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

Preliminary Results for the Year Ended 31 December 2020

London, UK, 29 April 2021: 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 results for the year ended 31 December 2020.

Operational highlights

- Feraccru® licensed to ASK Pharm in China
- AEGIS-H2H re-analysis confirms Feraccru®/Accrufer® is a credible alternative to IV therapy for iron deficiency anaemia
- Teva withdraw all oppositions to Shield's European patents
- 2020 sales of Feraccru® packs increase by 70% in Germany and UK compared with 2019
- First stage of paediatric study conducted successfully

Financial highlights

- Revenues of £10.4 million (2019: £0.7 million)
- Loss for the year of £2.6 million (2019: £8.8 million)
- Net cash of £2.9 million (2019: £4.1 million)

Post-period highlights

- £29.2 million gross proceeds raised by means of placing, subscription and open offer
- Decision made for Shield to launch Accrufer® in US

Commenting on the preliminary results, Tim Watts, CEO of Shield Therapeutics plc, said: *"The last fifteen months have presented a number of challenges, including the pandemic, and I am very proud of the way in which our employees have worked tirelessly to overcome the challenges and would like to thank them all for their contribution. However I believe Shield this period has been transformational for Shield and the Group is now well placed for substantial future growth. I am excited about the prospects for Accrufer®, which we remain on track to launch in the US by the end of June 2021, and we will update shareholders in mid-May as to our progress towards the US launch."*

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About Shield

Shield is a commercial stage, pharmaceutical company with a focus on addressing iron deficiency with its lead product Feraccru® /Accrufer® (ferric maltol), a novel, stable, non-salt based oral therapy for adults with iron deficiency with or without anaemia.

Shield's lead product, Feraccru®/Accrufer®, has been approved for use in the United States, European Union, UK and Switzerland and has exclusive IP rights until the mid-2030s. The Group plans to launch Accrufer® in the US during 2021 through a highly experienced sales and marketing team. Feraccru® is already being commercialised in the UK and European Union by Norgine B.V., who also have the marketing rights in Australia and New Zealand. Shield also has an exclusive licence agreement with Jiangsu Aosaikang Pharmaceutical Co., Ltd., for the development and commercialisation of Feraccru®/Accrufer® in China, Hong Kong, Macau and Taiwan.

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

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 was delighted and honoured to be appointed as Chairman of Shield when James Karis stepped down in June 2020 and I believe that 2020 has been a major turning point for the

better in the Group's fortunes. I would like to thank James for his contribution to Shield between 2016 and 2020, first as a non-executive director and then Chairman.

2020 was not an easy year for anyone due to the pandemic and I would like to express my gratitude to Shield's employees for their hard work and perseverance during the several lockdowns and for making a success of working from home for most of the last twelve months. Fortunately our team was able to continue to move the business forward and Shield was not severely affected. I would also like to thank the Group's key business partners on which we depend for a wide range of services and support.

In the first half of 2020 we also faced the challenge of the anomalies that surfaced in March 2020 regarding the analysis of the data from the AEGIS-H2H clinical study that had previously been announced in 2019. This study compared Feraccru®/Accrufer®, an oral product, with intravenous iron therapy over a 52 week period and is an important pillar in supporting the rationale for the product. The team responded extremely well by conducting a full re-analysis of the data and I am very pleased that after several months we were able to demonstrate conclusively that Feraccru®/Accrufer® has the ideal attributes of convenience, efficacy and being well tolerated and is therefore a highly credible alternative to intravenous iron.

Probably the most significant activity during 2020, however, was the effort made to find a route to the US market for Accrufer®. Shield's commercialisation strategy since early 2018 has been to out-licence Feraccru®/Accrufer® to regional partners who are well placed to market the product. We have already established major partnerships with Norgine, covering most of Europe, Australia and New Zealand, and ASK Pharm for China, Taiwan, Hong Kong and Macau. In the US, Accrufer® was granted marketing approval for the treatment of iron deficiency in adults by the FDA in July 2019. We spent the rest of 2019 and much of 2020 looking for a US licence partner which would have been able to exploit the full value of Accrufer® across the range of disease areas where iron deficiency is prevalent. Ultimately, although we came close on two occasions to deals with potential partners that we believed would have been successful, we were not able to complete a satisfactory licence transaction. However over that time we came to realise that, provided that we could recruit a high calibre, experienced US commercial team and raise the necessary finance, Shield could launch Accrufer® itself and generate greater value for shareholders than a licence deal. As this was such a significant change in strategy we had multiple discussions with our two largest shareholders, W Health and AOP Orphan International AG ('AOP'), to ensure that we had their full support. I am very grateful to them for backing this change in strategy and for supporting the £29.2 million fundraise, including a significant financial investment by AOP, that completed during March 2021 and which provides the finance required for the Accrufer® launch. I am now looking forward confidently to the launch, expected towards the end of the second quarter of 2021.

As a result of these developments I believe that the prospects for Shield have been transformed. Instead of receiving a royalty stream, perhaps averaging 15%-20%, on a US partner's sales, we will now benefit from a high margin product whose sales could grow to $300 million to $400 million over the next five to six years and which is patent protected until 2035. I am also confident that Norgine and ASK Pharm will have great success with Feraccru®/Accrufer® over the next 15 years and that we will be able to out-licence the product in other parts of the world. All of this has the potential to generate very substantial returns for Shield's shareholders.

Finally, apart from James Karis, there have been two other board changes since the last Annual Report. In June 2020, Christian Schweiger joined the board as a non-executive director. Christian was a co-founder of Shield in 2008, and he brings great enthusiasm for Feraccru®/Accrufer® and medical expertise to the board. Rolf Hoffman, who has been a non-executive director and excellent chair of the Remuneration Committee since 2018, has decided not to seek re-election to the board at the 2021 AGM due to conflicting demands on his time from other appointments. I thank Rolf for his significant contribution to Shield and wish him every success in future.

Hans Peter Hasler, Non-Executive Chairman

Chief Executive Officer's statement and financial review

Life in a small pharmaceutical or biotech company is rarely dull and my first full year as CEO proved to be no exception, but I believe that by the end of the 1st quarter of 2021 the Group is positioned for very substantial growth. There were three major challenges which confronted the business during 2020 and I am immensely proud of the way in which Shield's small team responded to them. The first and all-pervasive challenge has been the coronavirus pandemic which has meant working from home for the entire team for almost all of the last year with the difficulties that has brought, and the inability to travel to meet business partners and potential partners face-to-face. Second was the uncertainty that arose in March 2020 about the quality of the analysis of the AEGIS-H2H (head-to-head) study. The third major challenge was to find a path to commercialising Accrufer® in the US which would give the best outcome to shareholders. I am proud of the manner in which the Shield team rose to these challenges and overcame them, leaving the Group far better placed now than it was at the start of 2020. In addition we mounted a strong and robust defence to the challenges to two of our European patents lodged in 2019 by Teva which ultimately led to them withdrawing the challenges in October 2020, which is a tribute both to the quality of the patents and the work done by the Shield team in preparing our defence.

Commercialisation of Feraccru®/Accrufer®

United States

Shield's commercialisation strategy for Feraccru®/Accrufer® since early 2018 has been to out-licence the product to suitable alliance partners. This has been successfully achieved in Europe and China and, from mid-2019 to late-2020, was the intention for the US market. Over that time we engaged in a major exercise to find a suitable US commercialisation out-licence partner and came close on two occasions to achieving a licence deal which we believe would have been satisfactory for our shareholders. Frustratingly on both occasions the counter-party pulled out at late stage for reasons unrelated to Accrufer®'s potential. We also had discussions during 2020 with many other companies that were very interested in Accrufer® but which were focused primarily on only one therapy area. However we were unable to identify any other company that we believed would successfully commercialise Accrufer® across the broad range of therapy areas where iron deficiency is prevalent to maximise the potential opportunity or, in cases where they might have been able to do so, that was willing to offer financial terms which would reward Shield's shareholders adequately. In the course of multiple discussions and negotiations we gained extensive insights into how other companies were contemplating the commercialisation of Accrufer® and, over time, this led us to the conclusion that with an experienced US commercial team

Shield could realistically contemplate launching Accrufer® itself. An opportunity arose in November 2020 to recruit four US executives, headed by Brian Groch, with extensive experience of launching, selling and marketing pharmaceutical products in the US and who had already spent considerable time assessing Accrufer® while they had been employed by a company which had been contemplating licensing the product from Shield. This enabled us to consider more seriously the option of launching Accrufer® ourselves and consequently we announced in December 2020 that we were exploring this option whilst still reviewing ongoing out-licence possibilities. During December 2020, January and February 2021 we developed plans for a Shield-led launch of Accrufer® and investigated financing options to raise the $30 million to $40 million needed for the launch. The Board reached the conclusion in mid-February that we would be able to raise these funds through an equity placing and made the decision to go ahead with the fundraise and to launch Accrufer® ourselves in 2021.

I am very excited about the potential for Accrufer® in the US. The current market is already large with over 10 million prescriptions of oral iron therapy and around 2.3 million intravenous infusions annually, but there are clear drawbacks with the existing therapies and Accrufer® offers solutions by being convenient to take, effective in restoring and maintaining iron and haemoglobin levels, and well tolerated. We are building an excellent team in the US and are looking forward to the product launch, expected in June 2021.

Europe/Australia

Norgine BV is our licence partner for commercialisation of Feraccru® in most of Europe, Australia and New Zealand.

2020 was clearly a difficult year for selling and marketing pharmaceuticals as the coronavirus pandemic had a severe impact on healthcare providers globally and led to massive re-prioritisation of doctors' areas of focus. Sales and marketing activities have inevitably been impacted but demand for Feraccru® has increased and there are signs that patients and their doctors are becoming more wary of being treated with intravenous iron which requires hospital visits. Despite the pandemic-related constraints, the number of Feraccru® packs sold in Germany and the UK increased by around 70% in 2020 compared with 2019.

Feraccru® was marketed by Norgine in Germany and the UK throughout 2020, and Norgine took over responsibility for marketing in Scandinavia from AOP in the autumn of 2020, and they launched the product in Belgium in January 2021. Norgine are using the updated AEGIS H2H detailed study results to reconfirm pricing and reimbursement strategy for Feraccru® in the major European markets of France, Italy and Spain.

In March 2021, the Australian Therapeutics Goods Administration (the local regulatory authority for medicinal products) registered Feraccru® in the Australian Register of Therapeutic Goods to treat iron deficiency with or without anaemia in adults.

China

We announced in January 2020 that we had entered into an exclusive licence agreement for Feraccru®/Accrufer® with Jiangsu Aosaikang Pharmaceutical Co. Ltd ("ASK Pharm") covering China, Hong Kong, Macau and Taiwan. We received an upfront payment of US$11.4 million when the agreement was signed. Based in Nanjing, Jiangsu Province, ASK Pharm was founded in 2003 and is listed on the Shenzhen stock exchange (XSEC:002755). ASK Pharm is an integrated pharmaceutical business 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 CNY12 billion (US$1.9 billion), 2019 sales revenues in China were equivalent to more than US$750 million and with over 900 sales representatives, ASK Pharm is well positioned to capitalise on the Feraccru®/Accrufer® opportunity in China, one of the world's largest and fastest growing prescription pharmaceutical markets.

Feraccru® is not yet approved in China but ASK Pharm has submitted an Investigational New Drug (IND) application for Feraccru® to the Chinese regulatory authority (CDE) which has indicated that, for the New Drug Application, it is likely to require only a short-term Phase III study in 120 Inflammatory Bowel Disease (IBD) patients and will not require a Phase III clinical study in Chronic Kidney Disease (CKD) patients. Clinical supplies have been manufactured and released for the study. The study could be completed by the end of 2022 and marketing approval and product launch could follow by late 2023. On approval, Shield is due to receive an $11.4 million milestone payment from ASK Pharm and tiered royalties of 10% or 15% depending on the level 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 all clinical and regulatory costs and activities as well as all manufacturing and distribution costs of goods sold in the territory.

We were also pleased to learn during 2020 from the Chinese Patent Office that our composition of matter patent application was allowed providing IP protection until 2035.

Business development

Although the US was our commercialisation priority during 2020 we have continued to have discussions with potential partners in several other countries and are aiming to complete a new licence transaction in 2021.

AEGIS-H2H (Head-to-Head) study

The AEGIS-H2H (head-to-head) study, which was conducted between 2015 and 2019, was a non-inferiority study comparing oral Feraccru®/Accrufer® against intravenous (IV) iron therapy in 250 inflammatory bowel disease (IBD) patients with mild to severe iron deficiency anaemia (IDA) and baseline haemoglobin (Hb) measurements at the start of the study as low as 8.0g/dL. The study was intended and designed to provide data from which health economics data and other analysis could be generated. In March 2020 we realised that there had been some anomalies in the original analysis of the results of study which we had announced in March 2019 and we announced that the Board had instigated a thorough and complete review into the analysis which was completed and announced in August 2020.

The study had two key phases. The primary end point was set at the end of week twelve and was measured in terms of the proportion of responders in each arm, where a responder was defined as a patient whose haemoglobin levels had increased from the start of the study by at least 2g/dl or had reached normal levels. Although the average increase in Hb levels seen in patients treated with Feraccru®/Accrufer® was 2.45g/dl, which is a clinically relevant result, and 67% of such patients were defined as responders, 84% of patients in the IV arm were responders and the average increase in the IV arm was 3.04g/dl. Despite these impressive results for Feraccru®/Accrufer®, the difference in responders between the two arms of the study was slightly too large and so the primary end point of non-inferiority was not met. This was a challenging study design and it is not entirely surprising that IV is seen to be faster at

restoring Hb levels in the early weeks. Most patients on the IV arm received 1,000mg or 1,500mg of iron in one or two infusions in the first week which is then immediately available in the blood stream for Hb production, whereas Feraccru®/Accrufer® patients taking two capsules daily, each containing 30mg iron, would take at least 2½ weeks to absorb this amount of iron. It is also worth noting that 82% of patients on the IV arm required more than one infusion in a hospital or clinic during the first 12 weeks of the study with the associated inconvenience and risk of hospital-acquired infections.

The subsequent extension phase from week 12 to week 52 followed the maintenance of Hb levels in the study patients. During this phase the average increase in Hb levels over the patients' original baselines was very similar between the two arms of the study but the main difference was that patients being treated with Feraccru®/Accrufer® were simply taking two capsules daily at home in order to maintain their Hb, whereas 58% of the patients on the IV arm who were monitored from week 12 onwards required at least one further infusion in hospital or clinic. This clearly demonstrates the convenience offered by Feraccru®/Accrufer® and the benefits of reducing the risk of hospital-acquired infections and avoiding the administration cost of infusions.

The AEGIS-H2H study data demonstrates that Feraccru®/Accrufer® is a credible oral alternative to IV therapy and offers economic advantages. Having resolved the anomalies seen in the original analysis the study results can now be used with confidence for health economics analysis and to support pricing and reimbursement applications worldwide. For example, a health economics analysis based on costs in Germany published in the Journal of Crohn's and Colitis (JCC) concluded "*Total per patient drug costs were approximately 1.6 times higher for treatment with IV FCM (ferric carboxymaltose) than FM (ferric maltol). The total cost of IV FCM is not only influenced by the higher drug cost, but additional costs associated with IV administration which was required to be carried out in a hospital or outpatient setting. FM has no additional costs or resource use associated with administration and is, therefore, less of a burden on local healthcare systems. FM is associated with substantially lower healthcare resource use than IV FCM, and may provide a cost-effective oral alternative to IV iron in patients with IBD.*"

Shield plans to publish the full AEGIS-H2H study results in a peer-reviewed paper during 2021.

Supply chain

Fortunately our contract manufacturing partners were able to manufacture bulk ferric maltol and Feraccru® packs for us during 2020 without significant disruption due to the pandemic. We rely on a UK company to manufacture ferric maltol, the active pharmaceutical ingredient (API) in Feraccru®, and a manufacturer in France to convert the API into finished packs. We manufactured 4.5 metric tonnes of ferric maltol in 2020, which provides sufficient ferric maltol for around 300,000 packs which we expect to be sufficient at least until the end of 2021, and multiple finished packs for sale in Europe. We have also manufactured US launch stocks and the packs needed for the China clinical study.

Towards the end of 2020 we gained approval in the US to manufacture Feraccru® using HPMC (hydroxypropyl methylcellulose) capsules as well as the original gelatin capsules. HPMC capsules provide an improved product with regards to stability and are more suitable for vegetarians and vegans. Also the FDA have approved an extension to the shelf life of Accrufer® packs from 21 months to 24 months and ongoing studies should demonstrate stability out to 36 months later this year.

Paediatric study

When Feraccru®/Accrufer® was approved by the EMA and the FDA, both agencies imposed a post-approval commitment on Shield to conduct a study to evaluate the safety, tolerability and efficacy of the product in infants, children and adolescents. The first stage was to develop an age-appropriate formulation suitable for small children and infants. This development was completed in the first half of 2020 and during the second half of the year the oral suspension formulation was tested in healthy adult volunteers for therapeutic equivalence with the capsule version. The results from the equivalence test were satisfactory and so the main study is expected to start recruiting 110 subjects in summer 2021 and to cost around £4.5 million and take up to 30 months. A positive outcome is expected to lead to the product's label being expanded to include children.

Intellectual Property

In early 2019 we reported that Teva Pharmaceutical Industries Ltd (Teva) had raised objections with the European Patent Office (EPO) to two of our European patents - No.2668175, which covers a "Process for preparing an iron hydroxypyrone" and No.3160951 which covers "Crystalline Forms of Ferric Maltol." On 14 March 2019 the EPO decided in favour of Shield in respect of the former patent as amended but Teva subsequently filed a notice of appeal to the EPO's decision. In October 2020 we were delighted to be able to announce that Teva had withdrawn their opposition to both of these patents. With respect to the process patent, the withdrawal of the opposition means that the March 2019 decision by the EPO has become final and that the patent will be maintained as amended. Further to the withdrawal of the opposition to the crystalline form patent, that patent is maintained as granted and will continue to provide protection through to October 2035.

Product development - PT20 (phosphate binder)

PT20 is a Phase III-ready novel iron-based phosphate binder in development for the treatment of hyperphosphatemia but development has been constrained in recent years due to lack of finance. Hyperphosphatemia is a metabolic disorder characterised by elevated serum phosphorus levels in kidney disease patients. The overall market size of the US market is around $1 billion per annum. This market continues to grow and, within it, the new iron-based phosphate binders are growing particularly rapidly.

Older generation phosphate binders have been based on metals (lanthanum, aluminium), calcium salts, and polymers and have side effects, poor tolerance and lack of effectiveness. PT20's novel formulation enhances phosphate binding with similar side effects compared to latest generation iron-based products, Velphoro and Auryxia. An issue associated with current treatments is that the pill burden for patients can be very high and taking and chewing the pills is often considered unpleasant. PT20 has already completed one pivotal clinical study giving us significant confidence in the potential of the product and now requires one further Phase III study to allow an NDA to be filed. The Phase III study, which has been discussed with the FDA, would be expected to cost around £20 million and take 2-3 years. However prior to beginning a Phase III study we will develop a sachet formulation containing very small particles which we anticipate will be considerably easier to take compared to existing products. This planned formulation work is expected to cost around £500,000 and take 15-18 months.

Brexit

Brexit has created some minor complications and extra work but has not had a serious impact on Shield. Shipping bulk ferric maltol from the UK manufacturer to our finished pack manufacturer in France requires additional paperwork and time, and our French manufacturer is now unable to use UK laboratories with which we have long-established relationships for any of the quality control testing during the production of the finished packs to be sold in the European Union.

Coronavirus pandemic

The pandemic has meant that since March 2020 all of our employees have worked almost entirely from home. Clearly there have been disadvantages in not having been able to meet as a team and also from not being able to meet our external business partners face-to-face to establish and maintain good relationships but I do not think that our business achievements have been seriously affected. We re-opened our Newcastle UK office briefly in September 2020 but had to close it again within a couple of weeks. The London office was closed in March 2020 and, partly due to the pandemic but also to the changes in senior management, we decided to close the office permanently in November 2020 such that all of our UK employees are now based at the Newcastle office or are on home-based contracts. I am extremely grateful to the entire team for the way in which they have willingly coped with working from home despite well-known issues such as home schooling children and having to adapt home spaces for office use.

Business outlook

In common with everyone I hope very much that the worst impacts of the coronavirus are now behind us and that business life can return to something approaching normality. Clearly the most important objective for Shield in 2021 is a successful launch of Accrufer® in the US and I am confident that this will go well as we have a great US team and Accrufer®'s attributes of convenience, effectiveness and tolerability should allow it to carve out a role in the treatment of iron deficiency. I also look forward to launches in further markets in Europe towards the end of 2021 and early 2022 and we will renew our efforts to out-licence the product in markets outside the US, Europe, China and Australia/New Zealand.

Financial review

Revenue

Revenue in 2020 was £10.4 million (2019: £0.7 million). £9.7 million of this was due to the $11.4 million upfront received from ASK Pharm on the signing of the Chinese licence agreement. This is £1.0 million higher than the £8.7 million reported in the results for the first six months of 2020 because it has been grossed up by £1.0 million withholding tax due on the payment by ASK Pharm which ASK Pharm absorbed. The £1.0 million withholding tax absorbed by ASK Pharm is included as a current tax charge (Note 9) and therefore has no net impact on the Group's results. The remaining £0.7 million of revenue in 2020 was royalty income received from Norgine, an increase of 18% over the equivalent £0.6 million in 2019. This percentage increase is less than the stated headline 70% increase in packs sold because

2019 revenue was inflated by the initial sale of Shield's inventory of Feraccru® packs to Norgine when Norgine took over marketing from Shield in early 2019.

Cost of sales

Cost of sales of £1.4 million (2019: £0.5 million) includes the cost of finished packs supplied to Norgine for sale in Europe and the 5% royalty payable to Vitra Pharmaceuticals Limited (Vitra) on European net sales, and the payment to Vitra of 10% of the licence upfront received from ASK Pharm. Vitra was the original owner of the intellectual property underpinning Feraccru® and, under the terms of the 2010 Asset Purchase Agreement, is entitled to receive either a 5% royalty on net sales or 10% of any licence upfront and sales milestones. For the Norgine licence covering European commercialisation, Vitra chose in 2018 to receive 5% on net sales whereas for the ASK Pharm agreement covering China Vitra has elected to receive 10% of the upfront and sales milestones instead of future sales royalties. 2020 cost of sales also includes the cost of finished goods supplied to Norgine along with the 5% royalty payable to Vitra on Norgine's net sales. In 2019 the £0.5 million cost of sales comprised cost of finished goods supplied to Norgine and the 5% royalty payable to Vitra due on Norgine's net sales.

Selling, general and administrative expenses

Selling, general and administrative expenses were £8.6 million in 2020 (2019: £6.8 million). £1.6 million of this increase was due partly to professional and legal fees connected with the licence transaction completed with ASK Pharm in January 2020 and partly to expenses incurred in resolving the analysis of the AEGIS-H2H study data between March and August 2020.

Research and development

The total cost of research and development was £2.6 million (2019: £2.5 million). Compared with 2019, expenditure on the paediatric study was higher in 2020 but manpower costs were lower, as were costs associated with the FDA filing and ongoing maintenance of the US licence. In 2019 a further £1.4 million of costs relating predominantly to the AEGIS-H2H study were capitalised. No R&D costs were capitalised during 2020.

Financial income

Financial income of £269,000 was recorded in 2020 compared with £18,000 in 2019. This was largely a result of currency gains on the cash held in US dollars following the receipt of the $11.4 million upfront receipt from ASK Pharm.

Tax

The tax charge of £0.7 million in 2020 compares with a tax credit of £0.3 million in 2019. The 2020 charge comprises the Chinese withholding tax of £1.0 million arising on the $11.4 million upfront from ASK Pharm offset by £0.3 million anticipated R&D tax credit for 2020. The withholding tax charge was settled by ASK Pharm and 2020 revenue has been grossed up accordingly. The 2019 tax credit of £0.3 million was an accrual for the expected £1.0 million R&D tax credit receivable in respect of 2019 offset by £0.5 million tax payable by Shield TX (Switzerland) AG and an adjustment of £0.2 million relating to prior years.

Balance sheet

Intangible assets at 31 December 2020 were £27.3 million (31 December 2019: £29.9 million). The components of this are £17.4 million (31 December 2018: £19.5 million) relating to the acquisition costs of PT20, the phosphate binder product in our development portfolio; £8.4 million (31 December 2019: £9.0 million) relating to capitalised Feraccru® development expenditure, in particular the AEGIS-H2H study and the paediatric pharmacokinetic study, and £1.4 million (31 December 2019: £1.5 million) expenditure on strengthening the Group's intellectual property.

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

Trade and other receivables of £0.6 million at 31 December 2020 are higher than in 2019 (£0.4 million) due to the timing of supply of product to Norgine.

The current tax asset of £0.3 million (31 December 2019: £1.0 million) represents the R&D Tax Credit expected to be received in respect of 2020.

Cash at 31 December 2020 was £2.9 million (31 December 2019: £4.1 million).

Trade and other payables were £1.5 million at 31 December 2020 compared with £3.5 million at 31 December 2019. Other payables at the end of 2019 included the €2.5 million milestone repayable to Norgine in respect of the AEGIS-H2H study which was found in March 2020 not to have met its primary endpoint.

Cash flow

The cash outflow during 2020 was £1.2 million. Although the loss for the year was £2.6 million after adjusting this for non-cash items (depreciation and amortisation £2.7 million, share-based payments £0.8 million, and the income tax charge £0.7 million), the operational cash inflow before working capital movements was £1.3 million. Working capital outflows totalled £2.7 million, of which £2.2 million was the repayment of the Norgine R&D milestone, leaving £1.4 million net cash outflow from operating activities. Currency gains of £0.3 million on US dollar denominated cash balances offset by lease payments on office accommodation reduced the total cash outflow to £1.2 million.

Going concern

Going concern

The group meets its day to day working capital needs from cash balances. It has no bank facilities.

At 31 December 2020 the Group held £2.9 million in cash. On 18 March 2021 shareholders approved an equity fundraise which raised £27.8 m net of expenses. The Group's unaudited cash balance at 31 March 2021 was £28.2m.
These financial statements have been prepared on a going concern basis, notwithstanding a loss of £2.6 million and operating cash outflows of £1.4 million for the year ended 31

December 2020. The directors consider this to be appropriate for the following reasons.

The Group is planning to launch and commercialise Accrufer® in the US during 2021 and to start the main stage of the paediatric clinical study. The Directors have considered the funding requirements of the Group through the preparation of detailed cash flow forecasts for 16 months from the date of approval of the financial statements including the Accrufer® US launch costs and prospective sales revenues and the costs of the paediatric study. The Directors' base case forecasts show that the Group's monthly cash flows start to turn positive within 15 months and that the recent fundraise will provide sufficient cash to allow the business to continue in operations throughout the forecast period. The Directors have also considered severe but plausible downside scenarios in which sales revenues fall below base case forecasts and a delay in market penetration. In these circumstances mitigating actions such as reduction of discretionary selling and marketing expenditure would be taken to preserve cash. The severe but plausible downside scenarios forecast that the Group's monthly cash flows start to turn positive within 15 months and that the recent fundraise and mitigating actions will provide sufficient cash to allow the business to continue in operations throughout the forecast period. The Directors do not believe that the ongoing coronavirus pandemic will significantly impact the revenues included in the cash flow forecasts.

Based on the above factors the Directors believe that the group will have sufficient funds to continue to meet its liabilities as they fall due for the forecast period and therefore have prepared the financial statements on a going concern basis.

Furthermore, the Directors also believe that other forms of finance, such as debt finance or royalty finance are likely to be available to the Group. However, the Directors have not included any such financing within their forecasts.

Financial outlook

Having raised £27.8 million net proceeds in March 2021, the Group plans to launch Accrufer® in the US during the second quarter of 2021. The Board anticipates that increasing sales in the US should result in the Group's monthly cash flow turning positive between 15-18 months after launch and the potential for net sales to reach $100 million in the third year after launch. As well as the US launch costs including sales representatives, market research and data analysis, marketing spend and other US operational costs, the Group will also be incurring the costs of the main stage of the paediatric study which is expected to start in mid-2021 and last for 2-2½
years and cost around £4.5 million over that time. Royalty revenues from the Norgine licence agreement in Europe will also continue to grow steadily.

Tim Watts, Chief Executive Officer

Consolidated statement of profit and loss and other comprehensive income

for the year ended 31 December

	Notes	**2020 £000**	2019 £000
Revenue	5	**10,387**	719
Cost of sales		**(1,354)**	(485)

Gross profit		**9,033**	234
Operating costs - selling, general and administrative expenses	6	**(8,608)**	(6,773)
Operating profit/(loss) before research and development expenditure		**425**	(6,539)
Research and development expenditure		**(2,579)**	(2,496)
Operating loss		**(2,154)**	(9,035)
Financial income	7	**269**	18
Financial expense	7	**(1)**	(49)
Loss before tax		**(1,886)**	(9,066)
Taxation	9	**(744)**	266
Loss for the year		**(2,630)**	(8,800)
Attributable to			
Equity holders of the parent		**(2,630)**	(8,800)
Other comprehensive income			
Items that are or may be reclassified subsequently to profit or loss:			
Foreign currency translation differences - foreign operations		**(16)**	33
Total comprehensive expenditure for the year		**(2,646)**	(8,767)
Attributable to			
Equity holders of the parent		**(2,646)**	(8,767)
Total comprehensive expenditure for the year		**(2,646)**	(8,767)
Earnings per share			
Basic and diluted loss per share	8	**£(0.02)**	£(0.08)

Group balance sheet

at 31 December

	Notes	**2020 £000**	2019 £000
Non-current assets			
Intangible assets	10	**27,266**	29,898
Property, plant and equipment		**32**	26
		27,298	29,924
Current assets			
Inventories	11	**1,379**	948
Trade and other receivables		**619**	356
Current tax asset		**292**	950
Cash and cash equivalents		**2,940**	4,141
		5,230	6,395
Total assets		**32,528**	36,319
Current liabilities			
Trade and other payables		**(1,471)**	(3,547)
Other liabilities		**(753)**	(607)
Lease liabilities		**(28)**	(20)
		(2,252)	(4,174)
Total liabilities		**(2,252)**	(4,174)
Net assets		**30,276**	32,145
Equity			
Share capital	12	**1,764**	1,758
Share premium		**88,352**	88,352
Merger reserve		**28,358**	28,358
Currency translation reserve		**53**	69
Retained earnings		**(88,251)**	(86,392)
Total equity		**30,276**	32,145

These financial statements were approved by the Board of Directors on 28 April 2021 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 2019	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
Loss for the year	-	-	-	-	(2,630)	(2,630)
Other comprehensive income:						
Foreign currency translation differences	-	-	-	(16)	-	(16)
Total comprehensive expense for the year	-	-	-	(16)	(2,630)	(2,646)
Transactions with owners, recorded directly in equity						
Equity-settled share-based payment transactions	6				771	777
Balance at 31 December 2020	**1,764**	**88,352**	**28,358**	**53**	**(88,251)**	**30,276**

Group statement of cash flows

for the year ended 31 December

	2020 £000	2019 £000
Cash flows from operating activities		
Loss for the year	**(2,630)**	(8,800)
Adjustments for:		
Depreciation and amortisation	**2,705**	2,621
Equity-settled share-based payment expenses	**771**	456
Financial income	**(269)**	(18)
Financial expense	**1**	49
Unrealised foreign exchange losses	**(11)**	33
Income tax	**744**	(266)
	1,311	(5,925)
(Increase) in inventories	**(431)**	(839)
(Increase) in trade and other receivables	**(264)**	681
(Decrease)/increase in trade and other payables	**(2,075)**	999
Increase/(decrease) in other liabilities	**140**	(286)
Change in lease assets and liabilities	**8**	(2)
Income tax (paid)/received	**(89)**	1,306
Net cash flows from operating activities	**(1,400)**	(4,066)
Cash flows from investing activities		
Financial income	**3**	18
Acquisitions of intangible assets	**(23)**	(34)
Capitalised development expenditure	**-**	(1,350)
Net cash flows from investing activities	**(20)**	(1,366)
Cash flows from financing activities		
Interest paid	**(1)**	(49)
Leases - interest payment	**(4)**	(4)
Proceeds of share options exercised	**6**	26
Total cash outflow for leases	**(48)**	(176)
Net cash flows from financing activities	**(47)**	(203)
Net decrease in cash	**(1,467)**	(5,635)
Effect of exchange rate fluctuations on cash held	**266**	
Cash and cash equivalents at 1 January	**4,141**	9,776
Cash and cash equivalents at 31 December	**2,940**	4,141

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 Accounting Standards in conformity with the requirements of the Companies Act 2006 ("Adopted IFRSs").

The accounting policies set out below have been applied consistently to all periods presented in these financial statements. 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 2020 or 2019 but is derived from those accounts. Statutory accounts for 2019 have been delivered to the registrar of companies, and those for 2020 will be delivered in due course. The auditor has reported on those accounts; their reports were (i) unqualified, (ii) for the year ended 2019 included reference to a matter to which the auditor drew attention by way of emphasis without qualifying their report in respect of a material uncertainty in respect of going concern (2020: no reference to such a matter), and (iii) did not contain a statement under section 498 (2) or (3) of the Companies Act 2006.

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 £1.2 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

The group meets its day to day working capital needs from cash balances. It has no bank facilities.

At 31 December 2020 the Group held £2.9 million in cash. On 18 March 2021 shareholders approved an equity fundraise which raised £27.8 m net of expenses. The Group's unaudited cash balance at 31 March 2021 was £28.2m.

These financial statements have been prepared on a going concern basis, notwithstanding a loss of £2.6 million and operating cash outflows of £1.4 million for the year ended 31 December 2020. The directors consider this to be appropriate for the following reasons.

The Group is planning to launch and commercialise Accrufer® in the US during 2021 and to start the main stage of the paediatric clinical study. The Directors have considered the funding requirements of the Group through the preparation of detailed cash flow forecasts for 16 months from the date of approval of the financial statements including the Accrufer® US launch costs and prospective sales revenues and the costs of the paediatric study. The Directors' base case forecasts show that the Group's monthly cash flows start to turn positive within 15 months and that the recent fundraise will provide sufficient cash to allow the business to continue in operations throughout the forecast period. The Directors have also considered severe but plausible downside scenarios in which sales revenues fall below base case forecasts and a delay in [market penetration]. In these circumstances mitigating actions such as reduction of discretionary selling and marketing expenditure would be taken to preserve cash. The severe but plausible downside scenarios forecast that the Group's monthly cash flows start to turn positive within 15 months and that the recent fundraise and mitigating actions will provide sufficient cash to allow the business to continue in operations throughout the forecast period. The Directors do not believe that the ongoing coronavirus pandemic will significantly impact the revenues included in the cash flow forecasts.

Based on the above factors the Directors believe that the group will have sufficient funds to continue to meet its liabilities as they fall due for the forecast period and therefore have prepared the financial statements on a going concern basis.

Furthermore, the Directors also believe that other forms of finance, such as debt finance or royalty finance are likely to be available to the Group. However, the Directors have not included any such financing within their forecasts.

Basis of consolidation

The consolidated financial statements comprise the financial statements of the Group and its subsidiaries as at 31 December 2020.

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 and ASK Pharm licence agreements have been assessed as right-to-use licences on the grounds that the Group's activities after the agreements were signed in September 2018 and January 2020 respectively were not expected to significantly enhance the value of the asset to Norgine and ASK Pharm. The agreements contain three types of performance obligation:

- Execution of the licence - revenue from both contracts was recognised at the time the agreements were signed;
- Event-based milestones such as completion of the paediatric clinical study, approval of the product in China 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 milestones in either 2019 or 2020; 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 5% royalty on net sales 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 and foreign exchange gains and losses arising on cash balances held in currencies other than GBP.

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. 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.

Expenditure in relation to patent registration is capitalised and recorded as an intangible asset. Amortisation on the straight-line basis commences when patents are issued.

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	- over the assumed five-year life associated with the process development costs

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. Estimates and judgments
In the application of the Group's accounting policies, which are described in Note 2, management is required to make judgments, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources.
The significant judgments made in relation to the financial statements are:

Going concern
The Board has formed a judgment that it is appropriate to adopt the going concern basis of preparation for the Group and parent company. This judgment 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 Note 1.

Development expenditure

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

Development expenditure in 2020, 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.

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:

Estimate of recoverable amount of intellectual property acquired with Phosphate Therapeutics Limited - £17.4 million

The valuation of intellectual property acquired with Phosphate Therapeutics Limited in 2016 is based on cash flow forecasts for the underlying product, PT20 and an assumed appropriate cost of capital and other inputs, such as the size of the market in major markets, in order to arrive at a value in use for the asset. The realisation of its value is ultimately dependent on the positive outcome of a PT20 Phase III clinical study followed by regulatory approval and successful commercialisation of the asset. Whilst earlier PT20 clinical studies provide grounds for confidence that the Phase III study would be successful, this cannot be guaranteed. Work on the development of a suitable commercial formulation of the drug product is ongoing. In the event that commercial returns are lower than current expectations this may lead to an impairment. Recoverability of intangible assets from the PT20 CGU is a significant source of estimation. See Note 10 for sensitivity analysis of key assumptions in this valuation.

Estimate of recoverable amount of intellectual property associated with Feraccru® - intangible assets of £9.9 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 10 for sensitivity analysis of key assumptions in this valuation. The Group does not expect a reasonable range of sensitivities in the assumptions used to give rise to material differences within the recoverability of Feraccru®.

4. New standards and interpretations

There are no new standards and interpretations within the financial statements to note.

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® 2020 £000	**PT20 2020 £000**	**Central and unallocated 2020 £000**	**Total 2020 £000**	Feraccru® 2019 £000	PT20 2019 £000	Central and unallocated 2019 £000	Total 2019 £000
Revenue	**10,387**	**-**	**-**	**10,387**	719	-	-	719
Operating (loss)/profit	**424**	**(2,047)**	**(531)**	**(2,154)**	(6,421)	(1,908)	(706)	(9,035)
Financial income				**269**				18
Financial expense				**(1)**				(49)
Tax				**(744)**				266
Loss for the year				**(2,630)**				(8,800)

The revenue analysis in the table below is based on the country of registration of the fee-paying party. £9.7 million (2019: £0.1 million) of revenue is derived from licence upfront and milestone payments from commercial partners. The remainder of revenue is derived from royalties and the sale of goods.

	Year ended 31 December 2020 £000	Year ended 31 December 2019 £000
UK	**-**	141
Europe	**729**	578
Asia	**9,658**	-
	10,387	719

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

	Year ended 31 December 2020 £000	Year ended 31 December 2019 £000
Customer A	**9,658**	-
Customer B	**729**	592
Customer C	**-**	83
Other customers	**-**	44
	10,387	719

As at 31 December 2020	Feraccru® £000	PT20 £000	Central and unallocated £000	Total £000
Segment assets	**11,573**	**17,605**	**3,350**	**32,528**
Segment liabilities	**(1,267)**	**(41)**	**(944)**	**(2,252)**
Total net assets	**10,306**	**17,564**	**2,406**	**30,276**
Depreciation, amortisation and impairment	**671**	**2,034**	**-**	**2,705**
Capital expenditure	**-**	**-**	**-**	**-**
Capitalised development costs	**-**	**-**	**-**	**-**

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

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 2020 £000	Year ended 31 December 2019 £000
Selling costs	**281**	59
General administrative expenses	**5,622**	4,093
Depreciation and amortisation	**2,705**	2,621
	8,608	6,773

7. Financial income and expenses

	Year ended 31 December 2020 £000	Year ended 31 December 2019 £000
Financial income		
Net foreign exchange gains	**266**	-
Total interest income on financial assets measured at amortised cost	**3**	18
	269	18

	Year ended 31 December 2020 £000	Year ended 31 December 2019 £000
Financial expense		
Net foreign exchange losses	**-**	(47)
Total interest expense on financial liabilities measured at amortised cost	**-**	(1)
Bank charges	**(1)**	(1)
	(1)	(49)

8. Loss per share

	2020			2019		
	Loss £000	Weighted shares 000	Loss per share £	Loss £000	Weighted shares 000	Loss per share £
Basic and diluted	**(2,630)**	**117,234**	**(0.02)**	(8,800)	116,987	(0.08)

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 3,950,357 of share options were in issue under the Company's share option plans which potentially provide 3,950,357 additional Ordinary Shares (approximately 1.8% of the current share capital).

9. Taxation

Recognised in the income statement:

	Year ended 31 December 2020 £000	Year ended 31 December 2019 £000
Current income tax - UK	**292**	460
Current income tax - Overseas	**(966)**	-
Current income tax - adjustments in respect of prior years	**(70)**	(194)
Deferred tax	**-**	-
Total tax (charge)/credit	**(744)**	266

10. Intangible assets

Group	Feraccru® Patents and trademarks £000	Feraccru® development costs £000	Phosphate Therapeutics licences £000	Total £000
Cost				
Balance at 1 January 2019	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**
Additions - externally purchased	-	-	23	23
Additions - internally developed	-	-	-	-
Disposals	-	-	-	-
Balance at 31 December 2020	**2,055**	**9,943**	**27,070**	**39,068**
Accumulated amortisation				
Balance at 1 January 2019	**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**
Charge for the period	**94**	**527**	**2,034**	**2,655**
Disposals	**-**	**-**	**-**	**-**
Balance at 31 December 2020	**668**	**1,509**	**9,625**	**11,802**
Net book value				
31 December 2020	**1,387**	**8,434**	**17,445**	**27,266**
31 December 2019	1,481	8,961	19,456	29,898

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

	2020 £000	2019 £000
Feraccru®	**9,821**	10,442
Phosphate Therapeutics Limited	**17,445**	19,456
	27,266	29,898

Management has reviewed for impairment the carrying value of the intangible assets as at 31 December 2020 The intangible assets relate to two CGUs, being the Feraccru® business and the Phosphate Therapeutics Limited business. The recoverable amount for Feraccru® has been determined based on value-in-use calculations, using pre-tax cash flow projections for the period of the patents. The recoverable amount for PT20 has been determined based on value-in-use calculators using projections of the licensing income which could be derived from the product until 2034, being the current patent life of the product including 5 years supplementary patent protection. 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 royalty 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 profits arising from Shield's own sales in the US market. The forecast for the sales and costs in the US are based primarily on management's detailed planning, assuming Accrufer® is launched by the end of the second quarter 2021 and that US prescriptions of Accrufer® grows to around 7.5% of prescriptions for oral iron therapy by 2030. These forecasts are supported by third party sales forecasts. Sales forecasts in each territory have been derived from discussions with partners and potential partners, and from other third party market projections. A discount rate of 15% has been applied to the Group cash flows arising from these assumptions. The discount rate has not changed since the previous year as the change in risk is reflected in the cash flows which recognise the risks associated with a Shield-led launch of Accrufer® compared with the out-licensing model assumed in 2019. Sensitivity analysis shows that sales in the US would need to be reduced by around 75% from management's base case assumptions, with no reduction in costs, before an impairment of the carrying value of the intangible asset would be required. The Group therefore does not expect a reasonable range of sensitivities in the assumptions used to give rise to material differences within the recoverability of Feraccru®.

Phosphate Therapeutics Limited

The value in use of PT20, Phosphate Therapeutics Limited's main asset, has been based on cash flow forecasts of assumed 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 and assume that PT20 can reach around 20% of iron-based phosphate binder market by the end of its patent life. The resulting sales forecast has been 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 in the US assumed in 2025, and Europe, Japan and China assumed in 2026. 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. Using a 15% discount rate, management's base case sales forecasts would need to be reduced by 40% 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 market penetration.

11. Inventories

Group	**2020 £000**	2019 £000
Raw materials	**1,379**	928
Finished goods	**-**	20
	1,379	948

The cost of inventories recognised as an expense and included in cost of sales was £480,000 (2019: £418,000). Cost of sales includes royalties payable to Vitra Pharmaceuticals Limited.

12. Share capital

	2020 Number 000	£000	2019 Number 000	£000
At 1 January	117,189	1,758	116,426	1,746
Exercise of share options	431	6	763	12
Issuance of shares pursuant to placing	-	-	-	-
Issuance of shares pursuant to subscription	-	-	-	-
At 31 December	**117,620**	**1,764**	**117,189**	**1,758**

431,533 share options were exercised during the year (2019: 762,806).

13. Subsequent events

On 18 March 2021 the Company announced the successful completion of a Placing, Subscription and Open Offer which resulted in £29.2 million gross proceeds (£27.8 million net of expenses), being raised and 97,279,730 new shares being issued.

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