Improving Lives Together

Shield Therapeutics plc Annual report and accounts 2020

SHIELD
THERAPEUTICS PLC

Improving Lives Together

Shield Therapeutics 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.

Our 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 Beijing Aosaikang Pharmaceutical Co., Ltd., for the development and commercialisation of Feraccru®/Accrufer® in China, Hong Kong, Macau and Taiwan.

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INVESTMENT HIGHLIGHTS

Reasons to invest in Shield

Iron deficiency is a large, diverse and undertreated market

Existing oral and IV therapies have significant drawbacks, including poor tolerability and effectiveness (oral), and high cost, inconvenience and risk of iron overload (IV)

Feraccru®/Accrufer® has a unique oral formulation and has been shown to be effective, convenient and well-tolerated

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

Revenue

£10.4m

Loss for the year

£2.6m

Net cash at year end

£2.9m

Keep up to date
For more information on our business and all our latest news and press releases, visit us at:

shieldtherapeutics.com

Shield is planning to launch Accrufer® in the US in 2021, targeting a market of at least
10 million
iron deficiency patients

Accrufer® has a
90%
gross margin and the potential to reach $300m-$400m sales revenue in the US

Feraccru®/Accrufer® has patent protection until
2035

Downside protection has been achieved through European and Chinese licence transactions

Shield Therapeutics is a commercial stage specialty pharmaceutical company

Delivering innovative specialty pharmaceuticals to address significant unmet needs in the treatment of iron deficiency and hyperphosphatemia.

FERACCRU® ACCRUFER®

Listed on the London Alternative Investment Market (AIM), Shield's primary current focus is the development and commercialisation of **Feraccru®/Accrufer®**, a novel oral therapy for the treatment of iron deficiency (ID).

Feraccru®/Accrufer® is a low-dose oral iron capsule taken twice daily without food:

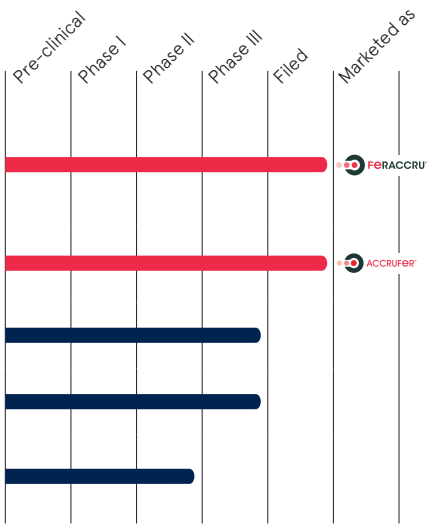
- ✔ Approved in the US and the EU
- ✔ Out-licensed for commercialisation in Europe and China

Patent protection until 2035

- ✔ Uniquely positioned to address unmet needs in iron deficiency patients:
  - ✔ Well-tolerated
  - ✔ Easily absorbed
  - ✔ High in iron availability
  - ✔ Effective in raising haemoglobin (Hb) and iron levels
  - ✔ Safe

OUR PRODUCT PIPELINE

Product	Indication	Recent or upcoming milestones
FERACCRU®	**Iron Deficiency in Adults** (Europe & Australia)	**Approved** for marketing in EU, UK, Norway, Iceland, Switzerland and Australia Commercialisation led by Norgine BV
ACCRUFER®	**Iron Deficiency in Adults** (USA)	**Approved** for marketing in USA Shield to launch in 2021
	Iron Deficiency Anaemia in Children (Europe/US)	Paediatric study to start in 2021
	Iron Deficiency in Adults (China)	Licensed to ASK Pharm. IND submission accepted by CDE
PT20 Iron-based phosphate binder	**Hyperphosphatemia**	Phase II pivotal study completed. Requires one further Phase III pivotal study to allow a NDA to be filed



PROGRESS WITH FERACCRU®/ACCRUFER®

↗ Learn more about the US opportunity on pages 8 and 9

US

- Approved by FDA for treatment of iron deficiency in adults
- £29m in fundraising completed in March 2021
- US team established
- Pre-launch activities ongoing
- US launch planned for summer 2021

Europe

- Licensed to Norgine for commercialisation
- Sales royalties of 25%-40%
- Sales milestones up to €50m
- On market in Germany, UK, Scandinavia and Belgium
- 2020 sales volumes in Germany and UK up 70% vs 2019, with £0.7m royalties
- Norgine reconfirming pricing and reimbursement strategy in France, Italy and Spain

China

- Licensed to ASK Pharm for development and commercialisation
- $11.4m upfront received in 2020
- IND application submitted; one Phase III 12-week study required in 120 IBD patients
- Potential approval and launch in 2023
- $11.4m due on approval
- Sales royalties of 10%-15%
- Sales milestones up to $40m

2020 – a major turning point

HANS PETER HASLER
Chairman

2020 was not an easy year, but Shield's prospects have been transformed for the better.

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 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-license 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, 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-license 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 Hoffmann, 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
Chairman
28 April 2021

How we operate

- The fundamental value in the business is the intellectual property embedded in Feraccru®/ Accrufer® and PT20 – i.e. the patents, know how and data from the clinical and pre-clinical studies
- Management's role is to exploit that intellectual property in the most effective way for the benefit of patients and the Group's shareholders
- Commercialisation
  - Commercialisation of Feraccru® outside the US is out-licensed to commercial partners. Our financial returns come from upfront payments, development and sales milestones, and sales royalties
    - Norgine BV is our commercialisation partner for most of Europe, Australia and New Zealand
    - Jiangsu Aosaikang Pharmaceutical Co. Ltd ("ASK Pharm") is our partner for China, Taiwan, Hong Kong and Macau
  - In the US we will launch Accrufer® ourselves. We have established a Shield US legal entity and are building a US team who will lead the launch and commercialisation using a mix of in-house employees and out-sourced service providers. By the time of launch we plan to have between 50-60 people working exclusively for Shield in the US, dedicated to the launch of Accrufer®
- Development and manufacturing
  - Product development and manufacturing in terms of strategy, planning and monitoring are led by our experienced UK team which has around 15 employees, but the bulk of these activities are outsourced to Contract Research and Manufacturing Organisations (CROs, CMOs)
- The Senior Executive Team comprises:
  - Tim Watts, Chief Executive Officer
  - Hans-Peter Rudolf, Chief Financial Officer
  - Brian Groch, President Shield US and Chief Commercial Officer
  - Lucy Huntington-Bailey, General Counsel and Company Secretary
  - David Childs, VP Commercial Operations
  - Jackie Mitchell, VP Clinical and Regulatory Affairs

The unmet need of iron deficiency

Up to one-third of the global population is affected by iron deficiency (ID). But with drawbacks in existing treatment options, many physicians agree there is an unmet need in the market for an effective, convenient and well-tolerated oral iron replacement therapy.

Maintaining normal iron levels in the blood is essential to the smooth running of multiple metabolic processes and the optimal functioning of the human body. Iron enables DNA synthesis, electron transport, cellular respiration, cell proliferation and differentiation, while also supporting immune response to bacterial infection. Iron is a key component in the production of haemoglobin (Hb), the blood protein that transports oxygen from the lungs to cells and tissues.

Insufficient levels of iron, or decreased total iron in the body, is defined as iron deficiency (ID). ID is caused by malnutrition, bleeding or reduced ability to absorb iron, and is associated with a range of diseases, notably: inflammatory bowel diseases (IBD), such as ulcerative colitis and Crohn's disease; chronic kidney disease (CKD); congestive heart failure (CHF); and cancer. It is often seen in pregnant and pre-menopausal women.

Left untreated, ID can lead to fatigue, neurobehavioural disorders and cognitive impairment. It is also the most common cause of anaemia, or iron deficiency anaemia (IDA). But as ID is a common comorbidity of other medical conditions and not the main cause of disease, it is often overlooked and undertreated.

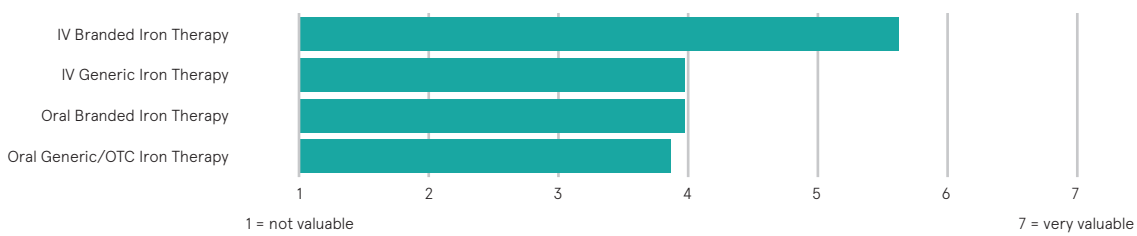
Iron deficiency treatment options

Once diagnosed, ID is typically treated with either generic oral iron salt products or intravenous (IV) iron therapy. Oral iron salts are usually prescribed as first line treatment because they are convenient and inexpensive. IV therapy, which is less convenient and more costly to administer, is normally used as a second line treatment.

Market research confirms unmet need

The significant unmet need in iron deficiency therapy is confirmed by market research among US physicians, who highlight issues linked principally to the poor effectiveness and tolerability of oral products and the inconvenience of IV. As the chart below illustrates, physicians are lukewarm about oral products and older, generic IV formulations but see recent IV formulations providing most value amongst existing treatments.

Existing therapy, average value ratings



First line treatment

Oral iron salts account for well over 80% of patient prescriptions for ID therapy. In the US, there are around 10-11 million annual prescriptions of oral products. These prescriptions are primarily generic iron salts which have not changed for many years.

Second line treatment

For patients who cannot tolerate oral iron salts, or for whom iron salts are ineffective, the alternative is intravenous (IV) iron infusion. This process typically involves the infusion of between 750mg – 1,500mg of iron between one and three IV sessions in a hospital or clinic. Between 2014 and 2019, the US IV iron therapy market grew at a compound annual growth rate of 16%, reaching around $1.2 billion. Over 90% of the US iron therapy prescription market in value terms now comes from IV therapy.

The unmet need

For both oral iron salts and IV treatments there are significant shortcomings and side effects.

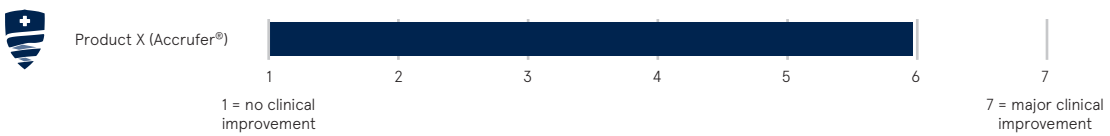
For oral iron salt products, the clear issues are poor tolerability, inefficient absorption and efficacy, and consequently poor compliance by patients. Among the adverse events, gastrointestinal (GI) side-effects are the most commonly reported in patients. When oral iron salt drugs are administered, the iron must first dissociate from the salt to allow the iron to be absorbed. This free iron often chelates to form insoluble clumps, producing damaging free radicals which can cause nausea, bloating, diarrhoea, constipation and, more seriously, damage to the gut lining, which is a particular issue for IBD patients.

In addition, many patients with ID are often simultaneously treated with medicines that raise the pH level in the stomach. This further reduces the effect of salt-based oral iron drugs, which require acidic conditions to be absorbed.

While IV iron therapy has generally fewer associated GI adverse effects, it does pose a risk of iron overload, allergic reaction and infection. In some rare cases, serious complications such as anaphylactic shock can occur. As a result, regulators require IV therapy to be administered in hospitals or clinics with resuscitation facilities, which leads to inconvenience and expense.

However, when presented with Accrufer's® profile – i.e. a well-tolerated and effective oral product – they perceive a high level of clinical improvement over existing therapies. Accrufer® was viewed favourably as providing clinically meaningful effectiveness, with a good tolerability profile. It was also seen to be preferable to both the oral iron salts and IV infusions.

Level of clinical improvement rating



Feraccru®/Accrufer® – convenient, effective and well tolerated

Feraccru®/Accrufer® is a novel oral product that addresses the needs of patients who cannot tolerate existing oral iron products and offers a clear alternative to IV iron therapy.

Composition and mechanism of action

- Feraccru®/Accrufer® is formulated as a capsule of ferric maltol containing 30mg iron which is taken twice daily
- Ferric maltol is a tightly bound iron complex which does not dissociate so it is well tolerated and delivers the iron to the duodenum where the body absorbs iron naturally
- Unabsorbed ferric maltol passes harmlessly through the digestive system as an unaltered complex and is excreted

Feraccru®/Accrufer® therefore offers a convenient, well tolerated and efficacious oral treatment alternative to IV iron therapy, without the need for hospital-based administration.

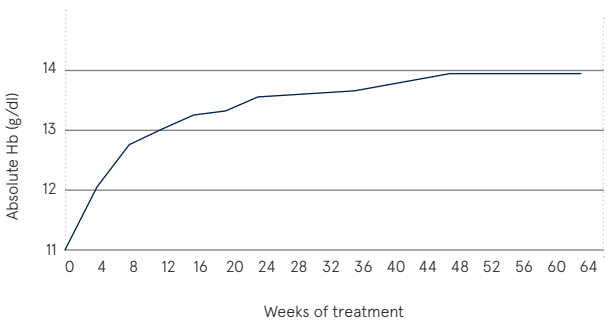
Clinical studies have demonstrated efficacy, tolerability and safety

- Two Phase III pivotal studies in patients suffering from IBD and CKD were used for regulatory approval in Europe and the US. These studies demonstrated that Feraccru®/Accrufer®:
  - Restores Hb levels quickly – over the 12 and 16 weeks set as the primary end points
  - Maintains Hb levels over the 40/52 weeks follow up periods
  - Is well-tolerated by patients

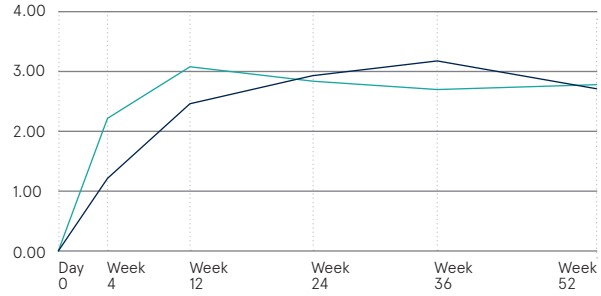
The AEGIS-IBD chart opposite summarises the increase in Hb levels seen in that study.

- In a Phase III "Head to Head" study, Feraccru®/Accrufer® was compared against the leading IV iron therapy. The headline results are shown in the chart opposite
  - Although IV iron restores Hb levels slightly faster than Feraccru®/Accrufer® over the first 12 weeks, the mean increase in Hb levels achieved by Feraccru®/Accrufer® of more than 1g/dL by week 4 and almost 2.5g/dL by week 12 are clinically relevant increases
  - Over the subsequent 40 week follow up period, Feraccru®/Accrufer® maintained the increase in Hb at levels comparable to IV iron
  - BUT, unlike patients on the IV arm, patients receiving Feraccru®/Accrufer® did not require visits to hospitals or clinics
  - On the IV arm:
    - 82% of patients required more than one IV infusion in the 1st 12 weeks
    - 58% of the patients who were monitored from week 12 onwards required at least one further IV infusion

AEGIS-IBD study results
Absolute levels of Hb seen in Feraccru®arm



AEGIS-H2H study results
Mean Change from Baseline Hb Concentration



Paediatric study

- Both the EMA and the FDA require us to evaluate the safety, tolerability and efficacy of Feraccru®/ Accrufer® in children
- During 2020 we successfully completed the development of a suitable oral suspension formulation and tested this in healthy adult volunteers for equivalence with the adult capsule formulation
- During 2021 we expect to start recruiting 110 subjects into the main study which is likely to take around 2½ years
- A positive outcome will lead to the product's label being expanded to include children

The US market opportunity

In the US there are estimated to be at least 10 million patients with iron deficiency across multiple disease areas. Of these patients, around 5 million are estimated to be treated for iron deficiency anaemia in a given year. The market is undertreated due to the shortcomings of existing therapies, and Shield is preparing for the US launch and commercialisation of Accrufer®. This novel therapy is an effective, well-tolerated and convenient oral product which has the potential to play a major role in this high-growth market.

Currently in the US, there are over 10 million annual prescriptions of oral iron therapy and around 2.3 million IV infusions. Between 2014 and 2019, IV infusions grew at a compound annual growth rate of 16%. However, these therapies are sub-optimal, comprising either poorly tolerated iron salts with limited effectiveness or IV iron, which is inconvenient to access and costly to administer. The market opportunity for an effective, accessible and easy-to-use therapy such as Accrufer® is therefore significant.

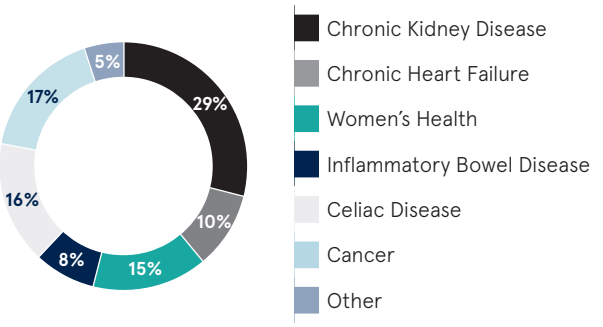
FDA-approved and US launch-ready, Accrufer® offers an effective, well-tolerated oral iron replacement therapy. It is both convenient for patients and effective in restoring and maintaining iron and haemoglobin levels. As such, it is the ideal candidate to address the unmet needs within the US market – needs which have been confirmed by market research among iron therapy prescribers.

Having raised the finance required for the US launch, we now stand to benefit from a high-margin product that is patent protected until 2035. We believe Accrufer® has the potential to generate $100 million in US sales within just three years from launch with only modest market penetration, rising to $300 million - $400 million in sales by year 5 or 6.

Iron deficiency in the US

In the US, around 10 million patients are at risk of iron deficiency across multiple therapeutic areas. These include:

- **Chronic Kidney Disease (CKD)**
  There are 37 million CKD patients (dialysis and non-dialysis) in the US. Around 50% of these patients are at risk, while roughly 2.5 million patients have Stage 3 or Stage 4 CKD with IDA.
- **Women's health**
  One in five US women of childbearing age are at risk of iron deficiency, with many experiencing heavy uterine or post-partum bleeding.



- **Gastrointestinal disorders**
  Iron deficiency affects up to three-quarters of patients with Inflammatory Bowel Disease (IBD).
- **Oncology**
  Between 32%-60% of cancer patients are at risk; those with solid tumours and hematological malignancies are particularly susceptible.
- **Cardiology**
  Iron deficiency may also affect around 17% of Chronic Heart Failure (CHF) patients.

Due to its broad label, Accrufer® allows for application across all these indications and patient populations, offering a viable iron replacement therapy in a wide range of cases. In addition, COVID-19 is changing healthcare delivery and recommendations for many at-risk patients. In the coming years, increased use of telemedicine, and a shift from IV treatment to oral therapies and/or home treatment options, provide significant growth potential for Accrufer® in the US.

US launch preparation

During the second half of 2019 and first nine months of 2020, we fully explored the possibility of out-licensing Accrufer® to a partner who could launch and commercialise the product in the US.

Although we twice came close to concluding licence transactions, these did not proceed to completion due to adverse business events specific to the counterparties concerned and unrelated to Accrufer®. We also had serious interest from numerous other parties, but were unable to find a partner capable of both commercialising the product successfully across the broad range of therapy areas and offering us acceptable financial terms. However, based on these multiple interactions, we came to the conclusion that in order to generate best value returns to Shield's shareholders, we should launch Accrufer® ourselves in the US.

During the last quarter of 2020, we recruited four experienced US commercial managers led by Brian Groch, who has now been appointed as Shield's US President and Chief Commercial Officer. Brian had previously been employed by a company contemplating licensing Accrufer®, and was therefore already advanced in his thinking about how to launch the product.

Since the £29 million fundraise completed in March 2021, we have been able to finance and ramp up launch preparation activities. These include:

- Further detailed analysis of the prescribers of iron therapies and their treatment pathways, which has helped us to target high prescribers and build key marketing messages
- Appointment of a contract sales organisation to provide a sales force of (initially) 30 representatives, with regional management and national account managers who will be fully dedicated to Accrufer®
- Recruitment of other experienced US employees to support activities including medical affairs, market access, marketing and supply chain logistics
- Designing and preparing scientific and promotional materials, a digital marketing platform and website
- Launch stocks of Accrufer® packs released for sale

The US launch of Accrufer® is expected by the end of June 2021.

US sales potential

We estimate that, on average, patients taking Accrufer® are likely to use around four packs per annum, although there will be a wide variety of usage by individual patients

We also estimate that the net selling price of each pack – one month's supply – will be about $250

Which means:

- **An average patient could generate $1,000 in sales revenue annually**
- **To achieve $100 million annual revenues would require 100,000 patients, only 2% of the estimated 5 million US patients who are currently treated annually**

Focused on strategy

Delivered in 2020

Out-license commercialisation of Accrufer® in the US

✗ Multiple licence discussions with third parties led the Board to the conclusion that shareholder value would be better served by launching the product ourselves.

Initiate paediatric Phase III study

✔ 1st stage of study, to confirm equivalence of paediatric formulation with adult capsule, successfully completed.

Out-license commercialisation of Feraccru® in other markets

✔ Feraccru® out-licensed to ASK Pharm in China.

Although priority was given to the US during 2020 we have received interest from potential partners in many other markets.

Ongoing focus for 2021

Launch Accrufer® in the US

Preparations for launch in the US are underway.

Continue paediatric Phase III study

Main paediatric study to start in Summer 2021.

Continue to out-license commercialisation of Feraccru® in other markets

Discussions with potential partners in several markets are underway.

Re-start development of PT20

PT20 formulation development to start in H1 2021.

Keep up to date
For more information on our business and all our latest news and press releases, visit us at:

shieldtherapeutics.com

FINANCIAL

Revenue

£10.4m

Description

The Group measures revenue as a key financial metric.

Performance

Revenues in 2020 and 2018 benefitted from licences upfront receipts from ASK Pharm and Norgine respectively. In 2019, revenues were predominantly from royalties rising on European sales by Norgine.

Loss for the year

£2.6m

Description

The Group's loss for the financial year measures its overall financial performance during the period.

Performance

Losses in 2020 and 2018 were reduced by the licence upfront receipts from ASK Pharm and Norgine.

Net cash at year end

£2.9m

Description

Given the funding requirements of the business to ensure successful commercialisation, the availability of cash is considered to be a key metric.

Performance

The Group closed 2020 with £2.9 million cash but has since raised £29.2 million gross proceeds from a fundraise completed in March 2021.

NON-FINANCIAL

Employees (year end)

16

Description

Given the strategic objectives of the Group between 2018 and 2020, headcount has been considered to be a key indicator of central cost control and the appropriateness of the Group's structure.

Performance

The Group's headcount has been tightly managed between 2018 and 2020 to keep costs under control.

European sales volume growth

+70%

Description

The Group monitors the packs being sold in Europe.

Performance

As at 31 December 2020, Feraccru® had been launched in Germany, the UK and Scandinavia. Sales volume growth was 70% in 2020, following 66% in both 2019 and 2018.

Transformation underway

TIM WATTS
Chief Executive Officer

2020 and early 2021 has been a truly transformational period for Shield during which the Group's strategy for commercialising Accrufer® in the US evolved from an out-license approach to the decision to launch the product ourselves. I believe this will be very beneficial for Shield's shareholders.

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-license 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-license 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-license 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 (Hb) 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 to 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.

Commercialisation of Feraccru®/Accrufer® continued

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 (Hb) 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 twelve 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-license the product in markets outside the US, Europe, China and Australia/New Zealand.

Revenue

£10.4m

Loss for the year

£2.6m

Net cash at year end

£2.9m

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 11) 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 2019: £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

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
28 April 2021

The Board ensures that all of the key risks are understood and appropriately managed in light of the Group's strategy and objectives.

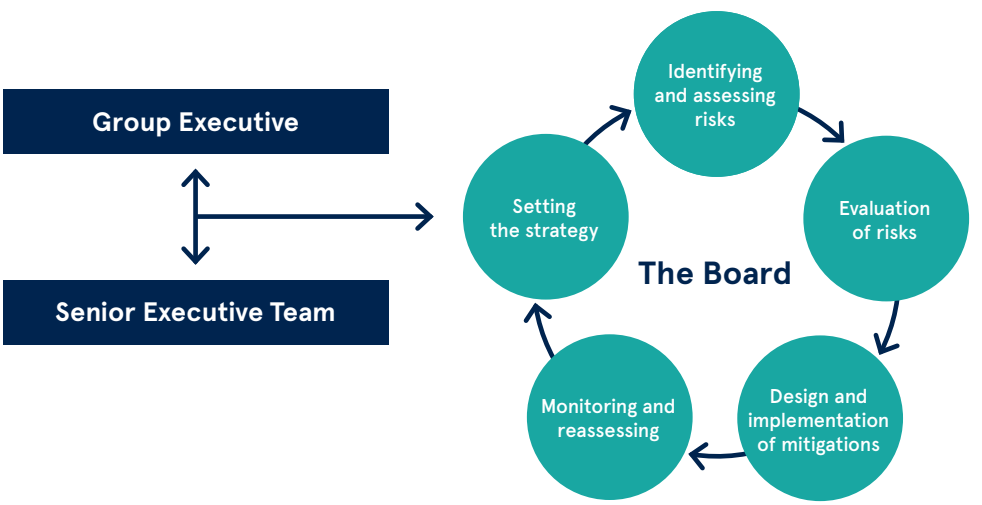
Risk management framework

The management of risk is a key responsibility of the Board of Directors. The Board ensures that the key risks are understood and appropriately managed in light of the Group's strategy and objectives, and that an effective internal risk management process, including internal controls, is in place to identify, assess, minimise and manage significant risks. The Audit Committee oversees risk management on behalf of the Board.

The key policy objectives include:

- Establishing the importance of risk management in the successful operation of the business;
- Ensuring that the risk appetite of the Board is fully understood by senior executives;
- Understanding the business risks that the Group faces, and ensuring that they are appropriately managed or mitigated in line with the risk appetite of the Board;
- Assigning responsibility for risk management and specific risks in the business; and
- Managing systematic risks within the organisation by maintaining a system of internal controls.

Operationally, the senior executives are responsible for identifying and managing risks in their functional areas. The senior executives meet each week which provides a further forum for risks to be identified and managed, including recording risks in the Group's risk register. The key risks identified in the Group's risk register are summarised for Audit Committee meetings and included on the full Board's agenda at least twice annually.



The current principal risks are:

Key ⇔ No change ↗ Increased ↘ Decreased N New risk

Risk description	Change	Potential impact	Mitigation
Failure to achieve significant sales of Accrufer® in the US	N	Material adverse impact on the Group's financial condition and prospects.	Experienced commercial team has been recruited in the US; detailed planning and monitoring.
Costs of launching and promoting Accrufer® in the US are significantly greater than planned	N	Higher than expected costs could lead to requirement for further funding.	Detailed planning of launch and commercialisation activities; forecasts updated frequently.
Ability to attract and retain key staff and members of management team	↗	Shield's ability to commercialise Accrufer® in the US and manage its relationships with its suppliers and commercialisation partners could be undermined by failure to retain or recruit key employees.	The Group endeavours to offer attractive remuneration and working environment to employees.
Commercialisation partners fail to achieve Feraccru®/Accrufer® potential	⇔	Shield will under-deliver shareholder value as royalties and sales milestones will not be maximised.	Commercialisation out-licensing agreements contain performance measures to enable Shield to monitor the performance of partners.
Disruption to product supply	⇔	Failure to supply product to the US and to commercialisation partners could undermine sales potential.	The Group holds substantial quantities of raw materials and has clearly defined agreements with its CMO suppliers.
CRO and CMO non-compliance with GxP regulatory requirements	⇔	Non-compliance with GxP by our outsource providers could invalidate results of clinical studies or result in disruption to product supply.	The Group has detailed Quality Management Agreements with providers and closely monitors performance against these.
Failure to protect IP	⇔	If a patent were to be successfully challenged, it could limit the commercial value of Feraccru®/Accrufer®.	The Company constantly monitors its patents and robustly defends challenges to them.
COVID-19 disrupts business operations	↘	Employees may need to self-isolate or become ill; meetings with third parties may be disrupted; supply chain may be disrupted.	Employees can work from home; meetings held by video conference, and the Company holds substantial quantities of raw materials.

TIM WATTS
Chief Executive Officer

Tenure
One year

Skills and experience
Tim has worked in the pharmaceuticals and biotech sectors since 1990 when he joined ICI Pharmaceuticals which evolved into AstraZeneca. In his 17 years with AstraZeneca he worked primarily in Finance roles supporting commercial operations, in particular as VP Finance in the International Sales and Marketing Organisation, but also spent two years in a commercial role. His last position in AstraZeneca was as Group Financial Controller. In 2007 Tim became CFO of Archimedes Pharma, a UK-based private equity backed specialty pharma company where he was Interim COO for a period, and then in 2012 joined Oxford BioMedica PLC, a UK-listed gene and cell therapy company, as CFO. Tim joined Shield as CFO in August 2018 and was appointed CEO in April 2020.

External appointments
Tim is a non-executive director of Fusion Antibodies PLC.

HANS PETER HASLER
Non-Executive Chairman

Tenure
Three years

Skills and experience
Hans Peter was the Chief Executive Officer of Vicarius Pharma AG, a privately held European Bio-Pharma company until 2020. His prior experiences include Elan Corporation, Dublin, where he was Chief Operating Officer, and Biogen Inc., Boston, where his positions included Chief Operating Officer, and EVP, Head of Global Neurology and International. Previously, he was at Wyeth Pharmaceuticals, Radnor, PA, as Senior Vice President, Chief Marketing Officer and beforehand Managing Director of Wyeth Group Germany, Münster. He holds a Federal Swiss Commercial Diploma and a Marketing Manager Certificate from the Swiss Institute of Business Economy SIB, Zurich.

External appointments
Hans Peter is Chairman of the Board of HBM Healthcare Investments AG in Switzerland (SIX:HBMN) and a Director of Minerva Neurosciences in Boston (NASDAQ:NERV) and Gain Therapeutics, Bethesda (NASDAQ:GANX).

Committee membership
A R N

PETER LLEWELLYN-DAVIES
Non-Executive Director

Tenure
Five years

Skills and experience
Peter has over 25 years' experience in international M&A deals, company turnarounds, licensing transactions and financing activities including IPOs with particular experience in chemical and healthcare industries. He is currently CEO/CFO of Apeiron Biologics AG. Peter was CFO/CBO of Medigene AG between 2012 and 2016 and was fundamental in the turnaround process by out-licensing marketed and legacy products. Prior to that he was CFO of Wilex AG, having orchestrated its IPO in 2006. Peter read Business Management, Banking, Marketing and Controlling in London, St. Gallen and Munich, and has a certificate in Business Studies from the University of London.

External appointments
Peter is a Fellow of the London Institute of Banking and Finance, a founder of Accellerate Partners and is President of the Austrian biotech industry association BIOTECH AUSTRIA.

Committee membership
A N

ROLF HOFFMANN
Non-Executive Director

Tenure
Three years

Skills and experience
Rolf brings to Shield over 30 years of international pharmaceutical experience, having served in several senior roles in the industry, most recently twelve years with Amgen as Senior Vice President of Commercial Operations for the United States, and before that as SVP International and Europe. He started his pharmaceutical career at Eli Lilly as a sales representative, progressing to senior positions including President of Latin America Operations and General Manager in Germany. Rolf holds an MBA from the University of North Carolina and a master's degree from the University of Cologne and is Adjunct Professor at UNC Kenan-Flagler Business School.

External appointments
Rolf is currently Chairman of Biotest AG and sits on the boards of Genmab AG, EUSA Pharma Inc., Paratek Pharmaceuticals Inc, and Trizell Holding SA.

Committee membership
R N

DR CHRISTIAN SCHWEIGER, MD. PhD
Non-Executive Director

Tenure
One year

Skills and experience
Christian was co-founder of Shield in 2008 and the Company's first Chief Medical Officer, responsible for the development of ferric maltol. Christian is an entrepreneurial senior medical affairs and clinical development executive with substantial experience working with both large and small pharmaceutical companies. He is also Lecturing Professor in Pharmaceutical Medicine at the University of Essen and actively working with different international patient and professional associations.

External appointments
Christian is a director of ARXX Therapeutics and TACHRIS AG.

Committee membership
N

Key
- A Audit Committee
- N Nomination Committee
- R Remuneration Committee
- ☐ Committee Chair

HANS PETER HASLER
Chairman

The Board is committed to the highest standards of corporate governance and to maintaining a sound framework for the control and management of the Group's business.

Leadership
The role of the Board
The Board is committed to the highest standards of corporate governance and to maintaining a sound framework for the control and management of the Group's business. It is responsible for leading and controlling the activities of the Group, with overall authority for the management and conduct of the Group's business, together with its strategy and development. The Board is also responsible for ensuring the maintenance of a sound system of internal control and risk management (including financial, operational and compliance controls), reviewing the overall effectiveness of controls and systems in place, the approval of the budget and the approval of any changes to the capital, corporate and/or management structure of the Group.

The Board holds meetings at least five times a year, with additional ad hoc meetings as required. A full briefing pack is circulated to the Board for review prior to each meeting. The Board delegates authority as appropriate to its Committees and members of the Group's management team.

AIM-listed companies are required to apply a recognised corporate governance code. Since November 2019 the Company has applied the Quoted Companies Alliance Corporate Governance Code (the "QCA Code"). The Board considers that it has complied with the QCA Code throughout the year.

Effectiveness
Composition of the Board
The Board was comprised of the following Directors during the course of the year, and up to the date of approval of this report.

Role	Name	Committee membership
Chairman	James Karis[(i)]	Member of Remuneration and Nomination Committees.
Chairman	Hans Peter Hasler[(ii)]	Chair of Nomination Committee. Member of Audit Committee.
CEO	Carl Sterritt[(iii)]	
CEO	Tim Watts[(iv)]	
Independent NED	Peter Llewellyn-Davies	Chair of Audit Committee. Member of Nomination Committee.
Independent NED	Rolf Hoffmann	Chair of Remuneration Committee. Member of Nomination Committee.
NED	Christian Schweiger[(v)]	

(i) Resigned 18 June 2020

(ii) Appointed 18 June 2020

(iii) Resigned 22 April 2020

(iv) Appointed 27 April 2020

(v) Appointed 26 June 2020

Effectiveness continued

Composition of the Board continued

James Karis resigned as Company Chairman with effect from 18 June 2020. Hans Peter Hasler was appointed as Company Chairman with effect from 18 June 2020, following the resignation of James Karis on that date. Hans Peter joined the Board in 2018 as an independent Non-Executive Director and was independent at the time of his appointment as Chairman.

Carl Sterritt resigned as CEO and from the Board on 22 April 2020. Tim Watts was appointed as CEO on 22 April 2020 and formally joined the Board on 27 April 2020.

There is a division of responsibilities between the roles of Chairman and Chief Executive Officer.

Christian Schweiger was appointed as a Non-Executive Director on 26 June 2020. He currently owns 5,665,580 ordinary shares of £0.015 each in the Company representing 2.6% of the Company's issued share capital, and therefore is not considered to be independent.

No Director holds a directorship of a FTSE 100 company.

Directors are re-elected at the first Annual General Meeting (AGM) following their appointment and are subject to annual re-election. Resolutions sent to shareholders proposing their re-election are accompanied by an explanation from the Board of their suitability for the post. The ongoing training needs of Directors are reviewed during the course of each year.

Details of attendance at Board and Committee meetings during the financial year are as follows:

2020 meetings	Number of meetings	Attendance
Main Board	7	All Directors attended
Audit Committee	3	All Committee members attended
Remuneration Committee	2	All Committee members attended
Nomination Committee	2	All Committee members attended

Due to the significant matters facing the Company during 2020, the Non-Executive Directors met frequently with the CEO and Company Secretary during the year.

The Non-Executive Directors also meet without the CEO present on an ad hoc basis during the course of the year. The Non-Executive Directors consider the performance of the CEO and the performance of each Non-Executive Director is considered by the remaining Non-Executive Directors. The Company does not currently operate with a named Senior Independent Director; however, all Non-Executive Directors are available to shareholders if required. Given the size of the Board and the shareholder structure, this is considered to be appropriate.

Independence of Non-Executive Directors

A majority of the Company's Directors are Non-Executive Directors and Rolf Hoffmann and Peter Llewellyn-Davies are considered to be independent. At IPO, W. Health LP signed a relationship agreement with Shield permitting it to appoint a Director to the Board so long as it holds over 20% of Shield's issued share capital (W. Health presently holds 26% of Shield's issued share capital). Although Peter Llewellyn-Davies was put forward for election by W. Health, he was nevertheless appointed independently and does not represent W. Health.

Hans Peter Hasler joined the Board in July 2018. Although he had served until January 2018 as Non-Executive Director of AOP, a commercial partner and significant shareholder in Shield, the Board considered Mr Hasler to be independent at the time of his appointment as he was no longer serving as a member of AOP's board and did not represent AOP's interests. He was still considered to be independent at the time of his appointment as Chairman in June 2020.

Christian Schweiger was appointed as a Director in June 2020. As Dr Schweiger was a co-founder and had been an employee of the Company, and at the time of his appointment he held 3.5% of the Company's share capital, he is not considered to be independent.

Appointments to the Board

The Nomination Committee is comprised of the Chair and the other Non-Executive Directors. New Directors received a formal induction following their appointment.

Re-election of Directors and term of service

Details of the proposed re-election of Directors and the terms of their service contracts/letters of appointment are provided within the Directors' remuneration report on page 31.

Directors' service contracts and letters of appointment, outlining their roles and responsibilities, are available for shareholders to inspect at the Company's registered office.

Information and support for Directors

Directors receive an induction on their appointment and ongoing briefings and training relevant to their roles.

In addition to the services of the Company's retained professional advisors, Directors have access to independent professional advice at the Company's expense where they judge it necessary to discharge their responsibilities as Directors.

The Board has the benefit of third-party qualifying indemnity insurance and has access to advice from the Company Secretary and the Group's external legal counsel.

Accountability

Composition of the Audit Committee

The Audit Committee is comprised of Peter Llewellyn-Davies and Hans Peter Hasler. Peter Llewellyn-Davies is Chair of the Committee and is considered to be independent and to have recent relevant financial experience, having previously held the role of CFO of other companies. Hans Peter Hasler's position on the Audit Committee pre-dates his appointment as Chairman when he was considered to be independent. The Company recognises that the Chairman's continued membership of the Committee is not best practice and will address this when the opportunity arises to appoint another Director with relevant experience. The Committee has written terms of reference, which are available for inspection on request to the Company Secretary. The activities of the Audit Committee, including those in relation to the Group's external auditor, are described in the audit and risk report on pages 27 and 28.

Risk management and internal control

The Board has overall responsibility for the adequacy of the Group's internal control arrangements and consideration of its exposure to risk. It approves and adopts the annual update to the Group's risk management plan, following recommendations made by the Audit Committee. The Directors have assessed the principal risks facing the Company and actions taken to mitigate them on pages 20 and 21 of the Annual Report.

Remuneration

The role of the Board and its Remuneration Committee in establishing a policy on Executive remuneration and an explanation of the level and components of remuneration are provided in the Directors' remuneration report on pages 29 to 33.

Engagement with stakeholders

The Company endeavours to communicate with stakeholders through a number of channels. Senior management and, if required, the Non-Executive Directors meet major shareholders on a regular basis. Management also frequently holds one-to-one meetings with institutional investors, including non-shareholders, and presents at both institutional and retail investor conferences. In addition, on a regular basis management records video and audio interviews about the business which are distributed through a variety of channels such as Proactive Investor and Vox Markets. The Company's presentations and recordings are published on the Company's website. The Company is also covered by several analysts whose research notes are widely available to shareholders and potential investors.

General meetings

Details of the Annual General Meeting (AGM) are provided in the Directors' report on page 35. Separate resolutions are proposed at the AGM for each substantially separate issue and a resolution will be proposed for approval of the Annual Report. Proxy voting is available for general meetings of the Company.

The Directors have assessed the principal risks facing the Company and actions taken to mitigate them on pages 20 and 21 of the Annual Report.

Hans Peter Hasler
Chairman
28 April 2021

PETER LLEWELLYN-DAVIES
Audit Committee Chair

The Audit Committee's responsibilities include monitoring of the financial integrity of the financial statements of the Group and the involvement of the Group's auditor in that process.

The Audit Committee
The Audit Committee's responsibilities include:

- Oversight of the risk management framework and regular risk reviews;
- Monitoring of the financial integrity of the financial statements of the Group and the involvement of the Group's auditor in that process;
- Reviewing the effectiveness of the Group's internal controls and risk management systems and overseeing the process for managing risks across the Group, including review of the Group's corporate risk profile; and
- Oversight of the Group's compliance with legal requirements and accounting standards and ensuring that an effective system of internal financial control is maintained.

Activities of the Audit Committee
The Committee met formally on three occasions during 2020.

In May 2020 the Committee met to receive the report from KPMG on the audit of the 2019 financial results, and to review the draft preliminary results announcement and the draft 2019 Annual Report. Other matters discussed at the meeting included a review of the Group's risk management procedures and the current risk register and updates to the Group's Financial Position and Prospects Procedures Memorandum (FPPP) and the Committee's Terms of Reference. The key audit issues discussed at the meeting were:

- The valuation of intangible assets, in particular that of PT20 – the Committee concluded that no impairment was required, based on a risk adjusted analysis of the commercial prospects for PT20 which had been prepared by management;
- The valuation of the investment in the parent company books of the carrying value of its subsidiaries – the Committee concluded that the carrying value was justified by the commercial prospects for Feraccru® which were supported by the licence agreements with Norgine and ASK Pharm to commercialise Feraccru® in Europe and China and the US approval of Accrufer®; and
- Going concern – the Group's latest cash flow forecast demonstrated sufficient cash resources to last until March 2021. Although the Group had good prospects of achieving licensing deals for the product with upfront payments which could extend the cash runway, the Committee noted that there was a material uncertainty which needed to be appropriately disclosed in the 2019 Annual Report. On this basis the Committee concluded that it was appropriate to prepare the 2019 financial statements on the going concern basis.

Activities of the Audit Committee continued

In September 2020 the Committee met to consider the draft announcement of the half year financial results. The main issues discussed were again the valuation of PT20 and going concern. Regarding going concern, management's internal forecasts showed that the cash runway, by including actions to slow the rate of spend, could extend into the fourth quarter of 2021 and consequently the Committee concluded that the use of the going concern basis of preparation was appropriate for the interim results.

The Committee met again in December 2020. The main topics discussed were:

- KPMG's plan for the 2020 audit. It was noted that key issues for 2020 would continue to include the valuation of intangible assets, in particular PT20, valuation of inventory which is becoming a more significant balance sheet item, the parent company's investment in subsidiaries, and going concern; and
- the latest risk register which had been prepared by management and circulated to the full Board.

In April 2021 the Audit Committee met to receive the report of the auditor and the outcome of the audit process. The key matters for discussion were the valuation of intangible assets and going concern.

External audit

The Group's external auditor, KPMG LLP, is engaged to provide its independent opinion on the Group's financial statements. The Group maintains a segregation between its external auditor and other advisors, with Ernst & Young LLP appointed as the Group's tax advisor to ensure a separation of the audit from other key advisory work.

The Group's external auditor last tendered for its appointment in 2015 and there are no current plans to retender the audit.

The Senior Statutory Auditor for 2019 was Mr David Mitchell. Following an internal reorganisation at KPMG in which audit partners will in future specialise either in public companies or private companies, Mr Mitchell has been replaced for the 2020 audit by Mr Stuart Burdass.

The Audit Committee approves any non-audit services provided by the external auditor, with consideration given to the threats posed to independence and safeguards in place. No such services have been provided during 2020.

Internal audit

The Committee is of the opinion that an internal audit function is not currently appropriate for the Group given its stage of development. The Committee will continue to review the appropriateness of these arrangements.

Peter Llewellyn-Davies
Audit Committee Chair
28 April 2021

ROLF HOFFMANN
Remuneration Committee Chair

The Remuneration Committee recognises the importance of shareholder engagement in relation to Executive remuneration.

On behalf of the Board of Directors, I am pleased to present the Directors' remuneration report for the year ended 31 December 2020. Although the Company is not subject to the reporting regulations of main market listed companies, the Remuneration Committee recognises the importance of shareholder engagement in relation to Executive remuneration. Accordingly, the Committee has prepared this report as a matter of best practice and has taken account of those regulations in doing so.

Remuneration Committee membership and activities

The current members of the Remuneration Committee are Hans Peter Hasler and Rolf Hoffmann; Rolf Hoffmann was appointed Committee Chair on 22 January 2019. Prior to his resignation, James Karis also served as a member of the Remuneration Committee up to 18 June 2020.

The Committee meets at least once a year and met twice during the course of 2020. It has responsibility for:

- Maintaining the remuneration policy;
- Reviewing and determining the remuneration packages of the Executive Directors;
- Monitoring the level and structure of remuneration of senior management, including share options and bonus awards; and
- Production of the Directors' remuneration report.

Aon Solutions UK Limited and Ashurst have acted as external advisors to the Committee during the year.

The CEO typically attends meetings and provides information and support as requested but is not present when his own remuneration is to be discussed. The duties of the Committee are set out in the terms of reference, which are available on request from the Company Secretary.

Key remuneration principles

Our remuneration arrangements for Executive Directors are based on the key principles set out below. We have articulated how those principles are addressed within the remuneration policy.

Key principle	How we reflect this in our policy
To promote the long term success of the Company.	The Executive Directors' remuneration opportunity is performance-based and earned only subject to the satisfaction of performance conditions.
To provide appropriate alignment with investors' expectations in relation to the Company's strategy and outcomes.	Performance conditions for the annual bonus and share option schemes are set such as to align with shareholders' interests.
To provide a competitive package of base salary, benefits and short and long term incentives, with an appropriate proportion being subject to the achievement of individual and corporate performance conditions.	Further alignment between Executive Directors and shareholders is achieved by structuring performance conditions to align with shareholder interests.

Executive remuneration in 2020

Base salary, bonus and share options for the Chief Executive Officer (CEO) were approved by the Remuneration Committee prior to the appointment of Tim Watts as CEO on 22 April 2020.

Awards were granted to the CEO under the Retention and Performance Share Plan during the year. Further details of these awards are provided on pages 32 and 33.

Looking forward to 2021

The CEO's bonus opportunity and share options award opportunity for 2021 is expected to be up to 75% of salary and 100% of salary respectively, with each award subject to the achievement of performance conditions and pro-rated for length of service during the year.

Board changes

On 22 April 2020 Carl Sterritt resigned as CEO of Shield Therapeutics plc. Tim Watts was appointed as CEO following the resignation of Carl Sterritt. On 27 April 2020, Tim Watts was appointed to the Board of Directors.

On 18 June 2020, Hans Peter Hasler was appointed Chairman of the Board following James Karis' announcement at the AGM that he would not be standing for re-election.

On 26 June 2020, Dr Christian Schweiger was appointed to the Board of Directors as a Non-Executive Director.

Executive Directors' remuneration policy

The table below sets out the elements of Executive Directors' compensation and how each element operates, as well as the maximum opportunity of each element and any applicable performance measures.

Element and purpose	Operation	Maximum opportunity
Fixed remuneration		
Basic salary		
To provide a competitive base salary for the market and size of company in order to attract and retain Executive Directors of a suitable calibre.	Usually reviewed annually, taking account of: • Salary increases awarded to the wider workforce; • Group performance; • Role and experience; • Individual performance; and • Competitive environment.	Salary increases will generally be in line with salary increases to other employees, but may be adjusted to take account of: • Promotion; • Change in scope of role; • Realignment with the market; and • Development and performance in role (for example, if a new Director is appointed on a salary which is increased over time to a market-competitive level).
Benefits		
To provide a competitive range of benefits as part of total remuneration.	Executive Directors currently receive: • Private medical insurance.	No overall maximum has been set, but the level of benefits provided is determined taking into account the overall cost to the Company. Other benefits may be provided to reflect individual circumstances, such as relocation expenses.
Retirement benefits		
To provide an appropriate level of retirement benefit (or cash allowance equivalent).	Executive Directors are eligible to participate in the Group defined contribution pension scheme. In appropriate circumstances, Directors may be permitted to take benefits as a salary cash supplement (which will ordinarily be reduced to take account of the employer National Insurance contributions).	Contributions for 2020 and 2021 have been set at 10% of salary.
Variable remuneration		
Annual bonus		
Rewards performance over the financial year, including in relation to performance which supports the Company's longer term objectives.	Awards for Executive Directors are based on performance, measured over the year to which they relate, and split between financial, strategic and individual objectives. The measures and weightings are determined each year to reflect the Company's strategic priorities.	The maximum bonus opportunity is 75% of base salary.

Executive Directors' remuneration policy continued

Element and purpose	Operation	Maximum opportunity
Variable remuneration continued		
Retention and Performance Share Plan (RPSP)		
To create alignment between Executive Directors' and shareholders' interests through the delivery of performance-based awards.	Awards are made in the form of nominal cost share options. Vesting is subject to the achievement of specific performance conditions over the 2020 financial year. The plan is subject to malus and clawback provisions.	Under the scheme rules, the maximum award in respect of any financial year is 125% of base salary. Awards are made based on an assessment of the Executive Directors' performance and cover a twelve-month period from grant. The current performance conditions are based on the achievement of specific corporate strategic objectives during 2020. Achievement of each objective entitles the recipient to a percentage of the total award. The Committee will review and set performance conditions for future awards.

Non-Executive remuneration policy

The remuneration policy for the Chairman and Non-Executive Directors is to pay fees necessary to attract and retain individuals of the calibre required, taking into account the size and complexity of the business and the market in which it operates.

The fees of the Non-Executive Directors are agreed by the Chairman and the CEO and the fees of the Chairman are determined by the Board as a whole.

Fees are paid as a base fee as a member of the Board, together with additional fees for chairmanship of a Board Committee. All Non-Executive Directors may be reimbursed for expenses reasonably incurred in the performance of their duties.

Neither the Chairman nor the Non-Executive Directors are eligible to participate in the Group's incentive arrangements.

During 2020 there were several matters which required the Non-Executive Directors to have a greater level of involvement in the day-to-day business of the Company and, in certain instances, to commit substantially more time and effort in supporting management and communicating with major shareholders than would ordinarily be expected of them. These matters included (i) the complexity of the strategic choices facing the business regarding the commercialisation of Accrufer® in the US; (ii) managing the consequences of the clarification of the AEGIS-H2H results in March 2020 and the subsequent investigation and re-analysis of the results which was reported in August 2020; and (iii) the change in CEO in April 2020 and the lack of a CFO and Chief Medical Officer from that time. As a consequence of this extra commitment, Mr Hasler, Mr Hoffmann and Mr Llewellyn-Davies each received additional fees of £20,000 during 2020 over and above their normal Directors' fees.

These payments are shown on page 32.

Directors' service contracts

Details of the service contracts of Directors in office at the date of approval of this report are set out below. All Directors are subject to annual reappointment at each Annual General Meeting.

Name	Position	Notice period	Notes
Tim Watts	CEO	Note 1	Subject to annual reappointment at AGM
Hans Peter Hasler	NED (Chairman, Chair of Nomination Committee)	3 months	Subject to annual reappointment at AGM
Peter Llewellyn-Davies	NED (Chair of Audit Committee)	3 months	Subject to annual reappointment at AGM
Rolf Hoffmann	NED (Chair of Remuneration Committee)	3 months	Subject to annual reappointment at AGM
Dr Christian Schweiger	NED	3 months	Subject to annual reappointment at AGM

Note 1 – Tim Watts was initially appointed under a twelve-month fixed contract expiring on 31 March 2021. This contract has been extended to 30 September 2021 unless terminated by either party with two months' notice.

Hans Peter Hasler is engaged under a letter of appointment dated 18 June 2020 with a term of three years.

Peter Llewellyn-Davies is engaged under a letter of appointment dated 25 January 2019 with a term of three years.

Rolf Hoffmann's letter of appointment is dated 5 April 2018 and is for a term of three years commencing on 6 April 2018.

Dr Christian Schweiger is engaged under a letter of appointment dated 25 June 2020 with a term of three years.

Directors' remuneration (audited)

The tables below detail the total remuneration received by each Director during 2020 and 2019.

Directors' remuneration – year ended 31 December 2020

Name	Salary/fees £000	Benefits £000	Bonus £000	Pensions £000	Total remuneration 2020 £000
Executive Director					
Tim Watts[i]	**219**	**–**	**–**	**24**	**243**
Carl Sterritt[ii]	**119**	**–**	**115**	**12**	**246**
Non-Executive Directors					
Hans Peter Hasler[iii]	**97**	**–**	**–**	**–**	**97**
Peter Llewellyn-Davies[iii]	**68**	**–**	**–**	**–**	**68**
Rolf Hoffmann[iii]	**65**	**–**	**–**	**–**	**65**
Dr Christian Schweiger[iv]	**20**	**–**	**–**	**–**	**20**
James Karis[v]	**47**	**–**	**–**	**–**	**47**
	635	**–**	**115**	**36**	**786**

(i) Tim Watts was appointed as a Director on 27 April 2020.

(ii) Carl Sterritt resigned on 22 April 2020. In addition he was paid £327,000 in lieu of notice following the termination of his contract in April 2020.

(iii) The fees for Hans Peter Hasler, Peter Llewellyn-Davies and Rolf Hoffmann each include the additional £20k for 2020 described on page 31.

(iv) Christian Schweiger was appointed on 26 June 2020,

(v) James Karis resigned on 18 June 2020.

Directors' remuneration – year ended 31 December 2019

Name	Salary/fees £000	Benefits £000	Bonus £000	Pensions £000	Total remuneration 2019 £000
Executive Director					
Carl Sterritt	316	50	190	–	556
Non-Executive Directors					
Hans Peter Hasler	40	–	–	–	40
Peter Llewellyn-Davies	48	–	–	–	48
Rolf Hoffmann	45	–	–	–	45
James Karis	99	–	–	–	99
	548	50	190	–	788

No Director waived any emoluments in respect of the year.

Retention and Performance Share Plan (RPSP) options granted in 2020 (audited)

During the year the Company issued share options under the RPSP to incentivise the CEO in order to align his interests closely with those of shareholders.

The awards during 2020 included the following awards to the CEO.

Name	Number of options	Vesting date
Tim Watts	625,000	By 31 December 2021

As at 31 December 2020, Tim Watts held 625,000 options. No other Director holds any options.

All options are exercisable at a nominal price of £0.015 per share. No amounts were paid on grant.

Performance conditions applicable to the award relate to objectives to be achieved by the end of the 2021 financial year, with a proportion of the award earned for the achievement of each objective. Attainment of the objectives is measured and if achieved will vest immediately.

Retention and Performance Share Plan (RPSP) options granted in 2020 (audited) continued

If the objectives are not met then the award will lapse at 31 December 2021. The performance conditions are:

Condition	Weighting
1 Company's market value is at or above £175m and sustained for five (5) consecutive trading days at any time during 2021.	60% of total option amount will be awarded if the performance condition is achieved.
2 The Company's market value is at or above £300m for five (5) consecutive days at any time during 2021.	40% of total option amount will be awarded if the performance condition is achieved.

2020 annual bonus (audited)

The CEO was awarded a bonus of £82,500 in respect of 2020, payable during 2021.

Directors' shareholdings (audited)

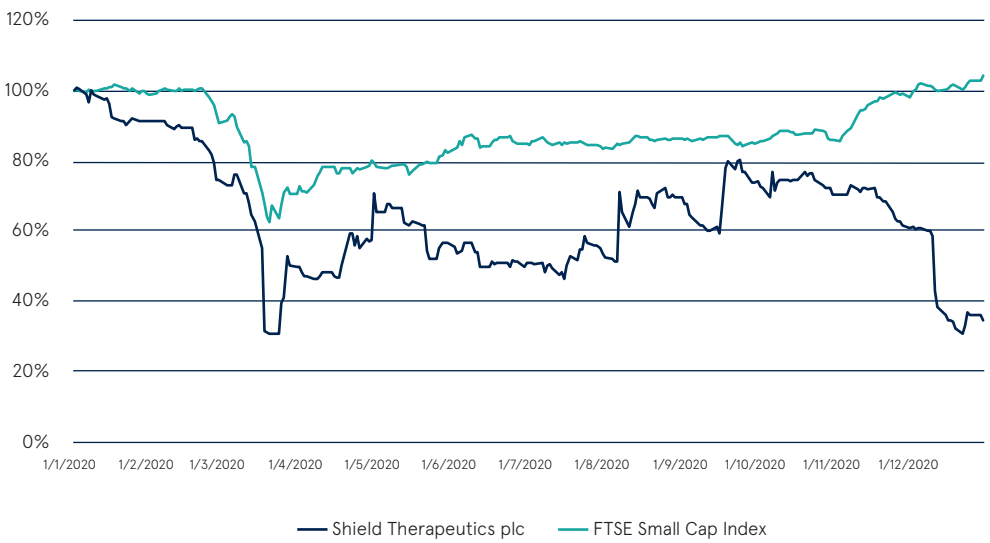
The table below discloses the interests of any Directors serving during the year in the shares of the Company at 31 December 2020.

Name	Shares at 31 December 2020	% of share capital
Christian Schweiger	**4,114,300**	3.5%
Carl Sterritt	**3,385,052**	2.9%
Tim Watts	**648,700**	0.6%
Peter Llewellyn-Davies	**10,000**	0.01%

At 31 December 2020 Tim Watts had 625,000 options outstanding under the Retention and Performance Share Plan (RPSP).

Share performance graph

The graph below shows the performance of the Company's shares during the year compared to the FTSE Small Cap Index.



The mid-market price of the Ordinary Shares as at 31 December 2020 was £0.635. The highest mid-market price of the Ordinary Shares during the year was £1.805 and the lowest price was £0.54.

This report was approved by the Board and signed on its behalf by:

Rolf Hoffmann
Remuneration Committee Chair
28 April 2021

The Directors present their Annual Report on the affairs of the Group, together with the financial statements and auditor's report, for the year ended 31 December 2020.

Principal activities

Shield Therapeutics plc is a specialty pharmaceutical company specialising in the development and commercialisation of late-stage pharmaceuticals which address areas of high unmet medical need.

Strategic report

The strategic report is set out on pages 1 to 21. The Directors consider that the Annual Report and Accounts, taken as a whole, are fair, balanced and understandable.

Section 172 statement

Under s172 of the Companies Act 2006 the Directors have a duty to act in good faith in a way that is most likely to promote the success of the Company for the benefit of its members as a whole, having regard to the likely consequences of decisions for the long term, the interests of the Company's employees, the need to foster relationships with other key stakeholders, the impact on the community and the environment, maintaining a reputation for high standards of business conduct, and the need to act fairly as between members of the Company.

Key decisions made by the Board during 2020 and early 2021 were related primarily to the commercialisation of Accrufer® in the US. During the course of 2020, in the light of experience gained through multiple licence discussions and negotiations, the Board reached the conclusion that shareholders' interests would potentially be better served by the Group launching Accrufer® in the US rather than by out-licensing the product to a third party (which had previously been the strategy). Between December 2020 and February 2021 options for financing a Shield launch were evaluated and in February 2021 the Board decided to proceed with an equity fundraise to finance the launch of Accrufer® in the US by Shield.

Approximately 39% of the Company's shares are held by two investors. The Chief Executive Officer and other members of the Board communicate from time to time with these shareholders and have a good understanding of their interests. The Chief Executive Officer and other members of the Senior Executive Team meet regularly with other shareholders, both institutional and private, to explain and discuss the Group's strategy and objectives and to understand the interests of smaller shareholders in the Company. The Board recognises its responsibility to act fairly between all shareholders of the Company.

The Group employed between 15 and 17 staff during 2020. The Chief Executive Officer and the other members of the Senior Executive Team interact daily with all employees. Management has implemented employee policies and procedures which are appropriate for the size of the Group.

Apart from its shareholders and employees the Group's main stakeholders are Norgine BV and Beijing Aosaikang Pharmaceutical Co. Ltd with whom the Group has signed licence development and commercialisation agreements relating to Feraccru®/Accrufer®. The agreements contain formal provisions for relationships between Shield and the licence partners but the Board and management also recognise the importance of establishing and maintaining good, less formal relationships with these stakeholders. The Chief Executive Officer and senior management meet, from time to time, with senior managers from the licence partners.

As a relatively small organisation the Group's impact on the community and the environment is modest but the Board endeavours to ensure that the business acts ethically and in an environmentally conscious manner.

Future development

Disclosures relating to future developments are included in the Chief Executive Officer's statement and financial review.

Capital structure

Details of the Company's share capital including shares issued during the year are provided in Note 21. The Company has one class of Ordinary Shares listed on the AIM market of the London Stock Exchange with a nominal value of £0.015. Each Ordinary Share carries the right to one vote at general meetings of the Company and carries no right to fixed income.

The Directors are not aware of any restrictions on the transfer of Ordinary Shares in the Company other than certain restrictions which may from time to time be imposed by law and regulations.

Details of employee share schemes and share options in issue are provided in Note 23.

Results and dividend

The consolidated statement of profit and loss and other comprehensive income is set out on page 44. The Group's loss after taxation for the year was £2.6 million.

The Directors do not recommend the payment of a dividend in respect of the year ended 31 December 2020.

Directors

The Directors of the Company during the year and up to the date of approval of the Annual Report were as follows:

Hans Peter Hasler

Tim Watts (appointed 24 April 2020)

Peter Llewellyn-Davies

Rolf Hoffmann

Christian Schweiger (appointed 26 June 2020)

Carl Sterritt (resigned 21 April 2020)

James Karis (resigned 18 June 2020)

The role of Company Secretary is undertaken by Lucy Huntington-Bailey.

Directors' indemnities
The Group has made qualifying third-party indemnity provisions for the benefit of its Directors, which remain in force at the date of this report.

Post-balance sheet 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.

Research and development
The Group undertakes significant research and development activities in the course of bringing its core pharmaceutical assets to market. Details of the expenditure charge to the consolidated statement of profit and loss, expenditure capitalised during the year and the accounting policy for capitalising development expenditure are provided in the financial statements.

Political donations
The Group made no political donations during the course of both the current and prior years.

Financial instruments
The Company's financial risk management objectives and policies and disclosures regarding its exposure to foreign currency risk, credit risk and liquidity risk are provided in Note 20 to the financial statements.

Corporate governance report
The Company's corporate governance report can be found on pages 24 to 26 of the Annual Report. The corporate governance report forms part of this Directors' report and is incorporated into it by cross-reference.

Major interests
As at the date of this report, the Company had been notified of the following shareholders with major interests in the shares of Shield Therapeutics plc:

W. Health LP	26.0%
AOP Orphan International AG	13.1%
Jupiter Asset Management	5.9%

Auditor
Each person who is a Director at the date of approval of this Annual Report confirms that:

- So far as the Director is aware, there is no relevant audit information of which the Group's auditor is unaware; and
- The Director has taken all reasonable steps as a Director in order to make himself aware of any relevant audit information and to establish that the Group's auditor is aware of that information.

This confirmation is given and should be interpreted in accordance with the provisions of Section 418 of the Companies Act 2006.

KPMG LLP have expressed their willingness to continue as auditor and a resolution to reappoint them will be proposed at the forthcoming Annual General Meeting (AGM).

Annual General Meeting
The AGM of the Company will be held by teleconference at 2.00pm on Thursday 17 June 2021.

By order of the Board

Tim Watts
Chief Executive Officer
28 April 2021

Statement of Directors' responsibilities

in respect of the Annual Report and the financial statements

The Directors are responsible for preparing the Annual Report and the Group and parent company financial statements in accordance with applicable law and regulations.

Company law requires the Directors to prepare Group and parent company financial statements for each financial year. Under the AIM Rules of the London Stock Exchange they are required to prepare the Group financial statements in accordance with International Accounting Standards in conformity with the requirements of the Companies Act 2006 and they have elected to prepare the parent company financial statements on the same basis.

Under company law the Directors must not approve the financial statements unless they are satisfied that they give a true and fair view of the state of affairs of the Group and parent company and of their profit or loss for that period.

In preparing each of the Group and parent company financial statements, the Directors are required to:

- Select suitable accounting policies and then apply them consistently;
- Make judgments and estimates that are reasonable, relevant and reliable;
- State whether they have been prepared in accordance with International Accounting Standards in conformity with the requirements of the Companies Act 2006;
- Assess the Group and parent company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern; and
- Use the going concern basis of accounting unless they either intend to liquidate the Group or the parent company or to cease operations, or have no realistic alternative but to do so.

The Directors are responsible for keeping adequate accounting records that are sufficient to show and explain the parent company's transactions and disclose with reasonable accuracy at any time the financial position of the parent company and enable them to ensure that its financial statements comply with the Companies Act 2006. They are responsible for such internal control as they determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error, and have general responsibility for taking such steps as are reasonably open to them to safeguard the assets of the Group and to prevent and detect fraud and other irregularities.

Under applicable law and regulations, the Directors are also responsible for preparing a strategic report and a Directors' report that complies with that law and those regulations.

The Directors are responsible for the maintenance and integrity of the corporate and financial information included on the Company's website. Legislation in the UK governing the preparation and dissemination of financial statements may differ from legislation in other jurisdictions.

We consider the Annual Report and Accounts, taken as a whole, is fair, balanced and understandable and provides the information necessary for shareholders to assess the Group's position and performance, business model and strategy.

By order of the Board

Tim Watts
Chief Executive Officer
28 April 2021

Independent auditor's report

to the members of Shield Therapeutics plc

1. Our opinion is unmodified

We have audited the financial statements of Shield Therapeutics plc (the "Company") for the year ended 31 December 2020 which comprise the consolidated statement of profit and loss and other comprehensive income, the Group and Company balance sheets, the Group and Company statements of changes in equity, the Group and Company statements of cash flows, and the related notes, including the accounting policies in Note 2.

In our opinion:

- The financial statements give a true and fair view of the state of the Group's and of the parent company's affairs as at 31 December 2020 and of the Group's loss for the year then ended;
- The Group financial statements have been properly prepared in accordance with international accounting standards in conformity with the requirements of the Companies Act 2006;
- The parent company financial statements have been properly prepared in accordance with international accounting standards in conformity with the requirements of, and as applied in accordance with the provisions of, the Companies Act 2006; and
- The financial statements have been prepared in accordance with the requirements of the Companies Act 2006.

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (UK) (ISAs (UK)) and applicable law. Our responsibilities are described below. We have fulfilled our ethical responsibilities under, and are independent of the Group in accordance with, UK ethical requirements including the FRC Ethical Standard as applied to listed entities. We believe that the audit evidence we have obtained is a sufficient and appropriate basis for our opinion.

Overview		
Materiality: Group financial statements as a whole	£0.4 million (2019: £0.5 million) 4.3% (2019: 4.3%) of normalised Group loss before tax	
Coverage	100% (2019: 100%) of Group loss before tax	
Key audit matters		**vs 2019**
Recurring risks	Recoverability of intangible assets	◆▶
	Parent company: Recoverability of investments in subsidiaries	◆▶
	Going concern	▼

2. Key audit matters: our assessment of risks of material misstatement

Key audit matters are those matters that, in our professional judgement, were of most significance in the audit of the financial statements and include the most significant assessed risks of material misstatement (whether or not due to fraud) identified by us, including those which had the greatest effect on: the overall audit strategy; the allocation of resources in the audit; and directing the efforts of the engagement team.

2. Key audit matters: our assessment of risks of material misstatement continued

These matters were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters. In arriving at our audit opinion above, the key audit matters, in decreasing order of audit significance, were as follows:

	The risk	Our response

Group: Recoverability of intangible assets (£27.3 million; 2019: £29.9 million)
 	
Refer to page 27 (Audit Committee report), page 53 (accounting policy) and page 61 (financial disclosures)
	Forecast-based assessment
	These intangible assets relate to the Group's two drug CGUs (Feraccru® and PT20) and their possibility of impairment is a significant estimate as the drugs are at a relatively early stage in their lifecycle. The valuation of these drugs is also the key consideration in assessing the recoverability of the parent company's investment in subsidiaries (see below).
	
	The estimated recoverable amount of the CGUs containing the assets relating to the drugs is subjective due to the inherent uncertainty involved in forecasting and discounting future cash flows.
	
	The cash flows include amounts in respect of the inflows from a combination of anticipated royalties and forecast sales, and other payments from current or prospective licensees and outflows of the estimated costs to progress the commercialisation of these assets.
	
	The effect of these matters is that, as part of our risk assessment for audit planning purposes, we determined that the value in use of both CGUs had a high degree of estimation uncertainty, with a potential range of reasonable outcomes greater than our materiality for the financial statements as a whole, and possibly many times that amount. In conducting our final audit work, we concluded that reasonably possible changes to the value in use of Feraccru® would not be expected to result in material impairment. Our risk assessment for the PT20 CGU remained unchanged through our final audit work. The financial statements (note 13) disclose the sensitivity estimated by the Company.
		Our procedures included:
		
		– **Our sector experience:** We evaluated and challenged the assumptions used, in particular those relating to forecast receipts from licensees, forecast sales and the discount rate applied to discount the cash flows.
		
		– **Benchmarking assumptions:**
		  – We compared the Group's assumptions to externally derived data in relation to key inputs such as projected market growth, royalty rates and discount rates.
		  – We agreed revenue inputs in the valuation models to external market analysis, and compared estimated royalty rates with those already agreed by the Group and other similar licence agreements in the sector.
		
		– **Sensitivity analysis:** We performed breakeven analysis on the key assumptions noted above.
		
		– **Assessing transparency:** We assessed whether the disclosures about the sensitivity of the outcome of the impairment assessment to changes in key assumptions reflected the risks inherent in the forecast-based assessment of recoverability.

Parent company: Recoverability of parent company's investment in subsidiaries (£104.7 million; 2019: £104.0 million)	**Forecast-based assessment** The carrying amount of the parent company's investments in subsidiaries is significant and at risk of irrecoverability due to the subsidiary companies being currently loss making. The estimated recoverable amount of these balances is subjective due to the inherent uncertainty in forecasting and discounting future cash flows.	Our procedures included: – **Test of detail:** With reference to our audit of the recoverability of intangible assets (see above), we compared the carrying value of the parent company's investments in each of the subsidiaries against the estimated recoverable value of the applicable intangible assets.

2. Key audit matters: our assessment of risks of material misstatement continued

Parent company: Recoverability of parent company's investment in subsidiaries continued Refer to page 27 (Audit Committee report), page 54 (accounting policy) and page 62 (financial disclosures)	**Forecast-based assessment** continued The effect of these matters is that, as part of our risk assessment, we determined that the recoverable amount of the cost of investment in subsidiaries has a high degree of estimation uncertainty, with a potential range of reasonable outcomes greater than our materiality for the financial statements as a whole, and possibly many times that amount. In conducting our final audit work, we concluded that reasonably possible changes to the value in use of the investment in Shield TX (Switzerland) AG would not be expected to result in material impairment. Our risk assessment for the investment in Phosphate Therapeutics Limited remained unchanged through our final audit work. The financial statements (note 14) disclose the sensitivity estimated by the Company.	Our procedures included: – **Assessing transparency:** We assessed whether the disclosures about the sensitivity of the outcome of the impairment assessment to changes in key assumptions reflected the risks inherent in the forecast-based assessment of recoverability.
Going concern see Note 2 to the Group financial statements Refer to page 27 (Audit Committee report)	**Disclosure quality** The financial statements explain how the Board has formed a judgement that it is appropriate to adopt the going concern basis of preparation for the Group and parent company. That judgement is based on an evaluation of the inherent risks to the Group's and Company's 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 16 months from the date of approval of the financial statements. The risk most likely to adversely affect the Group's and Company's available financial resources over this period was that the launch and commercialisation of the Accrufer® drug in the US is not successful. The risk for our audit was whether or not those risks were such that they amounted to a material uncertainty that may have cast significant doubt about the ability to continue as a going concern. Had they been such, then that fact would have been required to have been disclosed. The financial statements explain how the Board has formed a judgement that it is appropriate to adopt the going concern basis of preparation for the group and parent company.	We considered whether these risks could plausibly affect the liquidity in the going concern period by assessing the Directors' sensitivities over the level of available financial resources indicated by the Group's financial forecasts taking account of severe, but plausible, adverse effects that could arise from these risks individually and collectively. Our procedures included: – **Historical comparisons:** We assessed the Directors' previous forecasts against actual outcomes to form a view of the Directors' forecasting accuracy. – **Sensitivity analysis:** We considered sensitivities over the level of available financial resources indicated by the Group's financial forecasts, including revenue cash flows, taking account of reasonably possible (but not unrealistic) adverse effects that could arise individually and collectively. – **Benchmarking assumptions:** We challenged the appropriateness of the key assumptions, such as the costs for launching the Accrufer® product in the US, and revenue assumptions, used in the cash flow projections by reference to our knowledge of the business and quotes from external suppliers. We also assessed the projections and assumptions by reference to the general market conditions and post-year-end trading and cash flows. – **Assessing transparency:** We assessed the completeness and accuracy of the matters covered in the going concern disclosure by reference to our audit findings from the above procedures and our understanding of the Group's business and strategies.

2. Key audit matters: our assessment of risks of material misstatement continued

We continue to perform procedures over the capitalisation of development costs. However, the Group has not capitalised a material amount of these costs in the year and therefore we have not assessed this as one of the most significant risks in our current year audit. Therefore, this item is not separately identified in our report this year.

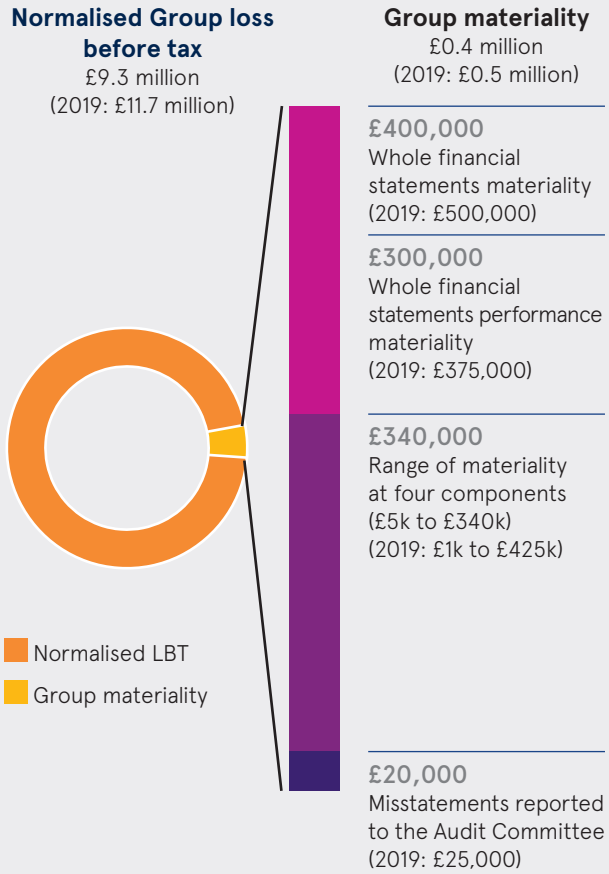
In the prior year, we reported a key audit matter in respect of the impact of uncertainties due to the UK exiting the European Union on our audit. As a result of developments since the prior year report, including the Group's own preparation, the relative significance of this matter on our audit work, including in relation to the impairment of intangible assets and the recoverability of the parent company's investment in its subsidiaries, and related disclosures, and the appropriateness of the going concern basis of preparation of the financial statements, which remain key audit matters, has reduced. Accordingly, we no longer consider this a key audit matter.

3. Our application of materiality and an overview of the scope of our audit

Materiality for the Group financial statements as a whole was set at £400,000 (2019: £500,000), determined with reference to a benchmark of Group loss before tax, normalised by averaging over the last four years due to fluctuations in the business cycle, of £9.3 million, of which it represents 4.3% (2019: 4.3%).

Materiality for the parent company financial statements as a whole was set at £50,000 (2019: £44,000), determined with reference to a benchmark of normalised loss before tax, of which it represents 5.3% (2019: 5.1%).

In line with our audit methodology, our procedures on individual account balances and disclosures were performed to a lower threshold, performance materiality, so as to reduce to an acceptable level the risk that individually immaterial



3. Our application of materiality and an overview of the scope of our audit continued

misstatements in individual account balances add up to a material amount across the financial statements as a whole.

Performance materiality was set at 75% (2019: 75%) of materiality for the financial statements as a whole, which equates to £300,000 (2019: £375,000) for the Group and £37,500 (2019: £33,000) for the parent company. We applied this percentage in our determination of performance materiality because we did not identify any factors indicating an elevated level of risk.

We agreed to report to the Audit Committee any corrected or uncorrected identified misstatements exceeding £20,000 (2019: £25,000), in addition to other identified misstatements that warranted reporting on qualitative grounds.

Of the Group's five (2019: five) reporting components, we subjected three (2019: three) to full scope audits for Group purposes and two (2019: two) to specified risk-focused audit procedures. The latter were not individually financially significant enough to require a full scope audit for Group purposes.

The components within the scope of our work accounted for the percentages illustrated opposite.

The Group team carried out all of the work on the five reporting components. We used component materialities, which range from £5,000 to £340,000 (2019: £1,000 to £425,000), having regard to the mix of size and risk profile of the Group across the components.

4. Going concern

The Directors have prepared the financial statements on the going concern basis as they do not intend to liquidate the Group or the Company or to cease their operations, and as they have concluded that the Group's and the Company's financial position means that this is realistic. They have also concluded that there are no material uncertainties that could have cast significant doubt over their ability to continue as a going concern for 16 months from the date of approval of the financial statements (the "going concern period").

An explanation of how we evaluated management's assessment of going concern is set out in the related key audit matter in section 2 of this report.

Our conclusions based on this work:

- We consider that the Directors' use of the going concern basis of accounting in the preparation of the financial statements is appropriate;
- We have not identified, and concur with the Directors' assessment that there is not, a material uncertainty related to events or conditions that, individually or collectively, may cast significant doubt on the Group's or Company's ability to continue as a going concern for the going concern period; and
- We found the going concern disclosure in Note 2 to be acceptable.

However, as we cannot predict all future events or conditions and as subsequent events may result in outcomes that are inconsistent with judgements that were reasonable at the time they were made, the above conclusions are not a guarantee that the Group or the Company will continue in operation.

5. Fraud and breaches of laws and regulations – ability to detect

Identifying and responding to risks of material misstatement due to fraud

To identify risks of material misstatement due to fraud ("fraud risks") we assessed events or conditions that could indicate an incentive or pressure to commit fraud or provide an opportunity to commit fraud. Our risk assessment procedures included:

- Enquiring of Directors, the Audit Committee and management as to the Group's high-level policies and procedures to prevent and detect fraud, as well as whether they have knowledge of any actual, suspected or alleged fraud;
- Reading Board and Audit Committee meeting minutes; and
- Considering remuneration incentive schemes and performance targets for management, Directors and eligible employees.

We communicated identified fraud risks throughout the audit team and remained alert to any indications of fraud throughout the audit.

As required by auditing standards, we perform procedures to address the risk of management override of controls, in particular the risk that Group management may be in a position to make inappropriate accounting entries. On this audit we do not believe there is a fraud risk related to revenue recognition because revenue recognised around the year end is not significant.

We did not identify any additional fraud risks.

In determining the audit procedures we took into account the results of our evaluation and testing of the operating effectiveness of the Group-wide fraud risk management controls.

We performed procedures including:

- Identifying journal entries to test based on risk criteria and comparing the identified entries to supporting documentation. These included those posted to unusual accounts.

We discussed with the Audit Committee matters related to actual or suspected fraud, for which disclosure is not necessary, and considered any implications for our audit.

5. Fraud and breaches of laws and regulations – ability to detect continued

Identifying and responding to risks of material misstatement due to non-compliance with laws and regulations

We identified areas of laws and regulations that could reasonably be expected to have a material effect on the financial statements from our general commercial and sector experience and through discussion with the Directors and other management (as required by auditing standards), and discussed with the Directors and other management the policies and procedures regarding compliance with laws and regulations.

We communicated identified laws and regulations throughout our team and remained alert to any indications of non-compliance throughout the audit.

The potential effect of these laws and regulations on the financial statements varies considerably.

Firstly, the Group is subject to laws and regulations that directly affect the financial statements including financial reporting legislation (including related companies legislation), distributable profits legislation and taxation legislation, and we assessed the extent of compliance with these laws and regulations as part of our procedures on the related financial statement items.

Secondly, the Group is subject to many other laws and regulations where the consequences of non-compliance could have a material effect on amounts or disclosures in the financial statements, for instance through the imposition of fines or litigation. We identified the following areas as those most likely to have such an effect: health and safety, anti-bribery, employment law, regulatory capital and liquidity and certain aspects of company legislation recognising the nature of the Group's activities. Auditing standards limit the required audit procedures to identify non-compliance with these laws and regulations to enquiry of the Directors and other management and inspection of regulatory and legal correspondence, if any. Therefore if a breach of operational regulations is not disclosed to us or evident from relevant correspondence, an audit will not detect that breach.

Context of the ability of the audit to detect fraud or breaches of law or regulation

Owing to the inherent limitations of an audit, there is an unavoidable risk that we may not have detected some material misstatements in the financial statements, even though we have properly planned and performed our audit in accordance with auditing standards. For example, the further removed non-compliance with laws and regulations is from the events and transactions reflected in the financial statements, the less likely the inherently limited procedures required by auditing standards would identify it.

In addition, as with any audit, there remained a higher risk of non-detection of fraud, as these may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal controls. Our audit procedures are designed to detect material misstatement. We are not responsible for preventing non-compliance or fraud and cannot be expected to detect non-compliance with all laws and regulations.

6. We have nothing to report on the other information in the Annual Report

The Directors are responsible for the other information presented in the Annual Report together with the financial statements. Our opinion on the financial statements does not cover the other information and, accordingly, we do not express an audit opinion or, except as explicitly stated below, any form of assurance conclusion thereon.

Our responsibility is to read the other information and, in doing so, consider whether, based on our financial statements audit work, the information therein is materially misstated or inconsistent with the financial statements or our audit knowledge. Based solely on that work we have not identified material misstatements in the other information.

Strategic report and Directors' report

Based solely on our work on the other information:

- We have not identified material misstatements in the strategic report and the Directors' report;
- In our opinion the information given in those reports for the financial year is consistent with the financial statements; and
- In our opinion those reports have been prepared in accordance with the Companies Act 2006.

7. We have nothing to report on the other matters on which we are required to report by exception

Under the Companies Act 2006, we are required to report to you if, in our opinion:

- Adequate accounting records have not been kept by the parent company, or returns adequate for our audit have not been received from branches not visited by us; or
- The parent company financial statements are not in agreement with the accounting records and returns; or
- Certain disclosures of Directors' remuneration specified by law are not made; or
- We have not received all the information and explanations we require for our audit.

We have nothing to report in these respects.

8. Respective responsibilities

Directors' responsibilities

As explained more fully in their statement set out on page 36, the Directors are responsible for: the preparation of the financial statements including being satisfied that they give a true and fair view; such internal control as they determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error; assessing the Group and parent company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern; and using the going concern basis of accounting unless they either intend to liquidate the Group or the parent company or to cease operations, or have no realistic alternative but to do so.

Auditor's responsibilities

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue our opinion in an auditor's report. Reasonable assurance is a high level of assurance, but does not guarantee that an audit conducted in accordance with ISAs (UK) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the financial statements.

A fuller description of our responsibilities is provided on the FRC's website at www.frc.org.uk/auditorsresponsibilities.

9. The purpose of our audit work and to whom we owe our responsibilities

This report is made solely to the Company's members, as a body, in accordance with Chapter 3 of Part 16 of the Companies Act 2006. Our audit work has been undertaken so that we might state to the Company's members those matters we are required to state to them in an auditor's report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the Company and the Company's members, as a body, for our audit work, for this report, or for the opinions we have formed.

Stuart Burdass
(Senior Statutory Auditor)
for and on behalf of KPMG LLP, Statutory Auditor
Chartered Accountants
Quayside House
110 Quayside
Newcastle upon Tyne
NE1 3DX
28 April 2021

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	7	**(8,608)**	(6,773)
Operating profit/(loss) before research and development expenditure		**425**	(6,539)
Research and development expenditure	6	**(2,579)**	(2,496)
Operating loss		**(2,154)**	(9,035)
Financial income	9	**269**	18
Financial expense	9	**(1)**	(49)
Loss before tax		**(1,886)**	(9,066)
Taxation	11	**(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	10	**£(0.02)**	£(0.08)

Group balance sheet
at 31 December

	Notes	2020 £000	2019 £000
Non-current assets			
Intangible assets	13	**27,266**	29,898
Property, plant and equipment	12	**32**	26
		27,298	29,924
Current assets			
Inventories	15	**1,379**	948
Trade and other receivables	16	**619**	356
Current tax asset	11	**292**	950
Cash and cash equivalents	17	**2,940**	4,141
		5,230	6,395
Total assets		**32,528**	36,319
Current liabilities			
Trade and other payables	18	**(1,471)**	(3,547)
Other liabilities	19	**(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	21	**1,764**	1,758
Share premium	22	**88,352**	88,352
Merger reserve	22	**28,358**	28,358
Currency translation reserve	22	**53**	69
Retained earnings	22	**(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

Company balance sheet
at 31 December

	Notes	2020 £000	2019 £000
Non-current assets			
Investments	14	**104,731**	104,054
Trade and other receivables	16	**41,472**	42,477
		146,203	146,531
Current assets			
Trade and other receivables	16	**39**	68
Cash and cash equivalents	17	**1,741**	1,786
		1,780	1,854
Total assets		**147,983**	148,385
Current liabilities			
Trade and other payables	18	**(276)**	(353)
Other liabilities	19	**–**	–
Total liabilities		**(276)**	(353)
Net assets		**147,707**	148,032
Equity			
Share capital	21	**1,764**	1,758
Share premium	22	**88,352**	88,352
Merger reserve	22	**117,323**	117,323
Retained earnings	22	**(59,732)**	(59,401)
Total equity		**147,707**	148,032

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**

Company statement of changes in equity

for the year ended 31 December

	Issued capital £000	Share premium £000	Merger reserve £000	Retained earnings £000	Total £000
Balance at 1 January 2019	1,746	88,338	117,323	(59,649)	147,758
Loss for the year	–	–	–	(298)	(298)
Total comprehensive expense for the year	–	–	–	(298)	(298)
Transactions with owners, recorded directly in equity					
Equity-settled share-based payment transactions	12	14	–	546	572
Balance at 31 December 2019	1,758	88,352	117,323	(59,401)	148,032
Loss for the year	–	–	–	(1,117)	(1,117)
Total comprehensive expense for the year	–	–	–	(1,117)	(1,117)
Transactions with owners, recorded directly in equity					
Equity-settled share-based payment transactions	6	–	–	786	792
Balance at 31 December 2020	**1,764**	**88,352**	**117,323**	**(59,732)**	**147,707**

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

Company statement of cash flows
for the year ended 31 December

	2020 £000	Restated (see Note 2) 2019 £000
Cash flows from operating activities		
Loss for the year	**(1,117)**	(298)
Adjustments for:		
Equity-settled share-based payment expenses	**109**	189
Financial income	**(395)**	(423)
	(1,403)	(532)
Decrease in trade and other receivables	**29**	4
Decrease in trade and other payables	**(77)**	(413)
Net cash flows from operating activities	**(1,451)**	(941)
Cash flows from investing activities		
Repayment of loans to Group undertakings	**1,005**	–
Loans made to Group undertakings	**–**	(6,725)
Net cash flows from investing activities	**1,005**	(6,725)
Cash flows from financing activities		
Proceeds of share option exercise	**6**	26
Financial income	**395**	423
Net cash flows from financing activities	**401**	449
Net decrease in cash	**(45)**	(7,217)
Cash and cash equivalents at 1 January	**1,786**	9,003
Cash and cash equivalents at 31 December	**1,741**	1,786

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.

Subsidiaries and their countries of incorporation are presented in Note 14.

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 IFRS").

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.

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.

2. Accounting policies continued

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.

2. Accounting policies continued

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.

2. Accounting policies continued

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.

Restatement

During the year the Directors identified that the parent company cash flows in respect of the movements in amounts due from Group undertakings in the year ended 31 December 2019 were presented as operating cash flows in the parent company statement of cash flows. On investigation, it was determined that these cash flows should have been presented as investing cash flows. Following this review, in the parent company statement of cash flows only, these outflows (£6,725,000) were reclassified in the year ended 31 December 2019 from operating activities into investing activities. This restatement was a reclassification only and had no impact on net assets or loss before tax, or cash.

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 on page 19.

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; 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, 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 13 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; investments in Company balance sheet of £77.8 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 14 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

5. Segmental reporting continued

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. Expenses and auditor's remuneration

	Year ended 31 December 2020 £000	Year ended 31 December 2019 £000
Loss for the year has been arrived at after charging:		
Research and development expenditure	**2,579**	2,496
Fees payable to Company's auditor and its associates for the audit of parent company and consolidated financial statements	**70**	34
Fees payable to Company's auditor and its associates for other services:		
The audit of Company's subsidiaries	**30**	26
Corporate finance transactions	**–**	–
Tax compliance services	**3**	3
Other services	**–**	–

7. 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

8. Staff numbers and costs

The average number of persons employed by the Group during the year, analysed by category, was as follows:

	Number of employees	
	2020 Number	2019 Number
R&D	**5**	4
Medical	**2**	3
Commercial	**1**	1
Management and administration	**8**	8
	16	16

The number of staff employed by the Group at 31 December 2020 was 15 (31 December 2019: 20).

The aggregate payroll costs of these persons were as follows:

	2020 £000	2019 £000
Wages and salaries	**3,076**	2,721
Share-based payments (see Note 23)	**786**	375
Other employee benefits	**61**	32
Pensions	**78**	98
	4,001	3,226

Key management compensation information is as follows:

	2020 £000	2019 £000
Wages and salaries	**1,580**	1,204
Share-based payments	**616**	87
Other employee benefits	**61**	104
Pensions	**56**	70
	2,313	1,465

9. 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)

10. 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 (see Note 23) which potentially provide 3,950,357 additional Ordinary Shares (approximately 1.8% of the current share capital).

11. 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

Reconciliation of total tax credit:

	Year ended 31 December 2020 £000	Year ended 31 December 2019 £000
Loss for the year	**(2,630)**	(8,800)
Taxation	**(744)**	266
Loss before tax	**(1,886)**	(9,066)
Standard rate of corporation tax in the UK	**19%**	19%
Tax using the UK corporation tax rate	**(358)**	(1,723)
Expenses not deductible for tax purposes	**117**	37
R&D tax credits – current year	**(292)**	(421)
Adjustments in respect of prior years	**70**	194
Foreign taxation suffered	**(966)**	–
Utilisation of previously unrecognised deferred tax assets	**–**	(1,587)
Unrelieved tax losses carried forward and other temporary differences not recognised for deferred tax	**685**	3,766
Total tax (charge)/credit	**(744)**	266

11. Taxation continued

Factors affecting the future tax charge

The UK corporation tax rate remains unchanged at 19%. The unrecognised UK deferred tax asset as at 31 December 2020 has been calculated based on this rate. The March 2021 Budget announced that a rate of 25% would apply with effect from 1 April 2023, but this has not yet been enacted.

Unrecognised deferred tax assets

There is a potential deferred tax asset in respect of the unutilised tax losses, which has not been recognised due to the uncertainty of available future taxable profits.

	2020 £000	2019 £000
Unutilised Swiss tax losses to carry forward	**–**	–
Potential deferred tax asset thereon	**–**	–
Unutilised German tax losses to carry forward	**25**	24
Potential deferred tax asset thereon	**4**	4
Unutilised UK tax losses to carry forward	**35,062**	33,145
Potential deferred tax asset thereon	**6,662**	6,298
Total potential deferred tax asset	**6,666**	6,302

Under the terms of the 2016 agreement by which Shield TX (UK) Limited acquired the rights to Feraccru® from Shield TX (Switzerland) AG, the FDA approval in July 2019 triggered a CHF 14.8 million payment from Shield TX (UK) Limited to Shield TX (Switzerland) AG and a taxable gain in Shield TX (Switzerland) AG. As a result all losses brought forward in Shield TX (Switzerland) AG have been utilised and Shield TX (Switzerland) AG had a tax liability of CHF 0.7 million at 31 December 2020 which was settled in February 2021.

The current asset of £0.4 million at 31 December 2020 (2019: £0.95 million) relates to the anticipated R&D tax credit claim in respect of the 2020 financial year.

12. Property, plant and equipment

Group	2020 £000	2019 £000
Cost		
1 January	**78**	512
Additions	**56**	49
Disposals	**(50)**	(483)
31 December	**84**	78
Accumulated depreciation		
1 January	**52**	357
Charge for the period	**50**	178
Disposals	**(50)**	(483)
31 December	**52**	52
Net book value	**32**	26

Included within property, plant and equipment are £28,000 (2019: £20,000) net book value of assets recognised as leases under IFRS 16. Further details of these leases are disclosed in Note 24. The Company had no property, plant and equipment (2019: £Nil).

13. 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 calculations using projections of the licensing income which could be derived from the product until 2034, being the current patent life of the product including five 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® grow 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®.

13. Intangible assets continued

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 the 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.

The Company has no intangible assets (2019: £Nil).

14. Investments

Company	2020 £000	2019 £000
Cost		
1 January	**164,454**	164,097
Additions	**677**	357
Disposals	**—**	—
31 December	**165,131**	164,454
Accumulated impairment		
1 January and 31 December	**(60,400)**	(60,400)
Net book value		
31 December	**104,731**	104,054
1 January	**104,054**	103,697

Other additions of £0.7 million (2019: £0.3 million) relate to investments during the year arising due to share-based payments costs in respect of Group share-based payments arrangements.

The Group's equity interests were as follows:

At 31 December 2020 and 31 December 2019

Group company	Holding	Country of incorporation
Phosphate Therapeutics Limited	100%	United Kingdom
Shield TX (Switzerland) AG (formerly Iron Therapeutics Holdings AG)	100%	Switzerland
Shield Therapeutics Inc.	100%	USA
Shield TX (UK) Limited (formerly Iron Therapeutics (UK) Limited)*	100%	United Kingdom
Shield Therapeutics (DE) GmbH*	100%	Germany

* Investment held indirectly

The carrying amount of investments has been allocated to the above companies as follows:

	2020 £000	2019 £000
Shield TX (Switzerland) AG	**77,967**	77,290
Phosphate Therapeutics Limited	**26,764**	26,764
	104,731	104,054

14. Investments continued

At 31 December 2020 and 31 December 2019 continued

At the year end management reviewed the carrying value of the investments for impairment. The investments relate to two companies, being Shield TX (Switzerland) AG (which holds indirectly the Group's Feraccru® asset) and Phosphate Therapeutics Limited. The recoverable amount has been determined based on value-in-use calculations, using pre-tax cash flow projections for the period of the patents.

Shield TX (Switzerland) AG

The Company's carrying value of Shield TX (Switzerland) AG is supported by the value in use of Feraccru®, the main asset of the subsidiary. Feraccru®'s value in use has been assessed and tested for impairment as described in Note 13. Sensitivity analysis shows that sales in the US would need to be reduced by around 65% from management's base case assumptions, with no reduction in costs, before an impairment of the carrying value of the investment by the parent company would be required.

Phosphate Therapeutics Limited

The Company's carrying value of Phosphate Therapeutics Limited is supported by the value in use of PT20, the main asset of the subsidiary. The value in use of PT20, Phosphate Therapeutics Limited's main asset, has been assessed and tested for impairment as described in Note 13. Using a 15% discount rate, management's base case sales forecasts would need to be reduced by 12% before triggering an impairment of the carrying value of the Company's carrying value. Alternatively, using the unadjusted base case sales forecasts, a licence deal with no upfront payment or approval milestone, 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.

15. 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.

The Company had no inventories (2019: £Nil).

16. Trade and other receivables

	Group		Company	
	2020 £000	2019 £000	**2020 £000**	2019 £000
Trade receivables	**219**	–	**–**	–
Other receivables	**145**	197	**39**	21
Prepayments	**255**	159	**–**	47
Amounts due from Group undertakings	**–**	–	**41,472**	42,477
	619	356	**41,511**	42,545

The amounts due from Group undertakings in the Company's balance sheet are not expected to be recovered within the next 12 months.

	Group		Company	
	2020 £000	2019 £000	**2020 £000**	2019 £000
Non-current	**–**	–	**41,472**	42,477
Current	**619**	356	**39**	68
	619	356	**41,511**	42,545

At the year end no trade receivables were past due or impaired (2019: £Nil).

17. Cash and cash equivalents

	Group		Company	
	2020 £000	2019 £000	**2020 £000**	2019 £000
Cash at bank and in hand	**2,940**	4,141	**1,741**	1,786

18. Trade and other payables

	Group		Company	
	2020 £000	2019 £000	**2020 £000**	2019 £000
Trade payables	**395**	2,666	**–**	41
Accruals	**1,076**	881	**276**	312
	1,471	3,547	**276**	353

19. Other liabilities

	Group		Company	
	2020 £000	2019 £000	**2020 £000**	2019 £000
Taxation and social security	**672**	554	**–**	–
Other payables	**81**	53	**–**	–
	753	607	**–**	–

20. Financial instruments and financial risk management

The Group and Company's financial instruments comprise cash and cash equivalents, trade and other receivables, trade and other payables, and leases.

The Group had the following financial instruments at 31 December:

	2020 £000	2019 £000
Cash and cash equivalents (Note 17)	**2,940**	4,141
Trade and other receivables	**619**	356
Trade and other payables	**1,471**	3,547
Lease liabilities	**28**	20

The Directors consider that the fair values of the Group's financial instruments do not differ significantly from their book values.

The Group's cash and cash equivalents are denominated in the following currencies:

	2020 £000	2019 £000
Sterling	**1,807**	2,130
US Dollar	**821**	9
Swiss Franc	**44**	36
Euro	**268**	1,966
	2,940	4,141

All of the Group's financial liabilities are due within twelve months of the balance sheet date.

20. Financial instruments and financial risk management continued

Financial risk factors

The Group has a simple corporate structure with the Company and its only operating subsidiary both being UK domiciled. Monitoring of financial risk is part of the Board's ongoing risk management, the effectiveness of which is reviewed annually. The Group does not use financial derivatives, and it is the Group's policy not to undertake any trading in financial instruments.

(a) Foreign exchange risk

In 2020 the Group's recurring revenues from royalties were mostly denominated in Euros. The majority of operating costs are denominated in Sterling although certain of its expenditures were payable in Euros and US Dollars. A 5% difference in the exchange rates would have had the impacts set out in the table below:

		Effect on loss before tax	
	Change in GBP vs. EUR rate	**Year ended 31 December 2020 £000**	Year ended 31 December 2019 £000
EUR	+5.00%	**(13)**	(94)
	-5.00%	**13**	94
USD	+5.00%	**(39)**	–
	-5.00%	**39**	–

(b) Interest rate risk

The Group's policy is to maximise interest receivable on deposits, subject to maintaining access to sufficient liquid funds to meet day-to-day operational requirements and preserving the security of invested funds. With the current low level of bank interest rates, interest receivable on bank deposits in 2020 was £5,000 (2019: £18,000). If interest rates had been 1% higher in 2020 the impact on cash interest received would have been £34,000 (2019: £59,000).

Interest payable arises principally on the Group's leases. If interest rates had been 1% higher in 2020 the impact on cash interest paid would have been £1,000 (2019: £1,000).

(c) Credit risk

Cash balances are mainly held on short and medium term deposits with financial institutions with a credit rating of at least A, in line with the Group's policy to minimise the risk of loss.

Trade debtors are monitored closely to minimise the risk of loss (Note 14).

21. 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).

22. Reserves

The Group's balance sheet contains the following reserves:

- Share capital – the share capital reserve contains the nominal value of the issued Ordinary Shares of the Company.
- Share premium – the share premium reserve contains the proceeds of share capital issued, less the nominal cost and the issue cost of the Company's shares.
- Merger reserve – this reserve records any difference in share capital between the former Shield Holdings AG Group and the Shield Therapeutics plc Group, which replaced it on reorganisation.
- Currency translation reserve – this reserve contains currency translation differences arising from the translation of foreign operations.
- Retained earnings – this reserve contains the accumulated losses and other comprehensive expenditure of the Group.

23. Share-based payments

The Group operates and has operated a number of employee share option schemes under which it grants and has granted share options to the parent entity's share capital to eligible employees. These are accounted for as equity settled or cash settled in the consolidated financial statements.

The schemes which the Group operates are:

Scheme	Eligible participants	Performance conditions
Long Term Incentive Plan (LTIP)[(i)]	Executive Directors and senior management	Yes
Bonus Share Plan (BSP)	Executive Directors and senior management	No
Company Share Option Plan (CSOP)[(i)]	All employees	No
Retention Share Plan (RSP)[(i)]	All employees	Continued employment at vesting date
Retention and Performance Share Plan (RPSP)	All employees	Continued employment at vesting date or performance conditions attached

(i) The LTIP, CSOP and RSP are no longer in use. No further awards will be made under these schemes which have been replaced for all employees with the BSP, RPSP.

The number of options outstanding at the start and end of both 2019 and 2020, the movements through both years, and the expense charged to the Group financial statements were as follows:

2020

Scheme	1 January 2020	Forfeited/ lapsed	Exercised	Granted	**31 December 2020**	Exercisable	Expense £000
LTIP	304,769	(132,885)	(28,851)	–	**143,033**	143,033	67
BSP	124,706	(124,706)	–	–	**–**	–	–
CSOP	394,429	(12,697)	–	–	**381,732**	38,095	11
RSP	54,219	(27,658)	(14,425)	–	**12,136**	12,136	–
RPSP	3,327,031	(654,521)	(388,257)	1,129,203	**3,413,456**	1,249,363	708
Total	4,205,154	(952,467)	(431,533)	1,129,203	**3,950,357**	1,442,627	786

2019

Scheme	1 January 2019	Forfeited/ lapsed	Exercised	Granted	31 December 2019	Exercisable	Expense £000
LTIP	627,026	(104,228)	(218,029)	–	304,769	108,490	(18)
BSP	386,327	(261,621)	–	–	124,706	124,706	(124)
CSOP	558,132	(104,879)	(58,824)	–	394,429	–	18
RSP	161,653	(21,481)	(85,953)	–	54,219	54,219	9
RPSP	1,879,747	(28,916)	(400,000)	1,876,200	3,327,031	–	490
Total	3,612,885	(521,125)	(762,806)	1,876,200	4,205,154	287,415	375

Following the Group's reorganisation in 2018 which led to the departure of senior staff a significant number of options have lapsed. The expense charged in 2019 in respect of the LTIP, RSP and CSOP schemes has been impacted by the reversal of amounts previously charged in respect of share options originally granted to those staff and which have now lapsed.

During 2019 the LTIP performance conditions applicable to the LTIP grants made during 2016 and 2017 were assessed. The performance targets were defined at the time of grant in terms of the compound annual growth rate in the share price over the vesting period. As a consequence of the assessments, 322,257 options lapsed and 304,769 vested. Of the vested shares, 108,490 were exercisable at 31 December 2019; the remaining 196,279 became exercisable in July 2020.

The BSP options were granted in 2018 in lieu of cash bonuses in respect of 2017. At the end of 2018 and in January 2019 most of the underlying bonuses were paid in cash and therefore the relevant options were forfeited, leading to the reversal in 2019 of £124,000 previously charged in 2018. The remaining 124,706 outstanding BSP options have now been forfeited.

23. Share-based payments continued

The CSOP scheme was used to issue both HMRC-approved and unapproved options to employees of the Group. Options were granted in July 2017, May 2018 and October 2018. Of the 394,430 outstanding at 31 December 2019, 50,795 are from the 2017 grant and will vest in 2020 and 343,634 are from the 2018 awards which will vest in 2021. Of the share options issued to CSOP participants in July 2017, 31,745 are issued to participants in the LTIP scheme and can vest under the same conditions described for the LTIP award in July 2017. LTIP participants have the choice of exercising their LTIP award in full or scaling back their LTIP award in order to receive their CSOP equivalent in order to take advantage of the tax efficiency. LTIP participants are unable to exercise both awards in full and potentially dilutive shares therefore exclude the element of the above options which is effectively double counted. Awards which are not associated with the LTIP have no vesting conditions.

The RSP and RPSP were introduced in 2018. The RSP was introduced as a specific retention scheme and vesting was dependent solely on continued employment at the vesting dates which were 31 December 2018 and 31 December 2019. The RPSP is an extension of the RSP scheme which allows the Company to issue either retention or performance-related awards under a single scheme.

The £490,000 expense charged in respect of the RPSP arises from grants made in October 2018, April 2019 and August 2019.

In October 2018 400,000 options were granted as an onboarding incentive package under the RPSP of which all 400,000 have now vested. In April 2019 962,600 options were granted under the RPSP to senior executives with a number of performance measures to be assessed after the end of 2019. To the extent that the performance measures are met, options will vest two years after the Board's assessment of the performance conditions. The fair value of these options has been measured at £0.77 using a Black Scholes valuation model. Also, in April 2019, 174,139 RPSP options were granted to other employees with no performance conditions and automatic vesting in April 2022. These options were valued at £0.77 using a Black Scholes model. In August 2019 739,461 RPSP options were granted to senior management, except the Chief Executive Officer, and other employees. These options have no performance conditions and were valued at £1.775 using a Black Scholes model and vest in August 2020.

In December 2020, 625,000 options were granted under the RPSP to the Chief Executive Officer with a number of performance measures to be assessed after the end of 2021. To the extent that the performance measures are met, options will vest one year after the Board's assessment of the performance conditions. The fair value of these options has been measured at £0.02 using a Monte Carlo valuation model. Also, in December 2020, 510,734 options were granted under the RPSP to senior executives with a number of performance measures to be assessed after the end of 2020. To the extent that the performance measures are met, options will vest two years after the Board's assessment of the performance conditions. The fair value of these options has been measured at £0.64 using a Black Scholes valuation model. Additionally, in December 2020, 325,446 options were granted under the RPSP to other employees with no performance conditions and automatic vesting in December 2022. These options were valued at £0.64 using a Black Scholes valuation model. Measurement inputs and assumptions used in the Monte Carlo and Black Scholes valuations were as follows:

	December 2020 Monte Carlo	December 2020 Black Scholes	December 2020 Black Scholes
Weighted average share price	**£0.54**	**£0.64**	**£0.64**
Exercise price	**£0.015**	**£0.015**	**£0.64**
Expected volatility	**51%**	**51%**	**51%**
Expected option life	**3 years**	**3 years**	**3 years**
Expected dividends	**Nil**	**Nil**	**Nil**
Risk-free interest rate (based on UK government bonds)	**0.70%**	**0.70%**	**0.70%**
Fair value at measurement date	**£0.02**	**£0.64**	**£0.64**

24. Leases

The Group leases assets including office accommodation that are held within property, plant and equipment. Further details of these leased assets are included in Note 12.

Information about leases for which the Group is a lessee is presented below.

Analysis of property, plant and equipment between owned and leased assets	2020	2019
Net book value property, plant and equipment owned	**4**	6
Net book value right-of-use assets	**28**	20
Total	**32**	26

Lease liabilities	2020	2019
Less than one year	**28**	20
Total	**28**	20

Amounts recognised in profit or loss	2020	2019
Interest on lease liabilities	**1**	4
Expenses relating to short term leases	**48**	175
Total	**49**	179

During 2020 the Group entered into a new operating lease arrangement for the Gateshead office. This lease has been capitalised in accordance with IFRS 16.

25. Capital management policy

The primary objective of the Group's capital management is to ensure that it has the capital required to operate and grow the business at a reasonable cost of capital without incurring undue financial risks. The Board periodically reviews its capital structure to ensure it meets changing business needs. The Group defines its capital as its share capital, share premium account and retained earnings. There have been changes to the capital requirements each year as the Group has required regular suitable levels of capital injections to fund development. As mentioned above the Board periodically monitors the capital structure of the Group. The table below details the net capital structure at the relevant balance sheet dates.

	2020 £000	2019 £000
Cash and cash equivalents	**2,940**	4,141

26. Related party transactions

During the year Dr C Schweiger invoiced the Company CHF 8,395 for consultancy services before his appointment as Director on 26 June 2020.

There were no other related party transactions to note during the year.

27. 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.

Glossary

AIM	Alternative Investment Market
CGU	Cash Generating Unit
CHF	Chronic Heart Failure
CKD	Chronic Kidney Disease
CMO	Contract Marketing Organisation
CRO	Contract Research Organisation
EMA	European Medicines Agency
EPO	European Patent Office
EU5	Five largest European markets (France, Germany, Italy, Spain and the UK)
FDA	US Food and Drug Administration
GI	Gastrointestinal
GFR	Glomerular Filtration Rate
GXP	Good Clinical/Laboratory/Manufacturing Practice
H2H	AEGIS-Head-to-Head clinical study
Hb	Haemoglobin
IBD	Inflammatory Bowel Disease
ID	Iron Deficiency
IDA	Iron Deficiency Anaemia
IP	Intellectual Property
IV	Intravenous
NDA	New Drug Application (US)
PDUFA	Prescription Drug User Fee Act (US)
QCA	Quoted Company Alliance
QMA	Quality Management Agreement
R&D	Research and Development
WHO	World Health Organization

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