intangible assets has been allocated to the cash-generating units (CGUs) as follows:

	2019	2018
	£000	£000
Feraccru®	**10,442**	9,475
Phosphate Therapeutics Limited	**19,456**	21,482
	29,898	30,957

Sensitivity analysis

Feraccru® - sensitivity analysis shows that, even if the USA and China are excluded entirely from the value in use, management's base case sales forecast for Europe would need to be reduced by around 95% before an impairment of the carrying value of the intangible asset would be required.

PT20 - Using a 15% discount rate, management's base case sales forecasts would need to be reduced by 55% before triggering an impairment of the carrying value of the intangible asset. Alternatively, using the unadjusted base case sales forecasts, a licence deal with no upfront payment, no development or sales milestones and a royalty of only 9%, which collectively would be well below a market-standard agreement, would still support the intangible asset valuation. Whilst the sensitivity analysis performed indicates the carrying value is supportable, as noted above, there are several key assumptions in the impairment review of the PT20 asset, including an assumption that the asset will be successfully taken through the clinical trials process, and high level assessments of the global market for such a treatment, and an assumption of the penetration we could expect to achieve in that market.

10. Inventories

Group	**2019 £000**	2018 £000
Raw materials	**928**	34
Finished goods	**20**	75
	948	109

The cost of inventories recognised as an expense and included in cost of sales was £418,000 (2018: £161,000). Cost of sales includes royalties payable to Vitra Pharmaceuticals Limited.

11. Share capital

	2019 Number 000		2018 Number 000	
		£000		£000
At 1 January	**116,426**	**1,746**	116,426	1,746
Exercise of share options	**763**	**12**	—	—
Issuance of shares pursuant to placing	**—**	**—**	—	—
Issuance of shares pursuant to subscription	**—**	**—**	—	—
At 31 December	**117,189**	**1,758**	116,426	1,746

762,806 share options were exercised during the year (2018: Nil).