# The art of therapeutics

**Shield Therapeutics plc** Annual report and accounts 2019

SHIELD
THERAPEUTICS PLC

Improving Lives Together

# Improving lives together

## Shield Therapeutics is a de-risked commercial stage pharmaceutical company focused on addressing iron deficiency in adults with or without anaemia.

Our clear purpose is to develop products that help patients become people again, enabling them to enjoy the things that make a difference in their everyday lives.

Our lead product, Feraccru®/Accrufer®, is a novel, non-salt based oral therapy for the treatment of iron deficiency in adults which is approved in the United States, European Union, UK and Switzerland. In Europe the product is marketed as Feraccru® by Norgine B.V. In the USA the product will be marketed as Accrufer®. We also have a licence agreement with ASK Pharm who will develop and commercialise the product in China.

CONTENTS

## FERACCRU® 2019 OPERATIONAL HIGHLIGHTS

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

## FINANCIAL HIGHLIGHTS

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

## POST-PERIOD HIGHLIGHTS

- Exclusive licence agreement with Beijing Aosaikang Pharmaceutical Co. Ltd ("ASK Pharm") for the development and commercialisation of Feraccru®/Accrufer® in China

Deal highlights:

- US$11.4 million upfront licence payment to Shield
- Up to US$51.4 million in development and sales milestones
- Ongoing tiered double-digit royalties on net sales payable to Shield
- ASK Pharm to be responsible for, and cover costs of, all development and regulatory activity
- Agreed to repay $2.5 million milestone to Norgine, originally recieved in respect of AEG15-H2H clinical study in the first half of 2019

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

shieldtherapeutics.com

**Revenue**

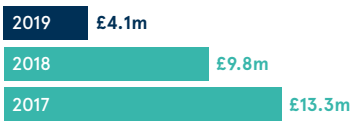
£0.7m


**Loss for the year**

£8.8m


**Net cash at year end**

£4.1m



# Shield Therapeutics is a commercial stage specialty pharmaceutical company

Delivering innovative specialty pharmaceuticals to address patients' unmet medical needs.

FERACCRU® ACCRUFER®

## Our lead asset for the treatment of iron deficiency (ID)


- ✔ Low dose oral iron capsule
- ✔ Twice daily without food
- ✔ High iron availability
- ✔ Raises Hb and iron levels effectively
- ✔ Well tolerated

Patent protection until 2035

## INVESTMENT HIGHLIGHTS

## Reasons to invest in Shield

Large markets of patients poorly treated for iron deficiency

**2 billion**

WHO estimate of global prevalence of Iron Deficiency

**Feraccru® approved and launched in Europe**

Partnered with Norgine in Europe, Australia and New Zealand

40 million ID sufferers in Europe

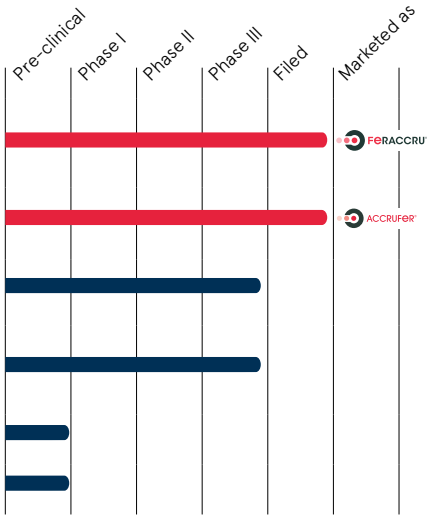
**Accrufer® approved in USA**

Partnering process underway

10 million IDA patients in USA

## OUR PRODUCT PIPELINE

| Product | Indication | Recent or upcoming milestones |
|---|---|---|
| FERACCRU® | **Iron deficiency in adults (EU)** | **Approved for marketing in EU, UK, Norway, Iceland and Switzerland Commercialisation led by Norgine BV** |
| ACCRUFER® | **Iron deficiency in adults (USA)** | **Approved for marketing in USA Currently selecting a US partner** |
| | **Iron deficiency anaemia in children (EU and US)** | **Expect to initiate Phase III trial in 2020** |
| **PT20** Iron-based phosphate binder | **Hyperphosphatemia (EU and US)** | **Phase II pivotal study completed. Requires one further Phase III pivotal study to allow a NDA to be filed** |
| **PT30** Novel IV Iron | **Iron deficiency anaemia** | |
| **PT40** Generic IV Iron | **Iron deficiency anaemia** | |




## PROGRESS WITH FERACCRU®/ACCRUFER®

↗ Learn more about Feraccru® on pages 8–9

### Europe

- Approved for the treatment of ID in adults, with or without anaemia
- Licensed to Norgine for commercialisation
- Norgine promoting in the UK and Germany
- Further EU launches expected in 2021

### USA

- Approved by FDA in July 2019
- Evaluating commercialisation options

### Rest of World

- Licensed to Norgine in Australia and New Zealand
- Exploring further out-licence opportunities

### China

- Licensed to ASK Pharm for development and commercialisation
- $11.4 million upfront received in January 2020

Licensed to ASK Pharm in China

Population of 1.4 billion people

Feraccru®/Accrufer® patents extend to

2035

Novel phosphate binder in pipeline

Current cash runway extends to

Q1-2021

# A year of delivery

**JAMES KARIS**
**Chairman**

## 2019 was a successful year for Shield Therapeutics, capped by the FDA's approval of Accrufer®

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

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

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

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

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

The achievements over the last 18 months have been a vindication of the Group's strategy. The identification of Feraccru®'s potential over ten years ago, followed by the clinical study programme in challenging patient populations in inflammatory bowel disease, chronic kidney disease and the head-to-head study, have resulted in an effective product with a good side-effect profile for use in a broad range of patients, which is now approved in Europe, where it is already marketed, the USA and with excellent prospects of approval in China and elsewhere.

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

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

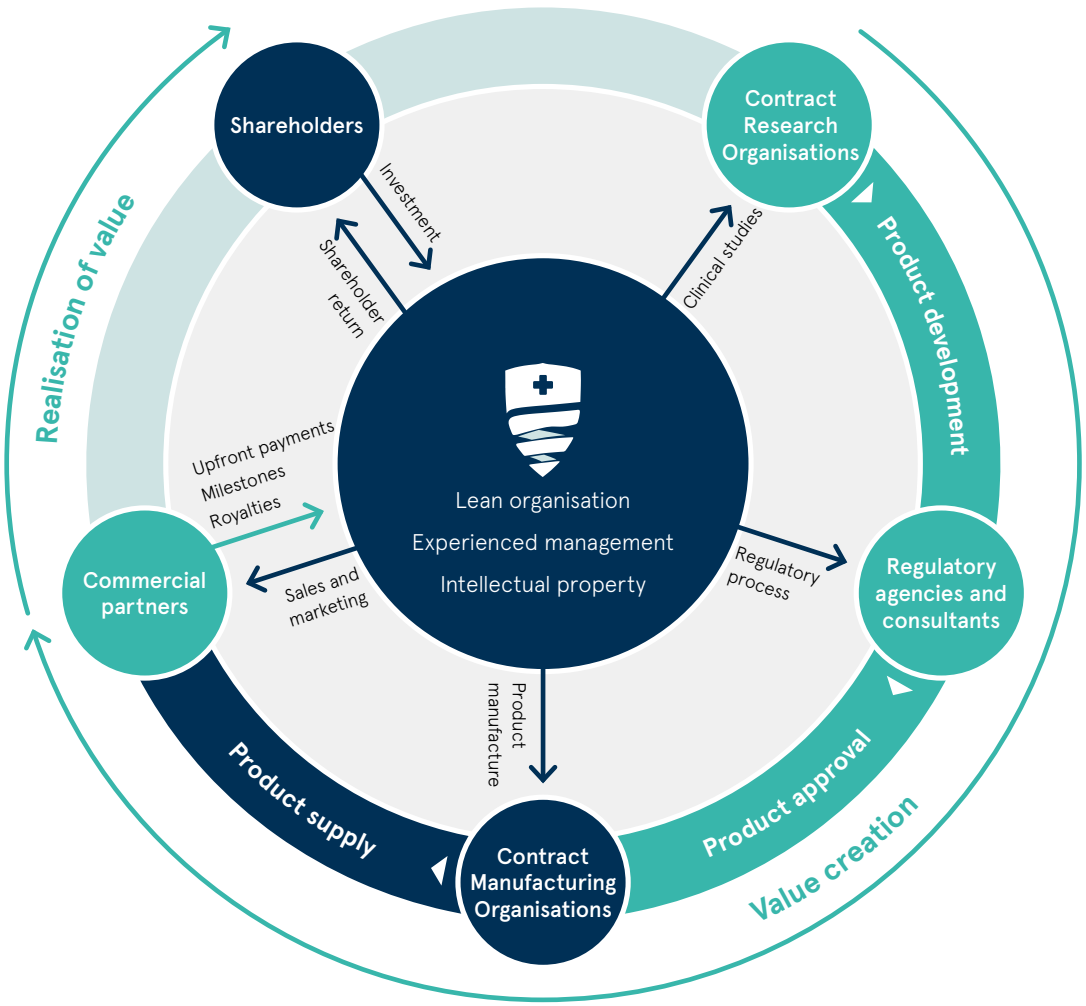
In April 2020 Carl Sterritt announced his decision to resign as Chief Executive Officer. I would like to reiterate my thanks to Mr Sterritt for the substantial contributions that he made to Shield since he founded the Company and I wish him and his family all the best for the future. I am very pleased that Tim Watts, formerly Chief Financial Officer, has been appointed as the new CEO and I wish him every success in the role.

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

**James Karis**
**Chairman**
20 May 2020

# How we do business

- The fundamental value in the business is the intellectual property surrounding Feraccu®/Accrufer®, comprising patents, know how and data from the clinical and pre-clinical studies
- Management's role is to exploit that intellectual property for the good of the Group and its shareholders
- The core activities in developing and commercialising pharmaceutical products are outsourced to Contract Research and Manufacturing Organisations (CROs, CMOs) and licensed to partners for commercialisation
- Shield runs a lean organisation with around 20 employees
- The Leadership Team is formed of Tim Watts and three other senior managers, all of whom have many years' experience in the pharmaceutical industry
- Leadership Team members and their teams define the deliverables required from the outsource organisations and partners and then manage that delivery



# The iron deficiency market

## A large market, with significant unmet needs

Iron is a vital component for all living organisms as it is essential for the smooth functioning of multiple metabolic processes. In particular, iron is involved in the production of red blood cells (RBCs), which transport oxygen in the blood. Maintaining normal iron levels in the blood and bone marrow is essential for optimal functioning of the human body. Iron is a core component of enzymes and proteins involved in processes such as DNA synthesis, electron transport, cell proliferation and differentiation, cellular respiration, and immune protection against bacteria. Most importantly, iron is an essential element in the production of haemoglobin (Hb), the blood protein that transports oxygen from the lungs to various tissues. Insufficient levels of iron or decreased total iron in the body is defined as iron deficiency (ID).

The clinical consequences of untreated ID include fatigue, neurobehavioural disorders and cognitive impairment. The World Health Organisation has estimated that some 2 billion people globally are affected by ID. As ID is a common comorbidity of other medical conditions and not the main cause of the disease, ID is often overlooked and undertreated. Untreated ID can lead to iron deficiency anaemia (IDA). Although every individual is different, typically IDA can begin when Hb levels fall below 13g/dl (men) and 12g/dl (women).

| Hb concentration | Anaemia stage | Common symptoms |
|---|---|---|
| 11–12g/dl (women)<br>11–13g/dl (men) | Mild | Fatigue, dizziness, headache, shortness of breath, irregular heartbeat, mild depression and irritability, reduced cognitive performance affecting concentration, memory, and learning abilities |
| 8–11g/dl | Moderate | |
| <8g/dl | Severe | |

### Causes of ID

ID is caused by reduced ability to absorb iron or by loss of blood. It is common in patients with chronic diseases which cause bleeding or reduced ability to absorb iron such as Chronic Kidney Disease (CKD), Inflammatory Bowel Disease (IBD), Congestive Heart Failure (CHF) and cancer. It is also often seen in pregnancy and pre-menopausal women.

### Treatment of ID

ID is typically treated with either generic oral iron salt products or with intravenous iron therapy. Oral iron salts are usually prescribed as first line therapy because they are convenient and inexpensive. IV therapy is normally used as second line therapy because it is less convenient and more expensive.

Oral iron salt products are associated with many adverse effects. Gastrointestinal (GI) side-effects are the most commonly reported adverse events in patients taking oral iron salt drugs. When salt-based oral iron drugs are administered, the iron must first dissociate from the salt to allow the iron to be absorbed. This free iron chelates to form insoluble clumps and produces damaging free radicals. These together cause a range of mild-to-severe adverse events in the GI tract, including nausea, bloating, diarrhoea and constipation. In addition, many patients with ID are simultaneously treated with medicines that raise the pH level in the stomach, which further reduces the effect of salt-based oral iron drugs which require highly acidic conditions to be absorbed. As a result, although oral iron therapy is considered as the first line of treatment option for ID, a high percentage of patients suffer from side-effects resulting in non-adherence and treatment failure.

Although IV iron therapy has fewer adverse effects, a rare but serious complication is a risk of anaphylactic shock and all IV treatment is required to be administered in a hospital or clinic setting which is inconvenient for the patient and adds cost to the treatment.

### Characteristics of oral and IV iron drugs

| Parameter | Oral Iron | IV Iron |
|---|---|---|
| Absorption | Low | High |
| Iron bioavailability | Inadequate | Generally high |
| GI adverse events | Affect 20–30% of patients, up to 50%–70% in IBD patients | Less frequent due to IV administration of iron |
| Hypersensitivity reactions | Not applicable | Risk of anaphylaxis with dextran-containing formulations<br>Risk of hypersensitivity reactions |
| Compliance | High pill burden as patients need to take three tablets per day usually | Administered by a health professional |
| Convenience | Convenient as it can be administered at home by patients themselves | Require hospital/clinic visit |
| Dosage | Typically 100–200mg iron/day | Up to 1,000mg iron in a single injection |
| Cost | Inexpensive | More expensive per dose but fewer doses required |
| Observation time | Not required | Patient should be observed for at least 30 minutes following each injection |

## Market size

The market for oral and IV ID drugs in 2018 is estimated to be around $4 billion and to be growing at around 10% annually.

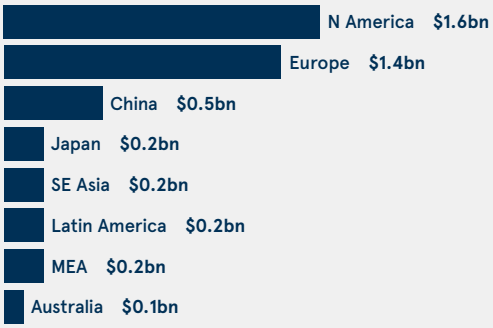
The prescription volumes for oral iron salts is much greater than for IV therapy because oral products tend to be given as first line therapy. However, by value, the global IV market is almost the same size as the oral market because many IV iron therapies are branded and therefore more expensive than the generic iron salts.

## Market size by global oral/IV split (2018)

$4.1bn


## Market size by geography

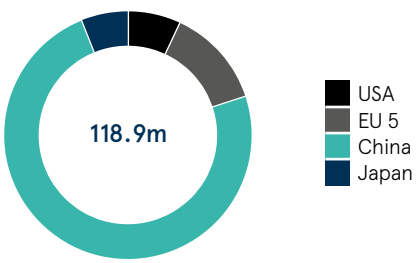
$4.1bn




## Prevalence of Iron Deficiency Anaemia (IDA)

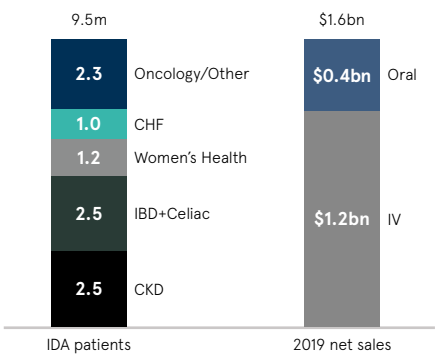
Many people with ID will not be treated. This could be because the symptoms are mild, but it is also because incidence of ID is very high in poorer countries where diet is inadequate and access to healthcare services is limited. Most of the prescribed iron therapy treatments will be prescribed for patients with IDA, where the ID has progressed to the point where it is causing more serious problems. The chart below shows the prevalence of IDA in the major pharmaceutical markets:

Number of patients




## IDA in the USA

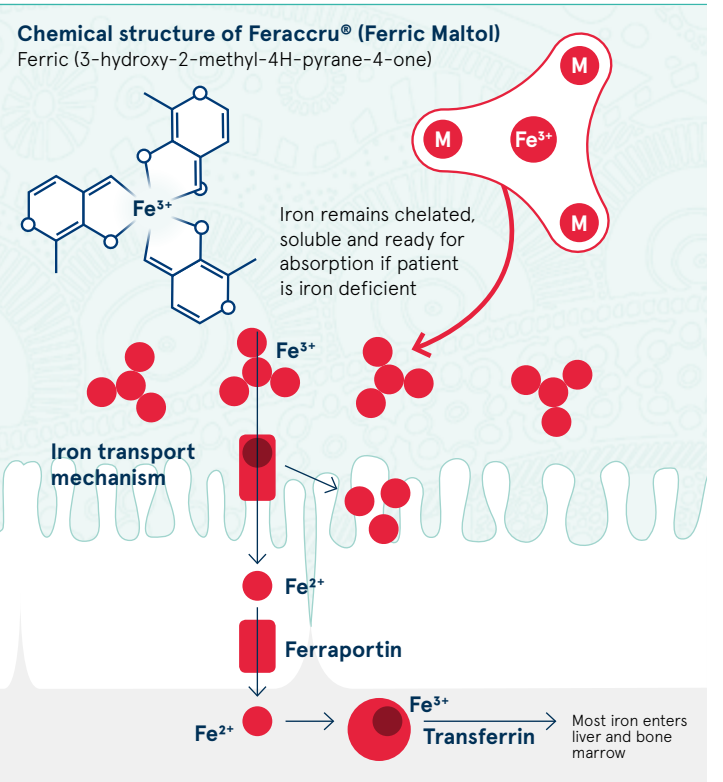
In the USA, the largest pharmaceutical market, there are estimated to be around 9.5 million patients suffering from IDA and who could be treated with iron replacement therapy. Most of the $1.6 billion iron replacement sales in the US are for the treatment of IDA.



# Feraccru® – a novel oral formulation that addresses the needs of patients who cannot tolerate existing oral iron products and offers a clear alternative to IV iron therapy

## Feraccru® mechanism of action

- Feraccru® is a low dose (60 mg/day) oral formulation of a complex of $Fe^{3+}$ (ferric maltol), which is stable in the gastrointestinal (GI) tract
  - Existing iron salts deliver iron as $Fe^{2+}$, which forms insoluble products in the GI tract or releases free radicals, both causing intolerance in patients
- The $Fe^{3+}$ in Feraccru® remains in complex with maltol until absorbed when the iron is delivered to the bloodstream, where it binds to transferrin
  - Maltol gets metabolised and excreted in urine
  - Unabsorbed Feraccru® passes through the digestive system as an unaltered complex and is excreted in faeces
- Feraccru® is a well-tolerated oral iron replacement therapy
  - Potential for use as a first line treatment for patients with ID or as an alternative to IV iron in patients failing with existing oral iron salts
  - Effectiveness demonstrated in three Phase III studies

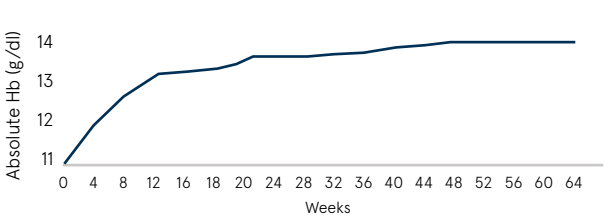



### Clinical studies provide compelling evidence of efficacy and tolerability

Two Phase III studies, in patients suffering from bowel disease (AEGIS-IBD) and chronic kidney disease (AEGIS-CKD), showed that twice daily Feraccru®/Accrufer®:

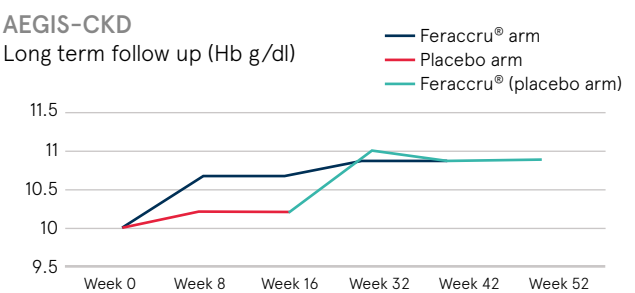
- Restored Hb levels quickly – over the 12 and 16 weeks set as the primary end points;
- Maintained Hb levels over the full 52 weeks of the studies; and
- Was well-tolerated by patients.

AEGIS-IBD



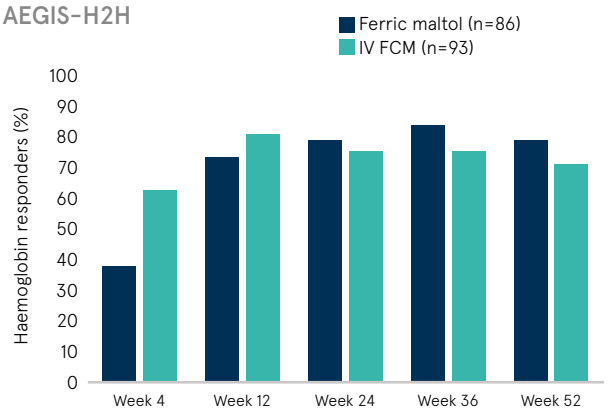

AEGIS-CKD

Long term follow up (Hb g/dl)



A third clinical study was conducted in IBD patients, this time comparing the performance of Feraccru®/Accrufer® against the market-leading IV iron therapy (AEGIS-H2H). This showed that Feraccru®/Accrufer®:

- prevented recurrence of IDA over 52 weeks whereas 39% of the subjects in the IV treatment group required intervention due to recurrence of IDA; and
- offers a simple, well tolerated and efficacious oral treatment alternative to IV iron therapy, without the need for hospital-based administration.

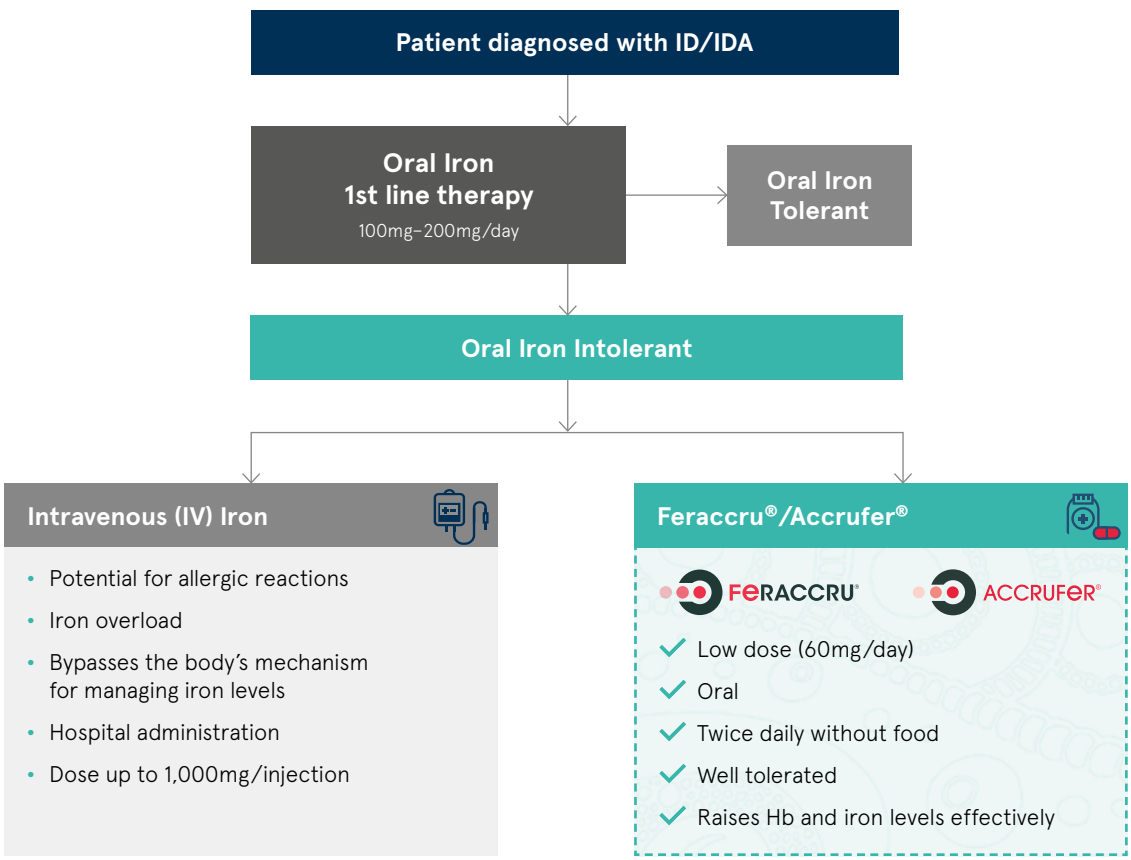



## Paediatric study

Subject to the impact of coronavirus the Group plans to start a paediatric study in infants and children towards the end of 2020 which will establish whether Feraccru®/Accrufer® can also be used in this population. A new liquid formulation is required for this population and so the first stage of the study is to compare the liquid formulation with the established capsule formulation in healthy volunteers, to ensure that the efficacy and tolerability profile is comparable. The main stage of the study is likely to start in 2021 and last around two years.

## Feraccru® is positioned to treat patients who cannot tolerate oral iron

With the evidence of the clinical studies, Feraccru®/Accrufer® is ideally positioned as a real oral alternative to IV.



# Focused on strategy

**Delivered in 2019**

## ✔ Gain marketing approval of Accrufer® in the USA

Accrufer® approved by FDA in July 2019.

## ✔ Out-license Feraccru® in at least one other significant market

Feraccru® outlicensed in China to ASK Pharm (announced January 2020).

**Ongoing focus for 2020**

## Out-license commercialisation of Accrufer® in the USA

Licensing discussions with potential partners in the USA are underway.

## Initiate paediatric Phase III study

Paediatric crossover study to start in H2 2020.

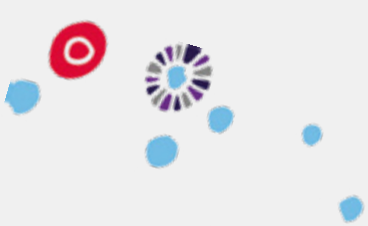
## Out-license commercialisation of Feraccru® in other markets

## Ongoing development of PT20

PT20 formulation development to start in H2 2020.

**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

£0.7m


#### Description

The Group measures revenue as a key financial metric.

#### Performance

Revenue can be significantly impacted by the timing of licence upfront and milestone receipts, In 2018, an £11.0 million upfront was received from Norgine.

### Loss for the year

£8.8m


#### Description

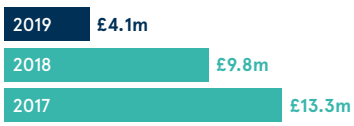
The Group's loss for the financial year measures its overall financial performance during the period.

#### Performance

Receipt of the £11.0 million upfront payment from Norgine in 2018 significantly reduced the loss in that period.

### Net cash at year end

£4.1m




#### 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's cash position has been significantly improved since the year end by receipt of the $11.4 million upfront payment from ASK Pharm in January 2020.

## NON-FINANCIAL

### Employees (year end)

18


#### Description

Given the current strategic objectives of the Group, headcount is considered to be a key indicator of central cost control and the appropriateness of the Group's structure.

#### Performance

The Group's headcount was significantly reduced following the decision in 2018 to rationalise central costs, close commercial operations and out-license the Group's commercial activities.

### European sales volume growth

+66%


#### Description

The Group monitors the packs being sold by Norgine in Europe.

#### Performance

Feraccru® has been launched in Germany and the UK, two of the five major markets in Europe. Sales volume growth was 66% in both 2018 and 2019.

# Continued progress

**TIM WATTS**
**Chief Executive Officer**

I am honoured to have been appointed as CEO at this important time for Shield and thank the Board for its support. Shield has a strong and dedicated team, and I look forward to working together to achieve the Company's goals.

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

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

### Regulatory and clinical studies

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

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

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

- The study did not meet its overall primary end-point of non-inferiority at 12 weeks because this was clearly not achieved in the "intention to treat" (ITT) population, although there was a high response rate;
- IDA re-occurred at least once in approximately 39% (49) of the subjects in the IV arm of the study following the initial treatment with IV therapy, requiring a total of 69 additional IV iron infusions to be administered; and
- Feraccru®/Accrufer™ was effective and generally well tolerated over 52 weeks of treatment with a side-effect profile consistent to that seen in previous placebo-controlled studies.

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

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

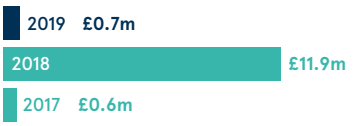
Both the European and US regulatory authorities require that the Group conducts a paediatric clinical study in children up to 18 years old. For small children and infants a liquid formulation is required rather than the capsule which is the formulation used in the adult patient population. A crucial first step is therefore to formulate a suitable liquid formulation and then to prove its equivalence to the capsule. We have been working on developing this formulation during 2019 but the process has taken somewhat longer than we originally envisaged. However, we now have a formulation and subject to the coronavirus pandemic situation, the equivalence study will be conducted towards the end of 2020.

## Commercialisation

In Europe we licensed Feraccru® to Norgine for commercialisation in September 2018. The first few months after this were taken up with the transfer to Norgine of knowledge, technical information and the Marketing Authorisation (MA), as well as a full suite of educational and marketing materials. During this period Norgine's own sales representatives were also trained on the product, resulting in commercial activities in Germany and England commencing in earnest in the first quarter of 2019. In Europe products are often commercialised first in these two markets as companies are able to set the selling prices and Feraccru® has been able to achieve attractive pricing levels in both markets. In most other European markets, and in particular the large markets of France, Italy and Spain, as well as the remaining countries in the UK, it is necessary to submit pricing and reimbursement applications to the relevant authorities and for these to be agreed before the product receives reimbursement and therefore can be commercialised effectively. With the positive long term results from the AEGIS-H2H study comparing Feraccru® with Ferinject®, the market-leading IV iron therapy, these pricing applications are now being prepared for filing with the authorities in France, Italy and Spain by Norgine using the AEGIS-H2H results to support the applications for reimbursement. These pricing and reimbursement processes do take time, however, so we do not expect launches to occur in these markets before 2021.

**Reported revenue**

£0.7m

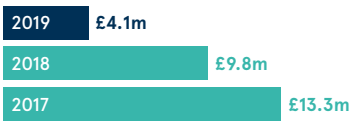



**Loss for the year**

£8.8m


**Net cash at year end**

£4.1m




## **Commercialisation** continued

In both Germany and England, in order to establish the product before broadening promotion to other indications, the initial promotional focus by Norgine has been on IDA in IBD, targeting gastroenterology specialists working in hospitals and office clinics. Norgine has a significant number of sales representatives and key account managers promoting Feraccru® in Germany and England and these teams are supported by medical and reimbursement specialists. Progress to date has been encouraging with combined in-market pack sales in these two markets in 2019 already being almost 70% higher than 2018.

As is usual with prescription pharmaceutical commercialisation in Europe, early growth in Germany has been stronger than that in England as Feraccru® benefits from nationwide reimbursement in Germany, whereas in England each of the nearly 200 Clinical Commissioning Groups (CCGs) has its own formulary, with each requiring new products to be reviewed before reimbursement is approved. This involves the submission of formulary applications for approval by each CCG, inevitably slowing down the initial uptake of a product across England. To date around one-third of the hospital trusts in England have approved reimbursement of Feraccru®. Norgine is continuing to work on persuading the remaining hospital trusts to place Feraccru® on their formularies. Scotland, Wales and Northern Ireland have their own procedures and, with the AEGIS-H2H data available, Norgine is in the process of preparing and submitting applications to these authorities.

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

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

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

Based in Nanjing, Jiangsu Province, ASK Pharm was founded in 2003 and is listed on the Shenzhen stock exchange. ASK Pharm is an integrated pharmaceutical enterprise that focuses on the GI and oncology therapeutic areas, being one of China's leading manufacturers of proton pump inhibitor and oncology medications. With a market capitalisation of approximately CNY15 billion (US$2.2 billion), 2018 sales revenues in China equivalent to more than US$560 million and over 1,000 sales representatives, ASK Pharm is both well resourced and very well positioned to capitalise on the Feraccru®/Accrufer® opportunity in China, one of the world's largest and fastest growing prescription pharmaceutical markets. I am delighted

that we have been able to partner with ASK Pharm in China. It is an ambitious and successful pharmaceutical company with an excellent track record of product development and commercial success. Its established product development and commercial infrastructure and expertise in China should speed the regulatory approval and drive subsequent sales of Feraccru®/Accrufer®. The market in China for novel prescription pharmaceuticals continues to grow rapidly and this agreement will mean more patients with iron deficiency will benefit from Feraccru®/Accrufer®.

We very much look forward to working with ASK Pharm and supporting it as it advances the Feraccru®/Accrufer® franchise in China.

## Intellectual property (IP)

We continue to work on strengthening our intellectual property, including patents. During 2019, both the US and Japanese patent offices have allowed a "treatment use" patent protecting Feraccru® until January 2035. This application (entitled "Dosage regimen of ferric trimaltol") allowed claims relating to the administration of Feraccru® twice daily on an empty stomach, where the percentage of ferric trimaltol is at least 60% of the combined weight of ferric trimaltol and excipients. More recently, in April 2020, the Chinese Patent Office has allowed our composition of matter patent.

We also continue to defend our patents robustly. As previously reported Teva has raised objections with the European Patent Office (EPO) to the Group's patents (#2 668 175 and #3 160 951) which cover "Process for preparing an iron hydroxypyrone" and "Crystalline forms of ferric maltol" respectively. On 14 March 2019 the Opposition Division of the EPO decided in favour of Shield in respect of the former patent as amended. However, as anticipated, in June 2019 Shield received notice that Teva had filed a notice of appeal to the EPO's decision. Currently no date has been set for the appeal hearing. The EPO had set a date of 23 June 2020 for the oral hearing in respect of patent #3 160 951, but this has now been postponed due to the coronavirus pandemic.

## Pipeline – PT20 (phosphate binder)

Although we were not able to prioritise PT20 for development during 2018 and 2019, we plan to re-start this programme. We continue to believe that PT20 has the potential to be a significant product in the phosphate binder market. This market continues to grow and, within it, the new iron-based phosphate binders are growing particularly rapidly. PT20, which is iron-based, has characteristics which could give it competitive advantages over existing iron-based products. PT20 has already completed one pivotal clinical study giving us significant confidence in the potential of the product. One further pivotal Phase III study is required to be carried out. Initially we will develop a new formulation of PT20 which will allow the next Phase III study to be carried out and which would be suitable for commercial use. We anticipate that the formulation development work and manufacturing clinical study material could start in the second half of 2020 and should take around 15-18 months, meaning that the Phase III study could potentially start in 2022, subject to finance being available.

## Brexit

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

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

## Coronavirus

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

## Outlook

Having secured FDA approval of Accrufer®, and with Feraccru® sales in Germany and the UK beginning to increase significantly, and the China licence secured, I have great confidence in the future for Shield. Having received $11.4 million from ASK Pharm we have a cash runway extending into the first quarter of 2021 which gives us the flexibility to negotiate the best possible commercialisation arrangement in the US. The positive results of the AEGIS-H2H comparator study combined with the broad iron deficiency labels in the US and Europe mean that Feraccru®/Accrufer® is a highly competitive product, which should drive Shield's royalty and sales milestone income for many years.

## Financial review

### Revenue

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

### Cost of sales

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

### Selling, general and administrative expenses

Selling, general and administrative expenses were £6.8 million in 2019 (2018: £12.4 million). £3.4 million of this reduction is attributable to the reduction in selling costs from £3.5 million in 2018 to £0.1 million following the decision taken in February 2018 to adopt an out-licensing strategy for commercialisation rather than the self-commercialisation strategy employed until then. General and administrative expenses also reduced, from £6.6 million in 2018 to £4.1 million in 2019, as a consequence of the change in commercialisation strategy which led to restructuring costs in 2018 which have not recurred in 2019 and a broader reduction of support and administration costs. The remaining £2.6 million of the 2019 costs arose on depreciation and amortisation, compared with £2.4 million in 2018, the increase being due largely to the increase in capitalised development costs.

## Research and development (R&D)

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

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

## Tax

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

## Balance sheet

Intangible assets at 31 December 2019 were £29.9 million (31 December 2018: £31.0 million). The components of this are £19.5 million (31 December 2018: £21.5 million) relating to the acquisition costs of PT20, the phosphate binder product in our development portfolio; £9.0 million (31 December 2018: £7.9 million) relating to capitalised Feraccru® development expenditure, in particular the AEGIS-H2H study and the paediatric pharmacokinetic study, and £1.5 million (31 December 2018: £1.5 million) expenditure on strengthening the Group's intellectual property.

Property, plant and equipment has been restated under IFRS 16 Leases as this has impacted the accounting treatment of our leasehold premises (see Note 2). At 31 December 2019 the balance was £26,000 (31 December 2018: £0.2 million, restated).

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

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

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

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

Lease liabilities of £20,000 at 31 December 2019 (31 December 2018: £0.1 million) have arisen as a result of the IFRS 16 restatement referred to under property, plant and equipment above.

## Cash flow

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

## Going concern

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

The Directors have considered the funding requirements of the Group through the preparation of detailed cash flow forecasts for the period to December 2021 including the repayment of the €2.5 million milestone to Norgine. Under current business plans the current cash resources will extend into the first quarter of 2021. As a result, additional revenue generating transactions or additional finance would therefore be needed by the first quarter of 2021 to allow the business plans to continue. The Directors are considering further commercialisation out-licensing opportunities for Feraccru®/Accrufer®, in the USA and also in other territories. These arrangements would be expected to include upfront payments which, if any one was achieved, would further extend the Group's cash runway. The Directors also believe that other forms of finance, such as debt finance or royalty finance underpinned by the existing European and Chinese out-licensing agreements, are likely to be available to the Group. However, there can be no guarantee that any of these opportunities will be successfully concluded. The Directors do not believe that the coronavirus pandemic will significantly impact the revenues included in the cash flow forecasts, nor the ability to complete commercialisation out-licensing transactions or to raise additional finance.

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

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

## Financial outlook

The Group expects that Feraccru® sales in the UK and Germany will continue to grow during 2020, and increased royalties will flow from that growth. However launches in the other major European markets are not expected until 2021 as pricing and reimbursement negotiations in those countries can take 12 to 18 months. Selling, general and administrative costs in 2020 will continue at levels seen during 2019 while total R&D expenditure (i.e. both the amount charged to the statement of profit and loss and any amounts capitalised) for the year will be broadly in line with the amounts incurred in 2019. Overall, the Group's cash runway extends into the first quarter of 2021 without including any potential upfront from an out-licensing agreement in the USA or other regions. In the event that such agreements are concluded, the Group would expect them to include upfront receipts which would extend the cash runway.

The strategic report was approved on 20 May 2020 by order of the Board.

**Tim Watts**
**Chief Executive Officer**
20 May 2020

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

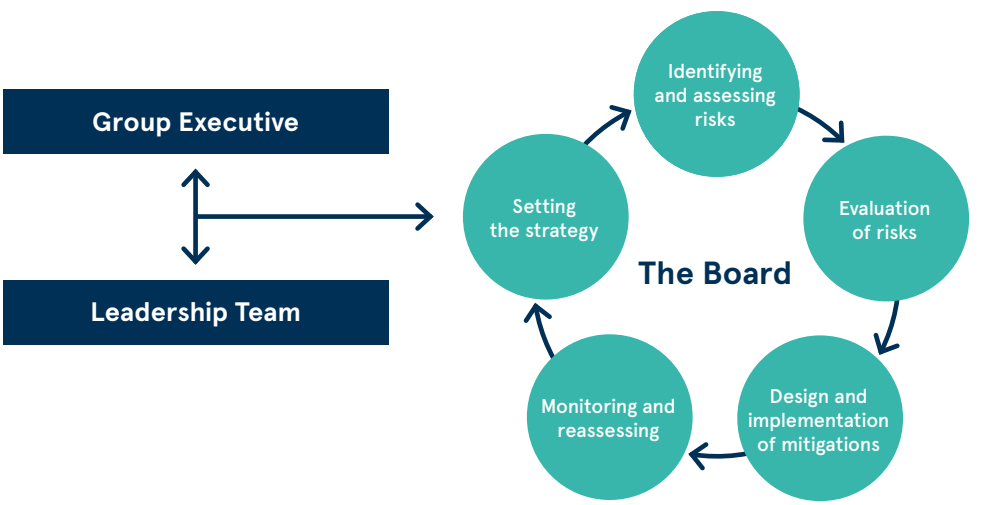
### Risk management framework

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 and in November 2019 the Committee reviewed the Group's risk management policy and procedures to ensure that they remain relevant.

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.



**Over the last twelve to eighteen months the Group's risk profile has changed considerably as the Feraccru®/Accrufer® Phase III clinical studies have been successfully concluded, the product has been approved in the USA to add to the earlier European approval, and it has been successfully out-licensed for commercialisation in Europe, and China.**

**The current principal risks are:**

**Key** ⟷ No change ↗ Increased ↘ Decreased

| Risk description | Change | Potential impact | Mitigation |
|---|---|---|---|
| **Commercialisation partners fail to achieve Feraccru®/ Accrufer® potential** | ↗ | Shield will under-deliver shareholder value as royalties and sales milestones will not be maximised.<br>This risk has been previously noted in relation to Europe but has now increased in scale following the licence agreement covering China. | Commercialisation out-licensing agreements contain performance measures to enable Shield to monitor the performance of partners. |
| **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. |
| **Disruption to product supply** | ↗ | Failure to supply product to the Group's commercialisation partners could undermine sales potential. | The Group holds substantial quantities of raw materials and has clearly defined agreements with its CMO suppliers. |
| **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. |
| **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. |
| **Ability to attract and retain key staff and members of management team** | ↘ | As a semi-virtual company with relatively few employees, Shield's ability to 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. |
| **Failure to develop PT20** | ↘ | PT20 has a carrying value of £19.5 million in intangible assets which could be at risk if PT20 is not commercialised. | The Group has appointed a contract manufacturer to develop and manufacture an appropriate formulation. |

**The following risks noted in the 2018 Annual Report are no longer regarded as principal risks:**

| Risk description | Explanation |
|---|---|
| **Failure to achieve US approval of Feraccru®** | In July 2019, the FDA approved Feraccru® (Accrufer® in USA) for the treatment of iron deficiency in adults. |
| **Dependency on a single product** | Although Shield's valuation is dependent on the success of Feraccru®/Accrufer®, the Board considers this risk to have diminished as the product is now approved in Europe and the USA, is licensed to partners for commercialisation, and has an excellent safety profile. |
| **Delays in local reimbursement**<br>**Reliance on wholesalers** | Pricing, reimbursement and local distribution activities are now controlled by Shield's commercialisation partners and these risks are therefore now absorbed into the risk that partners fail to achieve the product's potential. |

## TIM WATTS
### Chief Executive Officer

**Tenure**
One month

**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.

## JAMES KARIS
### Non-Executive Chairman

**Tenure**
Four years

**Skills and experience**
James is a life sciences and healthcare industry executive with over 35 years of experience in the pharmaceutical, healthcare services, technology and medical device industries. A proven entrepreneur he is also an experienced Board member for public and private companies with extensive experience in corporate strategy, M&A and all aspects of company financing. He has a BSc in Management and Economics from Purdue University and a MA in Applied Economics from the American University. Previously James was Chief Executive Officer of privately held MAPI Group and earlier he held executive management roles at CollabRx, Entelos, Inc., PAREXEL International, Pharmaco International and Baxter International.

**External appointments**
James is a Director of Saama Technologies Inc., an AI-based clinical analytics company.

**Committee membership**
N R

## PETER LLEWELLYN-DAVIES
### Non-Executive Director

**Tenure**
Four 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 and enhancing shareholder value with a new large international investor base. 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 founder of Accellerate Partners, and is a Non-Executive Director of 4 basebio AG (FSE).

**Committee membership**
A N

## ROLF HOFFMANN
**Non-Executive Director**

### Tenure
Two 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
N R

## HANS PETER HASLER
**Non-Executive Director**

### Tenure
Eighteen months

### Skills and experience
Hans Peter joined the Board of Shield Therapeutics plc in July 2018. His prior experience includes roles as COO at Elan Corporation, and several senior positions at Biogen, Inc., including Chief Operations Officer. Previously, Hans Peter was at Wyeth Pharmaceuticals as Senior Vice President, Chief Marketing Officer and Managing Director of Wyeth Group Germany, Wyeth-Lederle Switzerland, Austria and CEE.

### External appointments
He is the founder and CEO of Vicarius Pharma and an advisor to SBTech Global Advisory.

Hans Peter is Chairman of HBM Healthcare Investments AG in Switzerland, Chairman of MIAC Medical Imaging Analysis Center of the University Hospital of Basel, and a Director of the board of Minerva Neuroscience Inc., Boston.

### Committee membership
A N

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

**JAMES KARIS**
**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. In November 2019 the Company announced that, following a review by the Board of Directors and based on the size of the Company and its range of activities, it would be adopting the Quoted Companies Alliance Corporate Governance Code (the "QCA Code") with immediate effect. 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 Committee. |
| **CEO** | Carl Sterritt[(ii)] | |
| **CEO** | Tim Watts [(iii)] | |
| **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. |
| **Independent NED** | Hans Peter Hasler | Chair of Nomination Committee. Member of Audit Committee. |

(i) Appointed as Chairman 22 January 2019; previously a Non-Executive Director

(ii) Resigned 21 April 2020

(iii) Appointed 24 April 2020

## **Effectiveness** continued

### Composition of the Board continued

James Karis was appointed as Company Chairman on 22 January 2019, following the resignation of Andrew Heath on 27 June 2018. James joined the Board in 2016 as an independent Non-Executive Director and was independent at the time of his appointment as Chairman.

Carl Steritt resigned as CEO and from the Board on 21 April 2020. Tim Watts was appointed as CEO on 21 April 2020 and formally joined the Board on 24 April 2020.

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

No Executive Director holds a directorship of a FTSE 100 company. The ongoing training needs of Directors are reviewed during the course of each year.

Directors are re-elected at the first Annual General Meeting 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.

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

| 2019 meetings | Number of meetings | Attendance |
|---|---|---|
| Main Board | 9 | All Directors attended all meetings except that James Karis and Peter Hasier were each unable to attend one meeting |
| Audit Committee | 4 | All Committee members attended |
| Remuneration Committee | 8 | All committee members attended all meetings except that James Karis was unable to attend one meeting |
| Nomination Committee | 2 | All Committee members attended |

The Non-Executive Directors also meet without the Executive Directors present on an ad hoc basis during the course of the year. The Non-Executive Directors consider the performance of the Executive Directors 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 independent and are available to shareholders and as a sounding board for the other Directors. 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 all Non-Executive Directors 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 48% 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 served as a Director of AOP is a commercial partner of Shield, until January 2018. AOP a significant shareholder in Shield. The Board considers Mr Hasler to be independent as he no longer serves as a member of AOP's board and does not represent its interests.

### Appointments to the Board

The Nomination Committee is comprised of the Chair and the other Non-Executive Directors who are all considered independent. 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 29.

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 they 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, who are both considered to be independent Non-Executive Directors. Peter Llewellyn-Davies is Chair of the Committee and is considered to have recent relevant financial experience, having previously held the role of CFO of other companies. 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 page 25 and 26.

### 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 18 and 19 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 27 to 31.

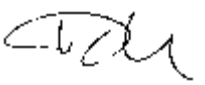
## Engagement with stakeholders

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 portals 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, which allows shareholders the opportunity to raise questions with the Company's Directors, are provided in the Directors' report on page 33. All Directors, including the Chairs of the Audit, Remuneration and Nomination Committees, will be available to answer questions. Separate resolutions are proposed at the Annual General Meeting 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 18 and 19 of the annual report.



**James Karis**
**Chairman**
20 May 2020

**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 four times during 2019. In March and April 2019 it met to receive the report from the auditor on the audit of the 2018 financial results, and to review the draft preliminary results announcement and the draft 2018 Annual Report. Key audit issues discussed at the meetings included:

- The recognition as revenue of the £11 million upfront received from Norgine in September 2018 – the Committee concluded this should be recognised in full in 2018 as all the IFRS 15 criteria were satisfied;
- The continued capitalisation of development expenditure incurred on the AEGIS-H2H clinical study – the Committee concluded that this accounting treatment remained appropriate in light of the positive results from the study;
- 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 September 2018 agreement with Norgine to commercialise Feraccru® in Europe and the likelihood at the time of securing US approval for the product; and
- Going concern – the Committee concluded that it was appropriate to prepare the 2018 financial statements on the going concern basis as management's cash flow projections showed the cash runway extending to the third quarter of 2020, and in the absence of any further revenues mitigating actions could be taken to extend the runway towards the end of 2020.

## Activities of the Audit Committee continued

On 30 July 2019 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, as the FDA had by this date granted approval to Feraccru®/Accrufer® in the USA and the processes to find commercialisation partners for both the USA and China were progressing well, the Committee concluded that the probability of securing an upfront receipt before the cash runway expired had increased significantly and therefore that the use of the going concern basis of preparation was appropriate for the interim results.

The Committee met again in November 2019. The main topics discussed were:

- The auditor's plan for the 2019 audit. It was noted that key issues for 2019 would continue to include the valuation of PT20. It was agreed that whether or not going concern would be a key issue would depend on a number of factors, not least whether an upfront receipt had been received from either or both the USA and China out-licensing processes;
- The audit plan was presented by David Mitchell, the new Senior Statutory Auditor, who has replaced Nick Plumb who has rotated off the audit;
- Management had prepared updated and revised Financial Position and Prospects Procedures (FPPP) and Risk Policy and Procedures documents in anticipation of the Board's decision, taken later the same day, to adopt the QCA Governance Code. The Committee approved the new procedures and documents, subject the Board's later decision; and
- The Committee reviewed the latest risk register which had been prepared by management and circulated to the full Board.

## 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 the years 2015 to 2018 was Mr Nick Plumb. For 2019 he has rotated off the audit of Shield and been replaced by Mr David Mitchell.

The Audit Committee approves any non-audit services provided by the external auditor, with consideration to the threats posed to independence and safeguards in place.

## 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**
20 May 2020

**ROLF HOFFMANN**
**Remuneration Committee Chair**

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

On behalf of the Board I am pleased to present the Directors' remuneration report for the year ended 31 December 2019. 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 members of the Remuneration Committee are James Karis and Rolf Hoffmann. Rolf Hoffmann took over the role of Committee Chair from James Karis following the latter's appointment as Company Chair on 22 January 2019.

The Committee meets at least once a year and met three times during the course of 2019. 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.

Baker & McKenzie LLP and Coulter Partners Ltd 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 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 our application of minimum shareholding guidelines. |

### Executive remuneration in 2019

Base salary for the Chief Executive Officer (CEO) was based on the prior year plus an inflationary increase.

Awards were granted to the CEO under the Retention and Performance Share Plan during the year. Further details are provided on pages 30 and 31.

### Looking forward to 2020

The Remuneration Committee is currently considering the final details of the Directors' remuneration for 2020. The Executive Directors' bonus opportunity and share options award opportunity for 2020 is expected to be up to 75% of salary and 125% of salary respectively, with each award subject to the achievement of performance conditions.

### Board changes

No changes were made to the Board during 2019.

## 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:<br>• Salary increases awarded to the wider workforce;<br>• Group performance;<br>• Role and experience;<br>• Individual performance; and<br>• Competitive environment. | Salary increases will generally be in line with salary increases to other employees, but may be adjusted to take account of:<br>• Promotion;<br>• Change in scope of role;<br>• Realignment with the market; and<br>• 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:<br>• Car allowance; and<br>• 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 have been set at 12% 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 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 share awards. | Awards are made in the form of nominal cost options. Vesting is subject to the achievement of specific performance conditions over the 2019 financial year.<br>The plan is subject to malus and clawback provisions. | The maximum award in respect of any financial year is 125% of base salary.<br>Awards are made based on an assessment of the Executive Directors' performance and cover a twelve-month period from grant.<br>The current performance conditions are based on the achievement of five corporate strategic objectives during 2019. 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.

## 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 |
| James Karis | NED (Chair) | 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) | 1 month | Subject to annual reappointment at AGM |
| Hans Peter Hasler | NED (Chair of Nomination Committee) | 1 month | Subject to annual reappointment at AGM |

Note 1 – Tim Watts is appointed under a twelve-month fixed term contract with no right of early termination other than following a US out-licensing or similar transaction in which case he is entitled to terminate his contract with four months' notice.

James Karis is engaged under a letter of appointment dated 9 January 2019 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.

Hans Peter Hasler's letter of appointment is dated 12 July 2018 and is for a term of three years commencing on 25 July 2018.

## Directors' remuneration

The tables below detail total remuneration earned by each Director in respect of the year.

### 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** | | | | | |
| James Karis | **99** | **–** | **–** | **–** | **99** |
| Peter Llewellyn-Davies | **48** | **–** | **–** | **–** | **48** |
| Rolf Hoffmann | **45** | **–** | **–** | **–** | **45** |
| Hans Peter Hasler | **40** | **–** | **–** | **–** | **40** |
| | **548** | **50** | **190** | **–** | **788** |

### Directors' remuneration – year ended 31 December 2018

| Name | Salary/fees £000 | Benefits £000 | Bonus £000 | Pensions £000 | Total remuneration 2018 £000 |
|---|---|---|---|---|---|
| **Executive Director** | | | | | |
| Carl Sterritt | 301 | 58 | 283 | – | 642 |
| **Non-Executive Directors** | | | | | |
| Andrew Heath | 75 | – | – | – | 75 |
| James Karis | 43 | – | – | – | 43 |
| Peter Llewellyn-Davies | 46 | – | – | – | 46 |
| Rolf Hoffmann | 43 | – | – | – | 43 |
| Hans Peter Hasler | 17 | – | – | – | 17 |
| | 525 | 58 | 283 | – | 866 |

No payments were made to past Directors.

No Director waived any emoluments in respect of the year.

## Retention and Performance Share Plan (RPSP) options granted in 2019

During the year the Company issued share options under the RPSP to incentivise the Executive Director and senior management and in order to align their interests more closely with those of shareholders.

The awards during 2019 included the following awards to the Executive Director.

| Name | Number of options | Vesting date |
|---|---|---|
| Carl Sterritt | 380,657 | 31 December 2021 |

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 corporate objectives for the 2019 financial year, with a proportion of the award earned for the achievement of each objective. Attainment of the objectives is measured on 31 December 2019 and options vest two years thereafter.

## 2019 annual bonus

The Executive Director was awarded a bonus of £115,000 in respect of 2019.

## Directors' shareholdings

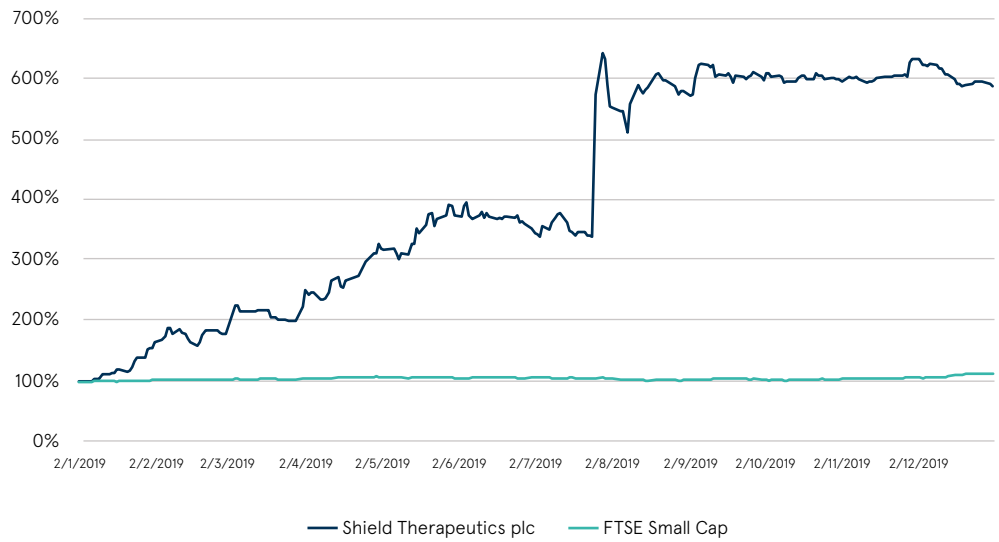
With effect from admission, the Company adopted share ownership guidelines under which Executive Directors must acquire shares with a value equal to twice their annual base salary. Until such time as the guideline is met, Executive Directors will be expected to retain 50% of shares acquired under the LTIP (net of sales to cover tax). The table below discloses the interests of any Directors serving during the year in the shares of the Company at 31 December 2019.

| Name | Shares at 31 December 2019 | % of share capital |
|---|---|---|
| Carl Sterritt | **10,287,186** | 8.73% |
| James Karis | **161,667** | 0.14% |
| Peter Llewellyn-Davies | **10,000** | 0.01% |

At 31 December 2019 Carl Sterritt had 1,233,915 options outstanding under various share option schemes.

## Share performance graph

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




The mid-market prices of the Ordinary Shares as at 31 December 2019 was £1.79. The highest mid-market price of the Ordinary Shares during the year was £1.96 and the lowest price was £0.305.

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

**Rolf Hoffmann**
**Remuneration Committee Chair**
20 May 2020

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 2019.

## 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 19. 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 2019 were related primarily to the processes to out-licence Feraccru®/Accrufer® in the USA and China. The Board believes that the decision taken in 2018 to out-licence the product for commercialisation was in the best long term interests of shareholders, taking into account the balance of financial and operational risk compared with the potential financial returns.

Approximately 75% of the Company's shares are held by 5 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 management 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 20 staff during 2019. The Chief Executive Officer and the other members of the senior management 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 42. The Group's loss after taxation for the year was £8.8 million.

The Directors do not recommend the payment of a dividend in respect of the year ended 31 December 2019.

## Directors
The Directors of the Company during the year and up to the date of approval of the annual report were as follows:

Carl Sterritt (resigned 21 April 2020)

Tim Watts (appointed 24 April 2020)

James Karis

Peter Llewellyn-Davies

Rolf Hoffmann

Hans Peter Hasler

The role of Company Secretary is undertaken by Lucy 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
None noted.

## 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 22 to 24 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 | 47.8% |
| AOP Orphan International AG* | 10.7% |
| Carl Sterritt | 8.7% |
| Universities Superannuation Scheme | 4.3% |
| Jupiter Asset Management | 4.0% |
| Christian Schweiger | 3.5% |

* Previously held by MaRu AG

## 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.

## Annual General Meeting
The Annual General Meeting of the Company will be held by teleconference at 1.00pm on Thursday 18 June 2020.

By order of the Board

**Tim Watts**
**Chief Executive Officer**
20 May 2020

## 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 Financial Reporting Standards as adopted by the European Union (IFRSs as adopted by the EU) and applicable law 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 IFRSs as adopted by the EU;
- 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**
20 May 2020

# 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 2019 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 2019 and of the Group's loss for the year then ended;
- the group financial statements have been properly prepared in accordance with International Financial Reporting Standards as adopted by the European Union (IFRSs as adopted by the EU);
- the parent Company financial statements have been properly prepared in accordance with IFRSs as adopted by the EU 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 | | £0.5m (2018:£0.6m) 4.3% (2018: 4.3%) of group loss before tax |
| **Coverage** | | 100% (2018:100%) of group loss before tax |
| **Key audit matters** | | **vs 2018** |
| **Recurring risks** | Going concern | ◆▶ |
| | Impairment of intangible assets | ◆▶ |
| | Capitalisation of development costs | ◆▶ |
| | Parent company: Recoverability of investments in subsidiaries | ▼ |
| **Event driven** | The impact of uncertainties due to the UK exiting the European Union on our audit | ◆▶ |

## 2. Material uncertainty related to going concern

| | The risk | Our response |
|---|---|---|
| **Going concern**<br>We draw attention to note 2 to the financial statements which indicates that the cash resources of the Group will cease to be sufficient after March 2021 in the absence of further funding received from the continued commercialisation of the Group's Feraccru asset, or other forms of finance such as debt finance or royalty finance, the success and timing of which are uncertain. There are also less predictable but realistic second order impacts, such as the impact of COVID-19 and the erosion of customer or supplier confidence, which could result in a rapid reduction of available financial resources.<br><br>These events and conditions, along with the other matters explained in note 2, constitute a material uncertainty that may cast significant doubt on the group's and the parent company's ability to continue as a going concern.<br><br>Our opinion is not modified in respect of this matter. | **Disclosure quality**<br>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.<br><br>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 at least a year from the date of approval of the financial statements.<br><br>The risk most likely to adversely affect the Group's and Company's available financial resources over this period was that expected cash inflows from signing agreements in new territories, or alternative sources of finance, are not secured.<br><br>The risk for our audit is whether or not those risks are such that they amount to a material uncertainty that may cast significant doubt about the ability to continue as a going concern. If so, that fact is required to be disclosed (as has been done) and, along with a description of the circumstances, is a key financial statement disclosure. | Our procedures included:<br><br>– **Historical comparisons:** We assessed the reasonableness of the cash flow projections by considering the historical accuracy of the previous forecasts;<br><br>– **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;<br><br>– **Test of detail:** We tested the integrity of the cash flow projections.<br><br>– **Benchmarking assumptions:** We challenged the appropriateness of the key assumptions, such as the costs for undertaking clinical trials and revenue assumptions, used in the cash flow projections by reference to our knowledge of the business. We also assessed the projections and assumptions by reference to the general market conditions and post year end trading and cash flows;<br><br>– **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. |

## 3. Other key audit matters: our assessment of risks of material misstatement

Key audit matters are those matters that, in our professional judgment, 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. 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. Going concern is a significant key audit matter and is described in section 2 of our report. In arriving at our audit opinion above, the other key audit matters were as follows:

## 3. Other key audit matters: our assessment of risks of material misstatement continued

| | The risk | Our response |
|---|---|---|
| **The impact of uncertainties due to the UK exiting the European Union on our audit**<br>Refer to page 15 (Chief Executive Officer's statement and financial review). | **Unprecedented levels of uncertainty**<br>All audits assess and challenge the reasonableness of estimates, in particular as described in the impairment of intangible assets and the recoverability of the parent company's investment in its subsidiaries below, and related disclosures and the appropriateness of the going concern basis of preparation of the financial statements (see below). All of these depend on assessments of the future economic environment and the group's future prospects and performance.<br><br>Brexit is one of the most significant economic events for the UK and its effects are subject to unprecedented levels of uncertainty of consequences, with the full range of possible effects unknown. | We developed a standardised firm-wide approach to the consideration of the uncertainties arising from Brexit in planning and performing our audits. Our procedures included:<br><br>— **Our Brexit knowledge –** We considered the directors' assessment of Brexit-related sources of risk for the group's business and financial resources compared with our own understanding of the risks. We considered the directors' plans to take action to mitigate the risks.<br><br>— **Sensitivity analysis –** When addressing the impairment of intangible assets, the recoverability of the parent company's investment in its subsidiaries, and the appropriateness of the going concern basis of preparation of the financial statements, and other areas that depend on forecasts, we compared the directors' analysis to our assessment of the full range of reasonably possible scenarios resulting from Brexit uncertainty and, where forecast cash flows are required to be discounted, considered adjustments to discount rates for the level of remaining uncertainty.<br><br>— **Assessing transparency –** As well as assessing individual disclosures as part of our procedures on the impairment of intangible assets, the recoverability of the parent company's investment in its subsidiaries and the appropriateness of the going concern basis of preparation of the financial statements, we considered all of the Brexit related disclosures together, including those in the strategic report, comparing the overall picture against our understanding of the risks.<br><br>However, no audit should be expected to predict the unknowable factors or all possible future implications for a company and this is particularly the case in relation to Brexit. |

## 3. Other key audit matters: our assessment of risks of material misstatement continued

| | The risk | Our response |
|---|---|---|
| **Group: Impairment of intangible assets** (£29.9 million; 2018: £31.0 million)<br><br>*Refer to page 25 (Audit Committee Report), page 51 (accounting policy) and page 58 (financial disclosures)* | **Forecast-based valuation**<br>These intangible assets relate to the Group's two drug businesses 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 are also the key consideration in assessing the recoverability of the parent company's investment in subsidiaries (see below).<br><br>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.<br><br>The cash flows include amounts in respect of the inflows from anticipated royalties and other payments from current or prospective licensees and outflows of the estimated costs to progress the commercialisation of these assets.<br><br>The effect of these matters is that, as part of our risk assessment, we determined that the value in use has a high degree of estimation uncertainty of these CGUs, with a potential range of reasonable outcomes greater than our materiality for the financial statements as a whole, and possibly many times that amount. The financial statements (note 14) disclose the sensitivity estimated by the Group. | Our procedures included:<br><br>– **Our sector experience:** We evaluated and challenged the assumptions used, in particular those relating to forecast receipts from licensees and the discount rate applied to discount the cashflows.<br><br>– **Benchmarking assumptions:**<br>  – Compared the group's assumptions to externally derived data in relation to key inputs such as projected market growth, royalty rates and discount rates.<br>  – 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.<br><br>– **Sensitivity analysis:** Performed breakeven analysis on certain of the assumptions noted above.<br><br>– **Assessing transparency:** 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 possible impairment assessment. |

## 3. Other key audit matters: our assessment of risks of material misstatement continued

| | The risk | Our response |
|---|---|---|
| **Parent company: Recoverability of parent company's investment in subsidiaries** (£104.0 million; 2018: £103.7 million)<br><br>Refer to page 25 (Audit Committee Report), page 51 (accounting policy) and page 59 (financial disclosures). | **Forecast-based valuation**<br>The carrying amount of the parent company's investments in subsidiaries is significant and at risk of irrecoverability since the subsidiary companies are currently loss-making. The estimated recoverable amount of these balances is subjective due to the inherent uncertainty in forecasting trading conditions and cash flows used in the budgets.<br><br>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. The financial statements (note 15) disclose the sensitivity estimated by the Company. | Our procedures included:<br><br>– **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.<br><br>– **Assessing transparency:** 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 recoverability of investments. |
| **Group: Capitalisation of development costs** (£1.4 million; 2018: £3.0 million)<br><br>Refer to page 25 (Audit Committee Report), page 50 (accounting policy) and page 58 (financial disclosures) | **Effects of irregularities**<br>The incentive to misstate research and development expenditure is a significant risk that could result in an over or understatement of the results for the current period.<br><br>This could occur whether specific project costs are expensed or capitalised, to either improve the Group's loss position by deferring costs to future periods or to recognise more expenditure whilst it is expected that the Group is loss-making, in order to reduce amortisation expenditure in the future is present. Costs could also be miscoded to projects and therefore incorrectly capitalised or expensed. | Our procedures included:<br><br>– **Control design:** Evaluated the group's process for capitalising and expensing research and development costs.<br><br>– **Tests of detail:** For specific projects ongoing in the period, assessed such projects against the accounting standards and industry knowledge on when it is reasonable to conclude that the capitalisation criteria has been met.<br><br>– **Tests of detail:** For a sample of costs both capitalised and expensed during the year assessed them against the applicable project to conclude whether the item has been correctly capitalised or expensed. |

### 4. 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 £500,000, determined with reference to a benchmark of group normalised loss before tax, normalised by averaging over the last three years due to fluctuations in the business cycle, of £11.7m, of which it represents 4.3% (2018: 4.3% of group normalised loss before tax).

Materiality for the parent company financial statements as a whole was set at £44,000 (2018: £37,000), determined with reference to a benchmark of normalised loss before tax, normalised by averaging over the last three years due to fluctuations in the business cycle, of which it represents 5.1% (2018: 2.4%).

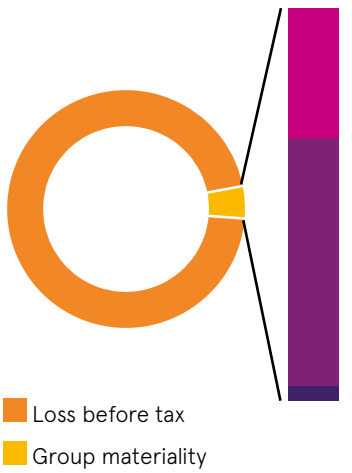
We agreed to report to the Audit Committee any corrected or uncorrected identified misstatements exceeding £25,000, in addition to other identified misstatements that warranted reporting on qualitative grounds.

Of the group's 5 (2018: 5) reporting components, we subjected 3 (2018: 3) to full scope audits for group purposes and 2 (2018: 2) 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 5 reporting components. We used component materialities, which range from £1,000 to £425,000 (2018: £3,000 to £450,000), having regard to the mix of size and risk profile of the Group across the components.

**Normalised loss before tax**
£11.7m (2018: £13.9m)



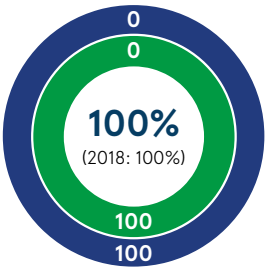

**Group materiality**
**£500,000**
(2018: £600,000)

£500,000
Whole financial statements materiality (2018: £600,000)

£425,000
Range of materiality at 5 components (£1k-£425k) (2018: £3,000 to £450,000)

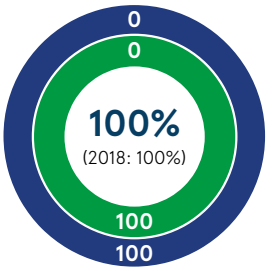
£25,000
Misstatements reported to the audit committee (2018: £30,000)

**Group revenue**




**Group loss before tax**


**Group total assets**




## 5. 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.

## 6. 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.

## 7. Respective responsibilities

### *Directors' responsibilities*

As explained more fully in their statement set out on page 34, 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.

## 8. 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.

**David Mitchell**
**(Senior Statutory Auditor)**
**for and on behalf of KPMG LLP, Statutory Auditor**
*Chartered Accountants*
Quayside House
110 Quayside
Newcastle upon Tyne
NE1 3DX
20 May 2020

## Consolidated statement of profit and loss and other comprehensive income

for the year ended 31 December

| | Notes | 2019 £000 | 2018 (restated – see note 4) £000 |
|---|---|---|---|
| Revenue | 5 | **719** | 11,881 |
| Cost of sales | | **(485)** | (311) |
| **Gross profit** | | **234** | 11,570 |
| Operating costs – selling, general and administrative expenses | 7 | **(6,773)** | (12,429) |
| Operating loss before research and development expenditure | | **(6,539)** | (859) |
| Research and development expenditure | 6 | **(2,496)** | (4,300) |
| **Operating loss** | | **(9,035)** | (5,159) |
| Financial income | 9 | **18** | 50 |
| Financial expense | 9 | **(49)** | (42) |
| **Loss before tax** | | **(9,066)** | (5,151) |
| Taxation | 11 | **266** | 3,359 |
| **Loss for the year** | | **(8,800)** | (1,792) |
| **Attributable to** | | | |
| Equity holders of the parent | | **(8,800)** | (1,792) |
| **Other comprehensive income** | | | |
| Items that are or may be reclassified subsequently to profit or loss: | | | |
| Foreign currency translation differences – foreign operations | | **33** | 4 |
| **Total comprehensive expenditure for the year** | | **(8,767)** | (1,788) |
| **Attributable to** | | | |
| Equity holders of the parent | | **(8,767)** | (1,788) |
| **Total comprehensive expenditure for the year** | | **(8,767)** | (1,788) |
| **Earnings per share** | | | |
| Basic and diluted loss per share | 10 | **£(0.08)** | £(0.02) |

# Group balance sheet
at 31 December

| | Notes | 2019 £000 | 2018 (restated – see note 4) £000 |
|---|---|---|---|
| **Non-current assets** | | | |
| Intangible assets | 13 | **29,898** | 30,957 |
| Property, plant and equipment | 12 | **26** | 155 |
| | | **29,924** | 31,112 |
| **Current assets** | | | |
| Inventories | 15 | **948** | 109 |
| Trade and other receivables | 16 | **356** | 1,031 |
| Current tax asset | 11 | **950** | 1,500 |
| Cash and cash equivalents | 17 | **4,141** | 9,776 |
| | | **6,395** | 12,416 |
| **Total assets** | | **36,319** | 43,528 |
| **Current liabilities** | | | |
| Trade and other payables | 18 | **(3,547)** | (2,548) |
| Other liabilities | 19 | **(607)** | (403) |
| Lease liabilities | | **(20)** | (147) |
| | | **(4,174)** | (3,098) |
| **Total liabilities** | | **(4,174)** | (3,098) |
| **Net assets** | | **32,145** | 40,430 |
| **Equity** | | | |
| Share capital | 21 | **1,758** | 1,746 |
| Share premium | 22 | **88,352** | 88,338 |
| Merger reserve | 22 | **28,358** | 28,358 |
| Currency translation reserve | 22 | **69** | 36 |
| Retained earnings | 22 | **(86,392)** | (78,048) |
| **Total equity** | | **32,145** | 40,430 |

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

**Tim Watts**
**Director**
Company registered number: 09761509

# Company balance sheet
at 31 December

| | Notes | 2019 £000 | 2018 (restated – see note 4) £000 |
|---|---|---|---|
| **Non-current assets** | | | |
| Investments | 14 | **104,054** | 103,697 |
| Trade and other receivables | 16 | **42,477** | – |
| | | **146,531** | 103,697 |
| **Current assets** | | | |
| Trade and other receivables | 16 | **68** | 35,824 |
| Cash and cash equivalents | 17 | **1,786** | 9,003 |
| | | **1,854** | 44,827 |
| **Total assets** | | **148,385** | 148,524 |
| **Current liabilities** | | | |
| Trade and other payables | 18 | **(353)** | (685) |
| Other liabilities | 19 | **–** | (81) |
| **Total liabilities** | | **(353)** | (766) |
| **Net assets** | | **148,032** | 147,758 |
| **Equity** | | | |
| Share capital | 21 | **1,758** | 1,746 |
| Share premium | 22 | **88,352** | 88,338 |
| Merger reserve | 22 | **117,323** | 117,323 |
| Retained earnings | 22 | **(59,401)** | (59,649) |
| **Total equity** | | **148,032** | 147,758 |

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

**Tim Watts**
**Director**
Company registered number: 09761509

## Group statement of changes in equity

for the year ended 31 December

| | Issued capital £000 | Share premium £000 | Merger reserve £000 | Currency translation reserve £000 | Retained earnings £000 | Total £000 |
|---|---|---|---|---|---|---|
| Balance at 1 January 2018 (as previously stated) | 1,746 | 88,338 | 28,358 | 32 | (77,267) | 41,207 |
| Prior period adjustment (see note 4) | – | – | – | – | (2) | (2) |
| Balance at 1 January 2018 (as restated) | 1,746 | 88,338 | 28,358 | 32 | (77,269) | 41,205 |
| Loss for the year | – | – | – | – | (1,792) | (1,792) |
| Other comprehensive income: | | | | | | |
| Foreign currency translation differences | – | – | – | 4 | – | 4 |
| Total comprehensive expense for the year | – | – | – | 4 | (1,792) | (1,788) |
| **Transactions with owners, recorded directly in equity** | | | | | | |
| Equity-settled share-based payment transactions | – | – | – | – | 1,013 | 1,013 |
| Balance at 31 December 2018 | 1,746 | 88,338 | 28,358 | 36 | (78,048) | 40,430 |
| Loss for the year | – | – | – | – | (8,800) | (8,800) |
| Other comprehensive income: | | | | | | |
| Foreign currency translation differences | – | – | – | 33 | – | 33 |
| Total comprehensive expense for the year | – | – | – | 33 | (8,800) | (8,767) |
| **Transactions with owners, recorded directly in equity** | | | | | | |
| Equity-settled share-based payment transactions | 12 | 14 | – | – | 456 | 482 |
| **Balance at 31 December 2019** | **1,758** | **88,352** | **28,358** | **69** | **(86,392)** | **32,145** |

## 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 2018 | 1,746 | 88,338 | 117,323 | (59,095) | 148,312 |
| Loss for the year | – | – | – | (1,567) | (1,567) |
| Total comprehensive expense for the year | – | – | – | (1,567) | (1,567) |
| **Transactions with owners, recorded directly in equity** | | | | | |
| Equity-settled share-based payment transactions | – | – | – | 1,013 | 1,013 |
| Balance at 31 December 2018 | 1,746 | 88,338 | 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** |

# Group statement of cash flows

for the year ended 31 December

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

## Company statement of cash flows

for the year ended 31 December

| | 2019 £000 | 2018 £000 |
|---|---|---|
| **Cash flows from operating activities** | | |
| Loss for the year | **(298)** | (1,567) |
| Adjustments for: | | |
| Equity-settled share-based payment expenses | **189** | 296 |
| Financial income | **(423)** | (426) |
| | **(532)** | (1,697) |
| Increase in trade and other receivables | **(6,721)** | (1,998) |
| (Decrease)/increase in trade and other payables | **(414)** | 465 |
| **Net cash flows from operating activities** | **(7,667)** | (3,230) |
| **Cash flows from financing activities** | | |
| Proceeds of share option exercise | **26** | – |
| Financial income | **423** | 426 |
| **Net cash flows from financing activities** | **449** | 426 |
| Net decrease in cash | **(7,217)** | (2,804) |
| Cash and cash equivalents at 1 January | **9,003** | 11,807 |
| **Cash and cash equivalents at 31 December** | **1,786** | 9,003 |

## 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 Financial Reporting Standards as adopted by the EU ("Adopted IFRSs").

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

### Company income statement

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

### Basis of preparation

#### Going concern

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

The Directors have considered the funding requirements of the Group through the preparation of detailed cash flow forecasts for the period to December 2021 including the repayment of the €2.5 million milestone to Norgine. Under current business plans the current cash resources will extend into the first quarter of 2021. As a result, additional revenue generating transactions or additional finance would therefore be needed by the first quarter of 2021 to allow the business plans to continue. The Directors are considering further commercialisation out-licensing opportunities for Feraccru®/Accrufer®, in the USA and also in other territories. These arrangements would be expected to include upfront payments which, if any one was achieved, would further extend the Group's cash runway. The Directors also believe that other forms of finance, such as debt finance or royalty finance underpinned by the existing European and Chinese out-licensing agreements, are likely to be available to the Group. However, there can be no guarantee that any of these opportunities will be successfully concluded. The Directors do not believe that the coronavirus pandemic will significantly impact the revenues included in the cash flow forecasts, nor the ability to complete commercialisation out-licensing transactions or to raise additional finance.

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

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

### Basis of consolidation

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

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

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

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

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

### Cost of sales

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

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

### Research and development

Research expenditure is charged to the statement of comprehensive income in the period in which it is incurred.

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

### Employee benefit costs

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

### Share-based payments

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

## 2. Accounting policies continued

### Finance income and costs

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

### Taxation

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

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

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

### Intangible assets

Intellectual property and in-process research and development acquired through business combinations are recognised as intangible assets at fair value. Other acquired intangible assets are initially recognised at cost. Expenditure incurred on development projects is recognised as an intangible asset when it is probable that the project will generate future economic benefits, considering factors including its commercial and technological feasibility, status of regulatory approval, and the ability to measure costs reliably.

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

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

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

### Impairment of intangible assets

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

### Property, plant and equipment

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

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

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

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

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

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

### Investments in subsidiaries

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

## 2. Accounting policies continued

### Inventories

Inventories are stated at the lower of cost and net realisable value. The cost of finished goods comprises raw materials and the costs charged by third party contract manufacturers. Net realisable value is the estimated selling price in the ordinary course of business, less applicable variable selling expenses. In arriving at net realisable value, provision is made for any obsolete or damaged inventories.

### Financial assets and liabilities

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

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

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

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

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

## 3. Critical accounting judgments and key sources of estimation uncertainty

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

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

### Going concern

The Board has formed a judgement that it is appropriate to adopt the going concern basis of preparation for the Group and parent company. This judgement is based on an evaluation of the Group's cash flow forecasts and risks to its business model and how those risks might affect the Group's and Company's financial resources or ability to continue operations over a period of at least twelve months from the date of approval of the financial statements. The Directors consider it appropriate to adopt the going concern basis of accounting in preparing the financial statements for the reasons set out on page 49, and note that these reasons give rise to a material uncertainty which may cast significant doubt on the Group's and the Company's ability to continue as a going concern.

### Development expenditure

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

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

Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognised in the period in which the estimate is revised if the revision affects only that period or in the period of the revision and future periods if the revision affects both current and future periods.

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

### Valuation of intellectual property acquired with Phosphate Therapeutics Limited – £19.5 million; investments in Company balance sheet of £26.8 million

The valuation of intellectual property acquired with Phosphate Therapeutics Limited in 2016 is based on cash flow forecasts for the underlying product, PT20 and an assumed appropriate cost of capital and other inputs, 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. See Note 13 for sensitivity analysis of key assumptions in this valuation.

## 3. Critical accounting judgments and key sources of estimation uncertainty continued

### Valuation of intellectual property associated with Feraccru® – intangible assets of £9.0 million; investments in Company balance sheet of £77.2 million

The valuation of intellectual property associated with Feraccru® (including patents, development costs and the Company's investment in Shield TX (Switzerland) AG) is based on cash flow forecasts for the underlying business and an assumed appropriate cost of capital and other inputs in order to arrive at a fair value for the asset. The realisation of its value is ultimately dependent on the successful commercialisation of the asset. In the event that commercial returns are lower than current expectations this may lead to an impairment. No impairment has been recognised to date. See Note 14 for sensitivity analysis of key assumptions in this valuation.

### Deferred tax assets

Estimates of future profitability are required for the decision whether or not to create a deferred tax asset. To date no deferred tax assets have been recognised.

## 4. New standards and interpretations

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

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

The impact of the retrospective application to the 2018 financial statements was:

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

Further information is provided in Note 12, property, plant and equipment and Note 24, leases.

## 5. Segmental reporting

The following analysis by segment is presented in accordance with IFRS 8 on the basis of those segments whose operating results are regularly reviewed by the Chief Operating Decision Maker (considered to be the Board of Directors) to assess performance and make strategic decisions about the allocation of resources. Segmental results are calculated on an IFRS basis.

A brief description of the segments of the business is as follows:

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

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

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

## 5. Segmental reporting continued

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

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

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

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

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

| As at 31 December 2018 | Feraccru® £000 | PT20 £000 | Central and unallocated £000 | Total £000 |
|---|---|---|---|---|
| Segment assets | 12,643 | 21,627 | 9,258 | 43,528 |
| Segment liabilities | (2,068) | (57) | (973) | (3,098) |
| **Total net assets** | 10,575 | 21,570 | 8,285 | 40,430 |
| Depreciation, amortisation and impairment | 435 | 1,919 | – | 2,354 |
| Capital expenditure | – | – | – | – |
| Capitalised development costs | 2,999 | – | – | 2,999 |

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

## 6. Expenses and auditor's remuneration

| | Year ended 31 December 2019 £000 | Year ended 31 December 2018 £000 |
|---|---|---|
| Loss for the year has been arrived at after charging: | | |
| Research and development expenditure | **2,496** | 4,300 |
| Fees payable to Company's auditor and its associates for the audit of parent company and consolidated financial statements | **34** | 34 |
| Fees payable to Company's auditor and its associates for other services: | | |
| The audit of Company's subsidiaries | **26** | 26 |
| Corporate finance transactions | **–** | 50 |
| Tax compliance services | **3** | 3 |
| Other services | **–** | 10 |

## 7. Operating costs – selling, general and administrative expenses

Operating costs are comprised of:

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

## 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 | |
|---|---|---|
| | 2019 Number | 2018 Number |
| R&D | **4** | 5 |
| Medical | **3** | 4 |
| Commercial | **1** | 8 |
| Finance and administration | **8** | 8 |
| | **16** | 25 |

The number of staff employed by the Group at 31 December 2019 was 20 (31 December 2018: 15).

The aggregate payroll costs of these persons were as follows:

| | 2019 £000 | 2018 £000 |
|---|---|---|
| Wages and salaries | **2,721** | 4,308 |
| Share-based payments (see Note 23) | **375** | 1,213 |
| Other employee benefits | **32** | 117 |
| Pensions | **98** | 138 |
| | **3,226** | 5,776 |

Key management compensation information is as follows:

| | 2019 £000 | 2018 £000 |
|---|---|---|
| Wages and salaries | **1,204** | 2,075 |
| Share-based payments | **87** | 1,018 |
| Other employee benefits | **104** | 104 |
| Pensions | **70** | 77 |
| | **1,465** | 3,274 |

## 9. Financial income and expenses

| | Year ended 31 December 2019 £000 | Year ended 31 December 2018 £000 |
|---|---|---|
| **Financial income** | | |
| Net foreign exchange gains | **–** | 30 |
| Total interest income on financial assets measured at amortised cost | **18** | 20 |
| | **18** | 50 |

| | Year ended 31 December 2019 £000 | Year ended 31 December 2018 £000 |
|---|---|---|
| **Financial expense** | | |
| Net foreign exchange losses | **(47)** | – |
| Total interest expense on financial liabilities measured at amortised cost | **(1)** | (29) |
| Bank charges | **(1)** | (13) |
| | **(49)** | (42) |

## 10. Loss per share

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

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

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

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

## 11. Taxation

Recognised in the income statement:

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

## 11. Taxation continued

Reconciliation of total tax credit:

| | Year ended 31 December 2019 £000 | Year ended 31 December 2018 £000 |
|---|---|---|
| Loss for the year | **(8,800)** | (1,792) |
| Taxation | **266** | 3,359 |
| Loss before tax | **(9,066)** | (5,151) |
| Standard rate of corporation tax in the UK | **19%** | 19% |
| Tax using the UK corporation tax rate | **(1,723)** | (979) |
| Expenses not deductible for tax purposes | **37** | 281 |
| R&D tax credits – current year | **(421)** | 1,500 |
| Adjustments in respect of prior years | **194** | 1,859 |
| Utilisation of previously unrecognised deferred tax assets | **(1,587)** | – |
| Unrelieved tax losses carried forward and other temporary differences not recognised for deferred tax | **3,766** | 698 |
| Total tax credit | **266** | 3,359 |

### Factors affecting the future tax charge

A reduction in the UK corporation tax rate from 19% to 17% (effective from 1 April 2020) was substantively enacted on 6 September 2016. The March 2020 Budget announced that a rate of 19% would continue to apply with effect from 1 April 2020, and this change was substantively enacted on 17 March 2020. The unregonised UK deferred tax asset as at 31 December 2019 has been calculated based on this rate.

### 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.

| | 2019 £000 | 2018 £000 |
|---|---|---|
| Unutilised Swiss tax losses to carry forward | **–** | 11,110 |
| Potential deferred tax asset thereon | **–** | 1,387 |
| Unutilised German tax losses to carry forward | **24** | 26 |
| Potential deferred tax asset thereon | **4** | 4 |
| Unutilised UK tax losses to carry forward | **33,145** | 20,114 |
| Potential deferred tax asset thereon | **6,298** | 3,419 |
| Total potential deferred tax asset | **6,302** | 4,810 |

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 14.8m 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 has a tax liability of CHF 0.5 million.

The current asset of £0.95 million at 31 December 2019 (2018: £1.5 million) relates to the anticipated R&D tax credit claim in respect of the 2019 financial year.

## 12. Property, plant and equipment

| Group | 2019 £000 | 2018 £000 |
|---|---|---|
| **Cost** | | |
| 1 January | **512** | 29 |
| Recognised on the application of IFRS 16 | **–** | 326 |
| Additions | **49** | 157 |
| Disposals | **(483)** | – |
| 31 December | **78** | 512 |
| **Accumulated depreciation** | | |
| 1 January | **357** | 16 |
| Charge for the period | **178** | 341 |
| Disposals | **(483)** | – |
| 31 December | **52** | 357 |
| Net book value | **26** | 155 |

Included within property, plant and equipment are £20,000 net book value of assets recognised as leases under IFRS 16. Further details of these leases are disclosed in Note 24. The Company had no property, plant and equipment (2018: £Nil).

## 13. Intangible assets

| Group | Patents and trademarks £000 | Feraccru® development costs £000 | Phosphate Therapeutics licences £000 | Total £000 |
|---|---|---|---|---|
| **Cost** | | | | |
| Balance at 1 January 2018 | 1,675 | 5,812 | 27,047 | 34,534 |
| Additions – externally purchased | 346 | – | – | 346 |
| Additions – internally developed | – | 2,999 | – | 2,999 |
| Balance at 31 December 2018 | 2,021 | 8,811 | 27,047 | 37,879 |
| Additions – externally purchased | 34 | – | – | 34 |
| Additions – internally developed | – | 1,350 | – | 1,350 |
| Disposals | – | (218) | – | (218) |
| **Balance at 31 December 2019** | **2,055** | **9,943** | **27,047** | **39,045** |
| **Accumulated amortisation** | | | | |
| Balance at 1 January 2018 | 417 | 442 | 3,714 | 4,573 |
| Charge for the period | 71 | 427 | 1,851 | 2,349 |
| Balance at 31 December 2018 | 488 | 869 | 5,565 | 6,922 |
| Charge for the period | 86 | 331 | 2,026 | 2,443 |
| Disposals | – | (218) | – | (218) |
| **Balance at 31 December 2019** | **574** | **982** | **7,591** | **9,147** |
| **Net book value** | | | | |
| **31 December 2019** | **1,481** | **8,961** | **19,456** | **29,898** |
| 31 December 2018 | 1,533 | 7,942 | 21,482 | 30,957 |

At the year end management reviewed the carrying value of the intangible assets for impairment. The intangible assets relate to two cash-generating units, being the Feraccru® business and the Phosphate Therapeutics Limited business. The recoverable amount has been determined based on value-in-use calculations, using pre-tax cash flow projections for the period of the patents. Management has considered the potential impact of the coronavirus pandemic but does not believe it will materially adversely affect the prospects for either Feraccru® or PT20 due to the ongoing worldwide patient need for treatment for iron deficiency and hyperphosphatemia respectively and the long patent lives of both products. The following key assumptions have been included in the value-in-use calculations:

## 13. Intangible assets continued

### Feraccru®

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

### Phosphate Therapeutics Limited

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

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

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

### Sensitivity analysis

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

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

The Company has no intangible assets (2018:Nil).

## 14. Investments

| Company | **2019 £000** | 2018 £000 |
|---|---|---|
| **Cost** | | |
| 1 January | **164,097** | 163,380 |
| Additions | **357** | 717 |
| Disposals | **—** | — |
| 31 December | **164,454** | 164,097 |
| **Accumulated impairment** | | |
| 1 January and 31 December | **(60,400)** | (60,400) |
| **Net book value** | | |
| 31 December | **104,054** | 103,697 |
| 1 January | **103,697** | 102,980 |

Other additions of £0.3 million (2018: £0.7 million) relate to investments during the year arising due to share-based payments costs in respect of Group share-based payments arrangements.

## 14. Investments continued

The Group's equity interests were as follows:

### At 31 December 2019 and 31 December 2018

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

* Investment held indirectly

The registered office address of Shield Therapeutics (DE) GmbH is c/o Lambsdorff Rechtsanwälte PartGmbB, Oranienburger Straße 3, 10178 Berlin.

The registered office address of Shield TX (Switzerland) AG is Sihleggstrasse 23, 8832 Wollerau, Switzerland.

The registered office address of Shield TX (UK) Limited and Phosphate Therapeutics Limited is the same as the Shield Therapeutics plc address shown in Note 1.

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. The following key assumptions have been included in the value-in-use calculations:

### 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 calculated based on out-licensing income which expires in 2035, being the current patent life of the asset, forecast to arise from the commercialisation licence agreements with Norgine BV covering Europe, Australia and New Zealand and with Beijing Aosaikang Pharmaceutical Co. Ltd covering China, Taiwan, Hong Kong and Macau, and also potential income from the US market once a commercial partner has been secured. Sales forecasts in each territory have been derived from discussions with partners and potential partners, and from other third party market projections. Discount rates of 10% have been applied to Europe, recognising the product is already marketed and 15% for the USA and China reflecting the fact that the product is not yet marketed in these territories.

### Phosphate Therapeutics Limited

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

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

| | **2019 £000** | 2018 £000 |
|---|---|---|
| Shield TX (Switzerland) AG | **77,290** | 76,933 |
| Phosphate Therapeutics Limited | **26,764** | 26,764 |
| | **104,054** | 103,697 |

## 14. Investments continued

### Sensitivity analysis

Feraccru® - sensitivity analysis shows that, even if the USA and China are excluded entirely from the value in use, management's base case sales forecast for Europe would need to be reduced by around 40% before an impairment of the carrying value of the investment would be required.

PT20 - Using a 15% discount rate, management's base case sales forecasts would need to be reduced by 35% before triggering an impairment of the carrying value of the investment. 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 11%, which collectively would be well below a market-standard agreement, would still support the investment valuation.

## 15. Inventories

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

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

The Company had no inventories (2018: £Nil).

## 16. Trade and other receivables

| | Group | | Company | |
|---|---|---|---|---|
| | **2019 £000** | 2018 £000 | **2019 £000** | 2018 £000 |
| Trade receivables | **–** | 256 | **–** | – |
| Other receivables | **197** | 206 | **21** | 58 |
| Prepayments | **159** | 569 | **47** | 14 |
| Amounts due from Group undertakings | **–** | – | **42,477** | 35,752 |
| | **356** | 1,031 | **42,545** | 35,824 |

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 | |
|---|---|---|---|---|
| | **2019 £000** | 2018 £000 | **2019 £000** | 2018 £000 |
| Non-current | **–** | – | **42,477** | – |
| Current | **356** | 1,031 | **68** | 35,824 |
| | **356** | 1,031 | **42,545** | 35,824 |

At the year end no trade receivables were past due or impaired (2018: £Nil).

## 17. Cash and cash equivalents

| | Group | | Company | |
|---|---|---|---|---|
| | **2019 £000** | 2018 £000 | **2019 £000** | 2018 £000 |
| Cash at bank and in hand | **4,141** | 9,776 | **1,786** | 9,003 |

## 18. Trade and other payables

| | Group | | Company | |
|---|---|---|---|---|
| | **2019 £000** | 2018 £000 | **2019 £000** | 2018 £000 |
| Trade payables | **2,666** | 22 | **41** | – |
| Accruals | **881** | 2,526 | **312** | 685 |
| | **3,547** | 2,548 | **353** | 685 |

## 19. Other liabilities

| | Group | | Company | |
|---|---|---|---|---|
| | **2019 £000** | 2018 £000 | **2019 £000** | 2018 £000 |
| Taxation and social security | **554** | 202 | **–** | – |
| Other payables | **53** | 201 | **–** | 81 |
| | **607** | 403 | **–** | 81 |

## 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:

| | **2019 £000** | 2018 £000 |
|---|---|---|
| Cash and cash equivalents (Note 17) | **4,141** | 9,776 |
| Trade and other receivables | **356** | 1,031 |
| Trade and other payables | **3,547** | 2,548 |
| Lease liabilities | **20** | 147 |

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:

| | **2019 £000** | 2018 £000 |
|---|---|---|
| Sterling | **2,130** | 9,429 |
| US Dollar | **9** | 47 |
| Swiss Francs | **36** | 36 |
| Euro | **1,966** | 264 |
| | **4,141** | 9,776 |

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

In accordance with IFRS 9 Financial instruments the Group has reviewed all contracts for embedded derivatives that are required to be separately accounted for if they meet certain requirements set out in the standard. There were no such derivatives identified at 31 December 2019 or 31 December 2018.

## 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 2019 the Group's revenues 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 | |
|---|---|---|---|
| | | **Year ended 31 December 2019** | Year ended 31 December 2018 |
| | Change in GBP vs. EUR rate | **£000** | £000 |
| EUR | +5.00% | **(94)** | (214) |
| | -5.00% | **94** | 214 |
| USD | +5.00% | **–** | (108) |
| | -5.00% | **–** | 108 |

### (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 2019 was just £18,000 (2018: £50,000). If interest rates had been 1% higher in 2019 the impact on cash interest received would have been £59,000 (2018: £148,000).

Interest payable arises principally on the Group's leases. If interest rates had been 1% higher in 2019 the impact on cash interest paid would have been £1,000 (2018: £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

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

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

## 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)* | Executive Directors and senior management | Yes |
| Bonus Share Plan (BSP) | Executive Directors and senior management | No |
| Company Share Option Plan (CSOP)* | All employees | No |
| Retention Share Plan (RSP)* | All employees | Continued employment at vesting date |
| Retention and Performance Share Plan (RPSP) | All employees | Continued employment at vesting date or performance conditions attached |

* 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 RPSP.

The number of options outstanding at the start and end of both 2018 and 2019, the movements through both years, and the expense charged to the Group financial statements were as follows:

### 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 |

### 2018

| Scheme | 1 January 2018 | Forfeited/ lapsed | Exercised | Granted | 31 December 2018 | Exercisable | Expense £000 |
|---|---|---|---|---|---|---|---|
| LTIP | 1,594,575 | (967,549) | – | – | 627,026 | – | 540 |
| BSP | – | (512,876) | – | 899,203 | 386,327 | – | 200 |
| CSOP | 171,658 | (280,690) | – | 667,164 | 558,132 | – | 21 |
| RPSP | – | (2,059,830) | – | 3,939,577 | 1,879,747 | – | 291 |
| RSP | – | (90,123) | – | 251,776 | 161,653 | 99,286 | 161 |
| **Total** | 1,766,233 | (3,911,068) | – | 5,757,720 | 3,612,885 | 99,286 | 1,213 |

## 23. Share-based payments continued

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 will become 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 are fully vested.

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.

Measurement inputs and assumptions used in the Monte Carlo and Black Scholes valuations were as follows:

| | April 2019 Black Scholes | April 2019 Black Scholes | August 2019 Black Scholes |
|---|---|---|---|
| Weighted average share price | £0.79 | £0.79 | £1.79 |
| Exercise price | £0.015 | £0.015 | £0.015 |
| Expected volatility | 52% | 52% | 54% |
| Expected option life | 3 years | 3 years | 1 year |
| Expected dividends | Nil | Nil | Nil |
| Risk-free interest rate (based on UK government bonds) | 0.70% | 0.70% | 0.34% |
| Fair value at measurement date | £0.77 | £0.77 | £1.775 |

## 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 | 2019 | 2018 |
|---|---|---|
| Net book value property, plant and equipment owned | **6** | 8 |
| Net book value right-of-use assets | **20** | 147 |
| **Total** | **26** | 155 |

| Lease liabilities | 2019 | 2018 |
|---|---|---|
| Less than one year | **20** | 147 |
| **Total** | **20** | 147 |

| Amounts recognised in profit or loss | 2019 | 2018 |
|---|---|---|
| Interest on lease liabilities | **4** | 7 |
| Expenses relating to short term leases | **175** | 326 |
| **Total** | **179** | 333 |

During 2019 the Group entered into one new operating lease arrangement for the Gateshead office. This lease has been capitalised on adoption of IFRS 16 on 1 January 2019.

## 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.

| | 2019 £000 | 2018 £000 |
|---|---|---|
| Cash and cash equivalents | **4,141** | 9,776 |

## 26. Related party transactions

There were no related party transactions in 2019 (2018: none).

| | |
|---|---|
| **CHF** | Chronic Heart Failure |
| **CKD** | Chronic Kidney Disease |
| **CMO** | Contract Marketing Organisation |
| **CRO** | Contract Research Organisation |
| **EU5** | Five largest European markets (France, Germany, Italy, Spain and the UK) |
| **EPO** | European Patent Office |
| **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 |

**Nominated advisor and joint broker**
Peel Hunt LLP
120 London Wall
London
EC2Y 5ET

**Joint broker**
finnCap Ltd
60 New Broad Street
London
EC2M 1JJ

**Auditor**
KPMG LLP
Quayside House
110 Quayside
Newcastle upon Tyne
NE1 3DX

**Legal advisor**
Stephenson Harwood LLP
1 Finsbury Circus
London
EC2M 7SH

**Tax advisor**
Ernst & Young LLP
Citygate
St James' Boulevard
Newcastle upon Tyne
NE1 4JD

**Registrar**
Link Asset Services Limited
The Registry
34 Beckenham Road
Beckenham
Kent
BR3 4TH

**Financial PR**
Walbrook PR Limited
4 Lombard Street
London
EC3V 9HD



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Produced by

designportfolio


**London**
Shield Therapeutics plc
16 Upper Woburn Place
Euston, London
WC1H 0AF

t +44 (0)207 186 8500
e info@shieldtx.com

**Newcastle**
Shield Therapeutics plc
Northern Design Centre
Baltic Business Quarter
Gateshead Quays
NE8 3DF

t +44 (0)191 511 8500
e info@shieldtx.com


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THERAPEUTICS PLC
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