



**SHIELD**  
THERAPEUTICS PLC

Improving Lives Together

# THE ART OF THERAPEUTICS

Shield Therapeutics plc  
Annual report and accounts 2018

# Improving lives together.



➤ Read more on pages 8 and 9

Shield Therapeutics is a commercial stage pharmaceutical company delivering innovative specialty pharmaceuticals to address patients' unmet medical needs.

Our clear purpose is to help our patients become people again, by enabling them to enjoy the things that make the difference in their everyday lives. The Group has a marketed product, Feraccru<sup>®</sup>, for the treatment of Iron Deficiency in adult patients with or without anaemia.

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## Highlights (including post-period)

### FERACCRU® 2018 OPERATIONAL HIGHLIGHTS

- Positive results for pivotal Phase III AEGIS-CKD study of Feraccru® vs placebo
- Approved label broadened in Europe to all adults with Iron Deficiency with or without anaemia – a market of 40 million patients
- Exclusive licence agreement with Norgine B.V. to commercialise Feraccru® in Europe, Australia and New Zealand
  - £11 million upfront payment
  - up to a €54.5 million in milestone payments
  - up to 40% sales royalties
- Recruitment completed for AEGIS-H2H Phase IIIb study of oral Feraccru® vs intravenous iron therapy
- US New Drug Application accepted for review by FDA; 27 July 2019 target ("PDUFA") date for review completion

### FINANCIAL HIGHLIGHTS

- Revenues of £11.9 million (2017: £0.6 million)
- Loss for the year of £1.8 million (2017: £19.6 million)
- Net cash of £9.8 million (2017: £13.3 million)
- £11.0 million upfront received from Norgine licence agreement extends cash runway significantly

### POST-PERIOD HIGHLIGHTS

- Positive results in AEGIS-H2H non-inferiority study triggering €2.5 million development milestone receivable from Norgine
- Positive results achieved in long term follow-up of patients enrolled in AEGIS-CKD clinical study
- Norgine has now commenced promotion of Feraccru® in UK and Germany



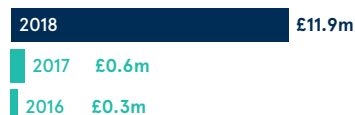
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[www.shieldtherapeutics.com](http://www.shieldtherapeutics.com)

### Revenue

# £11.9m



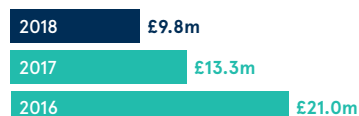
### Loss for the year

# £1.8m



### Net cash at year end

# £9.8m





# Shield Therapeutics is a commercial stage specialty pharmaceutical company

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



## The Group's lead asset for the treatment of Iron Deficiency



- ✓ Low dose Oral Iron capsule
- ✓ Twice-daily without food
- ✓ High iron availability
- ✓ Raises Hb and iron levels effectively
- ✓ Well tolerated
- ✓ Non-inferior to IV Iron



Patent protection until 2035

7 Learn more about Feracru® on pages 8 and 9

### PROGRESS WITH FERACCRU®

#### Europe

- Approved for the treatment of Iron Deficiency in adults, with or without anaemia
- Licensed to Norgine for commercialisation
- Norgine has started promotion in the UK and Germany
- Further EU launches expected in 2020

#### USA

- NDA filed in September 2018
- Filing accepted by the FDA in December 2018
- PDUFA date set for 27 July 2019
- Evaluating commercialisation options

#### Rest of World

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



## OUR PIPELINE

In addition to Feraccru®'s clinical pipeline, earlier stage pipeline products may be developed by the Company or licensed to partners.



## INVESTMENT HIGHLIGHTS



# A year of refocus



**JAMES KARIS**  
Chairman

I was delighted to be appointed as Chairman of the Board in January 2019. I have been a Non-Executive Director for three years and seen the business develop very significantly over that time, and I am now looking forward to the exciting prospects facing the Group.

## Operations and strategy

2018 was a challenging year for the Group but a great deal has been achieved and the year ended on a far stronger note than seemed likely in February 2018. The 2017 annual report set out how, in February 2018, the initial top-line analysis of the AEGIS-CKD pivotal Phase III study of Feraccru® suggested that the study had not met its primary endpoint but that the subsequent detailed analysis of the study showed that the initial results had been confounded by certain patient-specific events. After adjusting for appropriate patient inclusion criteria, the study did in fact meet its

primary and secondary endpoints. However, the requirement to announce the initial analysis in February caused a major fall in the Company's share price which in turn necessitated significant adjustments to the Group's strategy, which have been implemented during 2018.

The main change to the Group's strategy was the decision that Shield should no longer build its own sales and marketing capabilities to promote Feraccru® but should instead out-license the product. As a consequence the UK and German sales and marketing operations, which had already been established by the time of the readout from the AEGIS-CKD study, were closed down and corporate and administrative operations substantially reduced. Consequently, employee numbers have reduced from 50 at the start of 2018 to 15 at 31 December 2018, and the underlying cost base reduced accordingly. However, given the positive results which emerged from the detailed analysis of the CKD study and the broadening of the approved label in Europe to include all Iron Deficiency, with or without anaemia, the Group has continued to invest in the Feraccru® R&D programme, in particular the AEGIS-H2H study, which compared Feraccru® with intravenous iron therapy.



**The last twelve months have been transformational for Shield – the commercialisation strategy in Europe has been successfully switched to an out-licence approach with the Norgine agreement and we have seen some great results from the CKD and H2H studies. I am optimistic that 2019 will see further significant progress, particularly in the US.**

Despite the hiatus caused by the initial AEGIS-CKD results, the Group has made real and valuable operational progress in 2018. First, as mentioned above, in March 2018 the European Commission approved a major broadening of the approved indications for which Feraccru® can be prescribed to include all Iron Deficiency, with or without anaemia. Secondly, in September 2018, Feraccru® was licensed to Norgine B.V. for commercialisation in Europe, Australia and New Zealand, providing validation of the commercial prospects for the product and, importantly for the Group, an upfront payment of £11 million which has extended the Group's cash runway significantly. Also in September recruitment for the AEGIS-H2H study was completed and in March 2019 we were delighted to announce that the study showed that Feraccru® is non-inferior to Ferinject®, the market-leading intravenous iron therapy. Finally, and potentially most significantly, the Group filed a New Drug Application (NDA) for Feraccru® in the US in late September 2018 and the FDA has since confirmed its acceptance of the filing and set 27 July 2019 as the date for completion of the review. This opens up the possibility of commercialisation of Feraccru® in the near future in the US, the world's largest pharmaceutical market.

#### **Board changes**

As previously reported, Andrew Heath stepped down as Chair of the Board in June 2018 and I would like to thank Andrew for his contribution to Shield since 2015. In April 2018 and July 2018 respectively Rolf Hoffmann and Hans Peter Hasler joined the Board as Non-Executive Directors. They both have broad and deep experience of the pharmaceutical sector which has already proved invaluable and I welcome them both to the Board.

#### **People**

I would like to thank everyone who has worked for and with Shield during 2018. The considerable progress that has been delivered since the early part of the year could not have been achieved without the commitment, perseverance and resilience of all our employees.



**James Karis**  
Chairman  
2 April 2019



# The Iron Deficiency market

## A large market with significant unmet needs

### Overview

Feraccru® is a novel Oral Iron therapy which provides a compelling alternative to existing Oral and IV Iron treatments for Iron Deficiency. Feraccru® is approved in the EU, Norway and Iceland for the treatment of Iron Deficiency, with or without anaemia, and in Switzerland for the treatment of Iron Deficiency Anaemia (IDA) in patients with inflammatory bowel disease. A New Drug Application (NDA) has been accepted for review by the FDA in the US, with completion of the review expected by 27 July 2019.

Iron Deficiency is estimated by the World Health Organization (WHO) to affect some 2 billion patients globally. Iron Deficiency occurs when a body does not have enough iron to supply its needs either because it cannot absorb enough or is losing iron through bleeding. Iron is present in all cells in the human body and has several vital functions, such as carrying oxygen

to the tissues from the lungs as a key component of the haemoglobin protein, acting as a transport medium for electrons within the cells in the form of cytochromes, and facilitating oxygen enzyme reactions in various tissues. Iron Deficiency can be caused by malnutrition, bleeding and a number of diseases, in particular inflammatory bowel disease (IBD) and chronic kidney disease (CKD).

Iron Deficiency is one of the most common causes of anaemia. Anaemia is a condition characterised by abnormally low levels of red blood cells or low levels of haemoglobin within red blood cells. There are multiple symptoms of anaemia including lethargy, fatigue, weakness, depression, impaired immune system, gastrointestinal disturbances and neuromuscular imbalances.

The World Health Organization (WHO) has defined the stages of anaemia in the table below:

## World Health Organization (WHO) definition of the stages of anaemia

Anaemia stage	Haemoglobin concentration		Management
	Men	Women	
Mild	11-13g/dL	11-12g/dL	<ul style="list-style-type: none"> <li>• Often asymptomatic</li> <li>• May escape detection</li> <li>• May present with symptoms</li> <li>• Warrants timely management to prevent long term complications</li> <li>• Warrants investigation and prompt management</li> </ul>
Moderate	8-11g/dL	8-11g/dL	
Severe	<8g/dL	<8g/dL	

### IBD

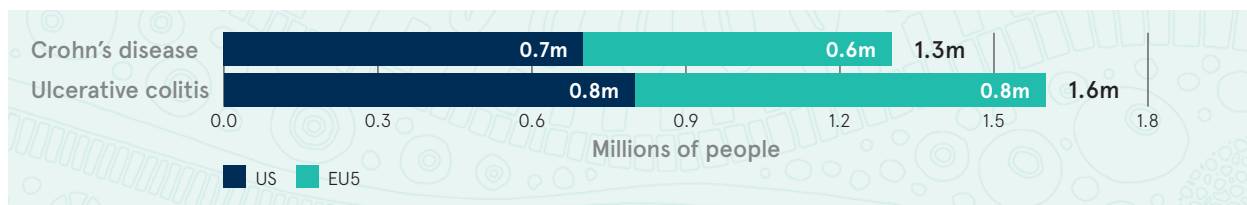
Inflammatory bowel disease (IBD) is a group of autoimmune disorders primarily comprised of Crohn's disease (CD) and ulcerative colitis (UC). Around 3 million people are estimated to be diagnosed with IBD in the US and "EU5" markets (France, Germany, Italy, Spain and the UK).

Iron Deficiency Anaemia (IDA) is one of the most frequent co-morbidities associated with hospitalisation and mortality in IBD patients. IDA in IBD is caused by reduced iron intake as patients may avoid specific food groups which increase gut irritation, poor absorption of iron from food and blood loss which can occur with an irritated gut.





## CD and UC diagnosed prevalence (US and EU5) 2017E



### CKD

Chronic kidney disease (CKD) is the gradual loss of kidney function over the course of months to years such that dangerous levels of fluid and waste accumulate in the body. CKD can result from many underlying diseases including diabetes, hypertension, glomerulonephritis and polycystic kidney disease. CKD can lead to cardiovascular disease, mineral and bone disorders, renal anaemia and renal failure.

CKD Stage 3–4 prevalence rate is around 7% of the population in the US and EU5, affecting approximately 45 million people. Prevalence is higher in the elderly population as kidney function declines with age. As CKD severity progresses, anaemia becomes increasingly common with incidence of around 50% in Stage 4 and Stage 5 patients. Iron Deficiency Anaemia is the cause of c.65% of anaemia in CKD. The diagnosis rate of IDA in CKD patients is very high as IDA is an area of focus for nephrologists.

### Therapies for Iron Deficiency

IDA is treated with iron replacement therapy, which can be delivered orally or intravenously. Oral salt-based iron therapies are typically used initially as they are inexpensive and convenient, but they can be slow or are unable to restore iron levels as they suffer from poor tolerability and poor compliance. Intravenous (IV) Iron tends to be used in more severe cases or for patients who do not respond well

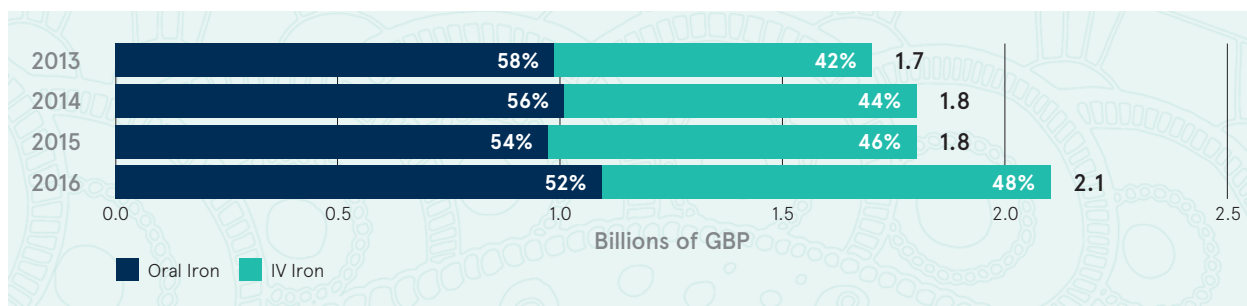
### CKD clinical staging

Stage	Description	eGFR (mL/min/1.73m <sup>2</sup> )
1	Kidney damage w/ normal GFR*	≥90
2	Kidney damage w/ mildly reduced GFR	60–89
3a	Mild to moderately reduced GFR	45–59
3b	Moderately reduced GFR	30–44
4	Severely reduced GFR	15–29
5	Kidney failure	<15 or dialysis

\* Glomerular Filtration Rate

or cannot tolerate salt-based Oral Iron. Due to the associated risks, IV Iron therapy requires infusion in a hospital/clinic setting and is therefore more expensive and inconvenient. Although salt-based Oral Iron has the majority of market share by prescription volume, IV Iron represents a substantial share of the iron market in value terms, due to increasing use and the launch of newer, more expensive formulations.

## Global market for Rx iron products (2013–16)



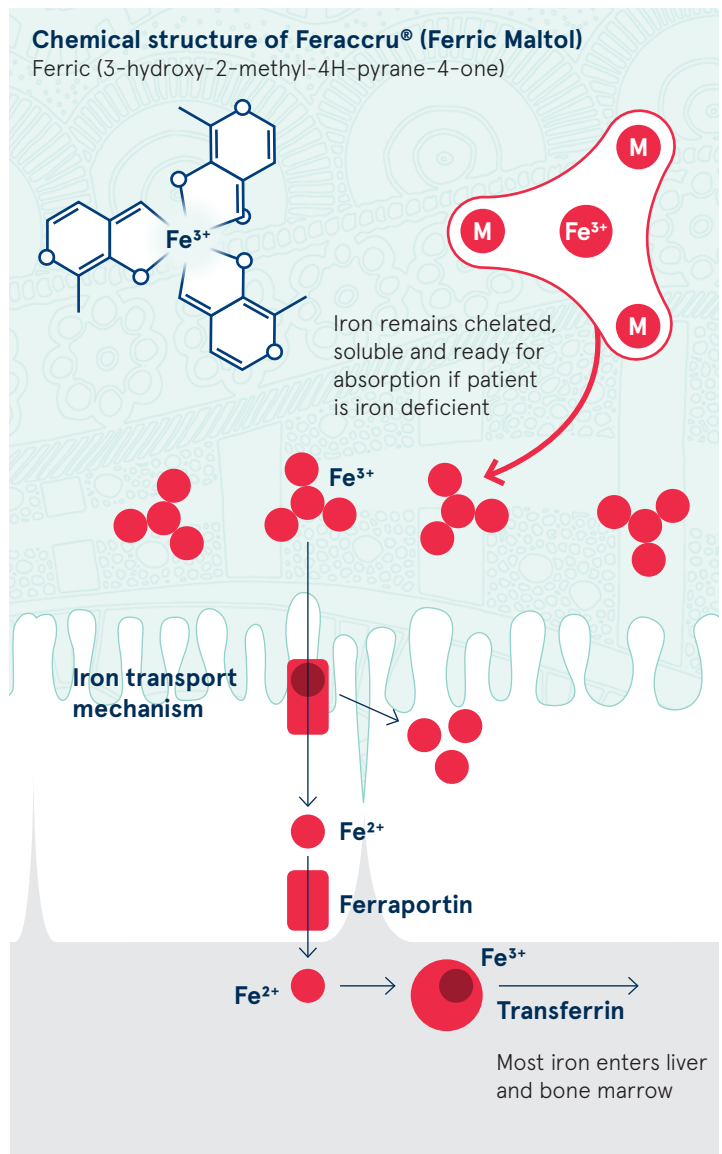
Feraccru® (Ferric Maltol) is a stable, non-salt, oral formulation of ferric iron, which has a novel mechanism of action compared to salt-based Oral Iron therapies. Feraccru® delivers iron to the blood stream with minimal formation

of insoluble complexes and free iron in the gut, unlike other oral therapies. It is well tolerated and has the potential to be used as a first line treatment for Iron Deficiency.

# Feraccru® is 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 oral formulation of a complex of  $\text{Fe}^{3+}$  (Ferric Maltol), which is stable in the gastrointestinal tract
  - Existing iron salts deliver iron as  $\text{Fe}^{2+}$ , which forms insoluble products in the GI tract or releases free radicals, both causing intolerance in patients
- The  $\text{Fe}^{3+}$  in Feraccru® remains in complex with maltol until absorbed and 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 Iron Deficiency or as an alternative to IV Iron in patients failing with existing Oral Iron salts
  - Effectiveness demonstrated in three Phase III studies



# Feraccru<sup>®</sup> is positioned to treat patients who cannot tolerate Oral Iron

## Patient diagnosed with ID

- ID causes significant morbidity and failure to treat it adequately with current therapies can cause the disease to progress to IDA
- IDA arises in diseases like IBD, CKD and chronic heart failure (CHF) and in women with excessive uterine bleeding, etc.

### Oral Iron

Many patients are intolerant of OFP, especially those with other diseases (e.g. IBD and CKD)  
Up to 70% suffer with gastro side effects

### Oral Iron Tolerant

- Able to tolerate salt-based Iron products

### Oral Iron Intolerant

- $Fe^{2+}$  +  $Fe^{2+}$  → Insoluble complexes + Free radicals → Intolerance
- Stomach pain
  - Constipation
  - Gut damage side effects
  - Nausea
  - Vomiting



### Intravenous (IV) Iron

- Iron directly into the blood, but:
  - Potential for allergic reactions
  - Iron overload
  - Bypasses the body's in-built safety valve for management of iron levels
  - Hospital only
  - Resuscitation team required
  - High overall cost
- No patients in long term studies of Feraccru<sup>®</sup> required interventional IV Iron therapy



### Oral Iron Intolerant

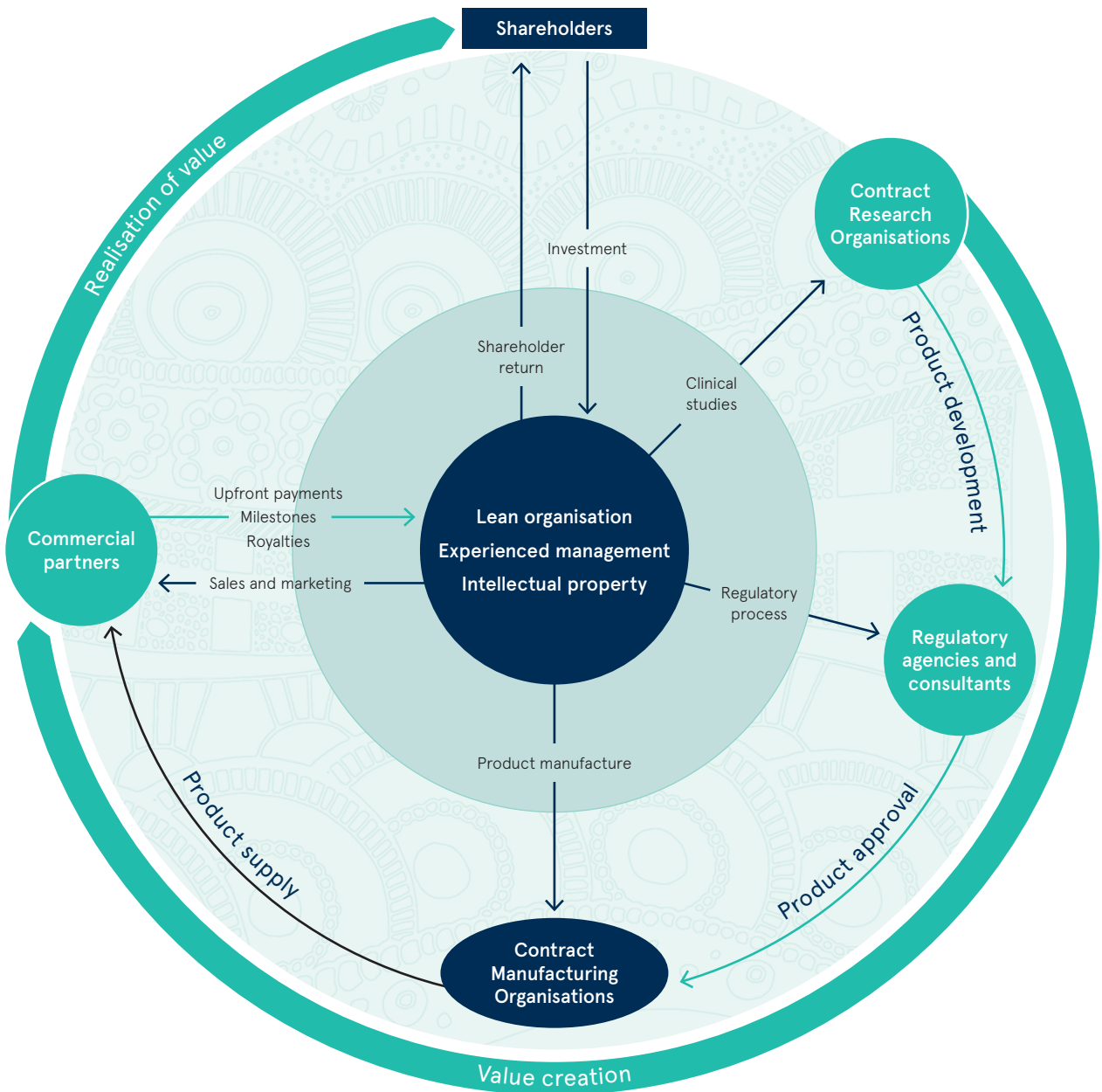
- FERACCRU<sup>®</sup>
- ✓ Low dose Oral Iron capsule
  - ✓ Twice-daily without food
  - ✓ High iron availability
  - ✓ Raises Hb and iron levels effectively
  - ✓ Well tolerated
  - ✓ Non-inferior to IV Iron

For patients who cannot tolerate traditional Oral Iron products Feraccru<sup>®</sup> offers the opportunity to be treated without progressing to intravenous iron therapy



# How we do business

- Shield operates a lean, semi-virtual operation.
- The fundamental value in the business is the intellectual property.
- Experienced management team uses a variety of external providers to translate the IP into products which can be sold to realise value for investors.



# Focused on strategy



## Delivered in 2018

### ✓ Achieve a broad label for Feraccru® in Europe

Feraccru® now approved for use in ID, with or without anaemia in adults.

### ✓ Maximise the commercial potential of Feraccru® in key European markets

Broad label achieved and sales and marketing out-licensed to Norgine.

### ✓ Feraccru® to be filed for NDA in the US

Feraccru® NDA submitted and accepted for review by the FDA. PDUFA date set for 27 July 2019.



## Ongoing

### Evaluate potential ways of commercialising Feraccru® in the US, either through a strategic partner or self-commercialisation

### Acquire or in-license additional clinical or commercial stage product candidates



## Future focus for 2019

### Gain marketing approval of Feraccru® in the US

### Out-license commercialisation of Feraccru® in the US

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

### Initiate paediatric Phase III study

### Clarify future development of PT20 and PT40

### Seek additional development candidates



## Keep up to date

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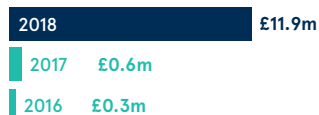


## Key performance indicators

### FINANCIAL

#### Revenue

# £11.9m



#### Description

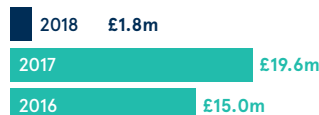
The Group measures sales performance as a key financial metric.

#### Performance

Revenue has been significantly impacted by receipt of an £11.0 million upfront payment in respect of the licensing deal with Norgine B.V.

#### Loss for the year

# £1.8m



#### Description

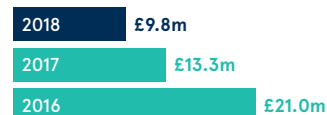
The Group's loss for the financial year measures its overall financial performance during the period.

#### Performance

Receipt of the upfront payment from Norgine B.V. and reduction of commercial spend have significantly reduced the Group's loss.

#### Net cash at year end

# £9.8m



#### 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 by receipt of the upfront payment from Norgine B.V.

### NON-FINANCIAL

#### Employees

# 15



#### Description

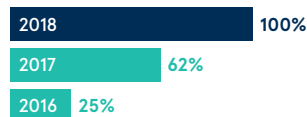
Given the current strategic objectives of the Group, headcount is considered to be a key indicator of central cost control and the appropriateness of the Group's structure.

#### Performance

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

#### Recruitment - AEGIS-H2H study

# 100%



#### Description

Recruitment of patients for the Group's key clinical trials is expressed as a percentage of total required patient numbers.

#### Performance

Shield's H2H study completed its enrolment during the year and positive results were announced in March 2019.





## Continued progress



**CARL STERRITT**  
Chief Executive Officer and founder

2018 was a year of transition and Shield is now well positioned to deliver further positive news through 2019. I expect Norgine to continue to develop the sales performance of Feraccru® in the UK and Germany, and we anticipate concluding further out-licence agreements to cover additional geographies. In the US I look forward to the 27 July 2019 PDUFA date, which has the potential to unlock the world's largest prescription pharmaceutical market to Feraccru®, which has continued to demonstrate its effectiveness over the last 12 months in two demanding clinical trials. In the meantime, we will continue to build upon these positive data, which have demonstrated Feraccru®'s non-inferiority to the leading IV iron therapy, its effectiveness in treating IDA in CKD patients, and the application of Feraccru® to patients with iron deficiency.

2018 has been a year of excellent operational progress for Shield and Feraccru®, despite the setback caused by the announcement of the initial top-line data from the AEGIS-CKD study which was covered extensively in the 2017 annual report. However, there was a very significant fall in share price at that time which necessitated major changes to the Group's strategy and resulted in a substantial refocusing of the Group, but I believe we are well on track to deliver meaningful value to investors.

The early part of the year was taken up with dealing with the results of the AEGIS-CKD study. The initial top-line data announced in February 2018 suggested that the study had not met its primary endpoint and this disappointed the market. However, during March 2018, the more detailed evaluation of the data revealed that there were a number of confounding factors which, when adjusted for as required by the study protocol, resulted in the study clearly meeting its primary endpoint and also achieving statistically significant positive results across a range of secondary parameters. Also in March 2018 the European Commission approved a major broadening of the indication for which Feraccru® can be marketed in Europe to include all Iron Deficiency in adults, with or without anaemia. Clearly this provides significant validation of the merits of Feraccru® and opens up a much larger patient population which can now be treated with Feraccru®.

The impact of the initial announcement led to the need to reduce cash burn and this resulted in the Board taking the decision that the Group should no longer aim to build its own sales and marketing operations in Europe but instead to out-license Feraccru®. We therefore immediately closed the sales and marketing operations which we had established in the UK and Germany and, over the next few months, reduced the size of the supporting organisation. From having 50 employees at the start of 2018, we now have only 15. I was saddened by the impact this will have had on the employees who we had to make redundant, and I thank them for the contributions they made to Shield, but it was absolutely necessary to secure the future of the business. I would also like to thank the remaining employees who continued to perform so professionally through this upheaval and period of significant change. We could not be where we now are without their commitment and hard work.

We immediately started working on the process to out-license Feraccru® in Europe and found serious interest from a number of potential licensees. After a competitive process I am delighted that we were able to conclude, in September 2018, an exclusive licence agreement with Norgine B.V. to commercialise Feraccru® in Europe, Australia and New Zealand. Norgine is a leading European specialist pharmaceutical company with a presence in all major European markets and employs over 1,000 people. It has a well-established European infrastructure to develop, manufacture and commercialise products and has an excellent track record of commercial success with specialty pharmaceutical products. Under the terms of the agreement, Shield received an immediate £11 million upfront payment, and is eligible to receive up to €4.5 million in short term development milestones and up to €50 million in sales milestones upon the achievement of specified targets. Shield will also receive tiered royalties ranging from 25% to 40% of net sales of Feraccru®.

It is worth noting that, although Shield had stopped its own sales and marketing efforts in the UK and Germany by the end of March 2018, the upward sales momentum of Feraccru® in those markets continued throughout the year. This suggests that once doctors and patients have experienced Feraccru® they want to continue to use it and I expect, now that Norgine has started its own promotion of the product in those markets, that sales will grow significantly.

During the second and third quarters of 2018, we were working hard on preparing a New Drug Application (NDA) for Feraccru® in the US and we announced on 1 October 2018 that we had successfully submitted the application. Since then, the FDA has accepted the NDA filing for review and confirmed that it will complete its review by 27 July 2019. This is clearly a very exciting opportunity as the US market remains the largest pharmaceutical market in the world and there are substantial numbers of patients who suffer from inflammatory bowel disease and chronic kidney disease, two of the leading causes of Iron Deficiency Anaemia. We have already started work on identifying potential sales and marketing partners for the US market.

During 2018 we also began discussions with a number of Chinese companies which are interested in acquiring sales and marketing rights to Feraccru® in China. I am optimistic that we should be able to conclude an agreement during 2019.

It is important to note that Shield retains ownership of, and control over, the intellectual property and further development of Feraccru®, and over the supply chain arrangements. We manage the supply chain and currently work with several suppliers to meet our requirements for the active ingredient and the formulation into finished product. These include a supplier on Continental Europe which we believe will give protection to our supply chain in the event of a disorderly Brexit.

Feraccru® has a strong IP position including granted patents in Europe and the US over the composition of matter until 2035. This means that Feraccru® offers substantial long term value to Shield for the next 16 years. It is not unusual in the pharmaceutical industry for patents to be challenged and one of our patents was recently the subject of a challenge from Teva. The European Patent Office found in favour of Shield in respect of the opposition application on 14 March 2019. Teva has challenged a second patent but I am confident in the validity and strength of the patent and we will defend it vigorously.

We are continuing to invest in targeted development of Feraccru® where we believe it will increase its commercial value. The AEGIS-CKD study delivered compelling evidence of Feraccru®'s benefits in chronic kidney disease to go alongside the 2016 study results in inflammatory bowel disease. In January 2019 we announced positive results for the long term phase of the AEGIS-CKD study. For the patients initially treated for 16 weeks with Feraccru®, haemoglobin levels were maintained over the 36-week follow-up period and the treatment continued to be well tolerated. Those subjects who were initially treated for 16 weeks with placebo and who switched to Feraccru® for the follow-up period demonstrated a similar rise in haemoglobin over their first 16 weeks of Feraccru® treatment when compared to those initially treated with Feraccru®, and subsequently maintained the improvement over the 36-week follow-up period. Much of our R&D effort during 2018 was spent on completing recruitment to the AEGIS-H2H study which compared the performance of Feraccru® with the leading intravenous iron therapy. The recruitment was completed in September 2018. I was delighted in March 2019 that the study results demonstrated that Feraccru® is non-inferior to Ferinject®. This is a very significant outcome as it means that, in Feraccru®, there is now an oral alternative to IV Iron therapy. Our plans for 2019 include starting a paediatric Phase III study which is likely to last two to three years. If successful, children and young adults suffering from Iron Deficiency will be able to benefit from Feraccru® along with adults for whom it is currently approved. We will also explore whether a once-daily formulation is feasible.



In 2018 we were not able to prioritise or invest in the rest of our development pipeline but 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. In 2019 we therefore intend to develop a new formulation of PT20, suitable for commercial use, and which will allow a Phase III study to be carried out. At this stage our intention is to out-license PT20 to a partner which could carry out the Phase III study and commercialise the product.

### Outlook

2018 was a year of transition and Shield is now well positioned to deliver further positive news through 2019. I expect Norgine to continue to develop the sales performance of Feraccru® in the UK and Germany, and we anticipate concluding further out-licence agreements to cover additional geographies. In the US I look forward to the 27 July 2019 PDUFA date, which has the potential to unlock the world's largest prescription pharmaceutical market to Feraccru®, which has continued to demonstrate its effectiveness over the last twelve months in two demanding clinical trials. In the meantime, we will continue to build upon these positive data, which have demonstrated Feraccru®'s non-inferiority to the leading IV Iron therapy, its effectiveness in treating IDA in CKD patients, and the application of Feraccru® to patients with Iron Deficiency.

### Financial review

The major financial events in 2018 have been the refocusing of the cost base to eliminate sales and marketing expenditure, reduction of administrative spend, and the licence agreement with Norgine, which resulted in an upfront receipt of £11 million.

#### Revenue

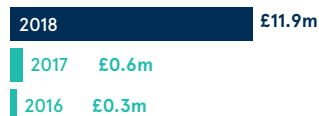
Revenue of £11.9 million in 2018 (2017: £0.6 million) was dominated by the £11.0 million receipt from Norgine as the non-refundable upfront payment for the licence agreement. The remaining £0.9 million comprised (a) £0.6 million Shield sales in the UK and Germany prior to the signing of the licence agreement, (b) £0.1 million royalties from Norgine on its sales in the UK and Germany since the signing of the licence agreement, and (c) £0.2 million sales to AOP Orphan Pharmaceuticals.

#### Selling, general and administrative expenses

Selling, general and administrative expenses reduced to £12.4 million in 2018 from £16.7 million in 2017. This reduction was largely due to the reduction of selling expenses from £9.1 million in 2017 to £3.5 million in 2018 as a consequence of the strategic decision in February 2018 to cease our own selling and marketing in Europe. General administrative expenses in 2018 were £6.6 million (2017: £5.2 million).

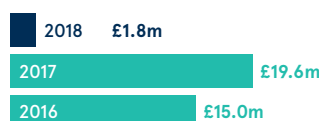
### Reported revenue

# £11.9m



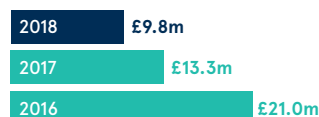
### Loss for the year

# £1.8m



### Net cash at year end

# £9.8m



The increase was created by redundancy payments and an increase in non-cash share-based payments from £0.6 million to £1.2 million. Depreciation and amortisation expenses were broadly flat at £2.3 million (2017: £2.4 million).

### Research and development

Research and development charged to the profit and loss account was £4.3 million in 2018 (2017: £4.7 million). This was incurred mainly on the AEGIS-CKD study.

Development costs of £3.3 million (2017: £3.2 million) incurred on the AEGIS-H2H and PK studies, together with patents and trademarks were capitalised in line with the Group's accounting policy.



### Financial review continued

#### Tax

The tax credit of £3.4 million (2017: £1.4 million) is comprised of £1.9 million of cash claimed and received during 2018 in respect of R&D tax credits for the 2017 financial year and an anticipated claim of £1.5 million in respect of the 2018 financial year.

#### Loss per share

The basic loss per share for 2018 was £0.02 (2017: £0.17). Details of the loss per share calculations are provided in Note 11.

#### Balance sheet

Net assets at 31 December 2018 were £40.4 million (2017: £41.2 million), including cash of £9.8 million (2017: £13.3 million) and intangible assets of £31.0 million (2017: £30.0 million).

#### Cash flow

The loss for the year of £1.8 million, after adjustment for non-cash items (depreciation and amortisation, share-based payments and the 2018 R&D tax credit accrual of £1.5 million), resulted in a cash inflow of £0.1 million before working capital adjustments. Working capital movements amounted to an outflow of £0.3 million such that the net cash outflows from operations was £0.2 million. Investment in development, mainly the AEGIS-H2H clinical study, and intangible assets totalled £3.3 million, resulting in an overall cash outflow for the year of £3.5 million.

#### Going concern

At the year end the Group held £9.8 million of cash. Since the year end, the Group has achieved a successful Head-to-Head study, resulting in a milestone receivable of €2.5 million under the current European out-licensing agreement with Norgine.

The Directors have considered the funding requirements of the Group through the preparation of detailed cash flow forecasts for the period to December 2020. Under current business plans the current cash resources will extend to the third quarter of 2020. Based on this, additional funding is expected to be required by the third quarter of 2020 in order to support the Group's going concern status. The Directors are considering further commercialisation out-licensing opportunities for Feraccru®, in particular in the USA and China. These arrangements would be expected to include upfront payments which, if any one was achieved, would further extend the Group's cash runway (being the period for which the Group's cash resources are expected to last). The Directors also believe that other forms of finance, such as royalty finance underpinned by the existing European out-licensing agreement with Norgine, are likely to be available to the Group. However, there can be no guarantee that any of these opportunities will be successfully concluded.

Based on the above factors the Directors believe that it remains appropriate to prepare the financial statements on a going concern basis. However, the above factors give rise to a material uncertainty which may cast 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 Norgine to grow Feraccru® sales in the UK and Germany during 2019, and increased royalties will flow from that growth, but launches in the other major European markets are unlikely in 2019 as Norgine will need to negotiate pricing and reimbursement in those countries. Following the results of the AEGIS-H2H clinical study, a €2.5m milestone is receivable from Norgine and further upfront receivables are possible in the event that the Group concludes any further out-licensing agreements. Costs in 2019 will be substantially lower than in 2018 as selling expenses have been removed and G&A expenditure will be reduced to around the levels previously seen in 2017. Total R&D expenditure (i.e. both the amount charged to the statement of profit and loss and any amounts capitalised) will be broadly in line with the amount charged to the statement of profit and loss in 2018. Overall, the Group's cash runway extends into the third quarter of 2020 without including potential upfronts from further out-licensing agreements.

This strategic report was approved on 2 April 2019, by order of the Board.



**Carl Sterritt**  
Chief Executive Officer  
2 April 2019



## Principal risks and uncertainties and risk management

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 all of 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. During the year the Committee has overseen the annual update to the risk management plan introduced in 2016, which has a number of key objectives:

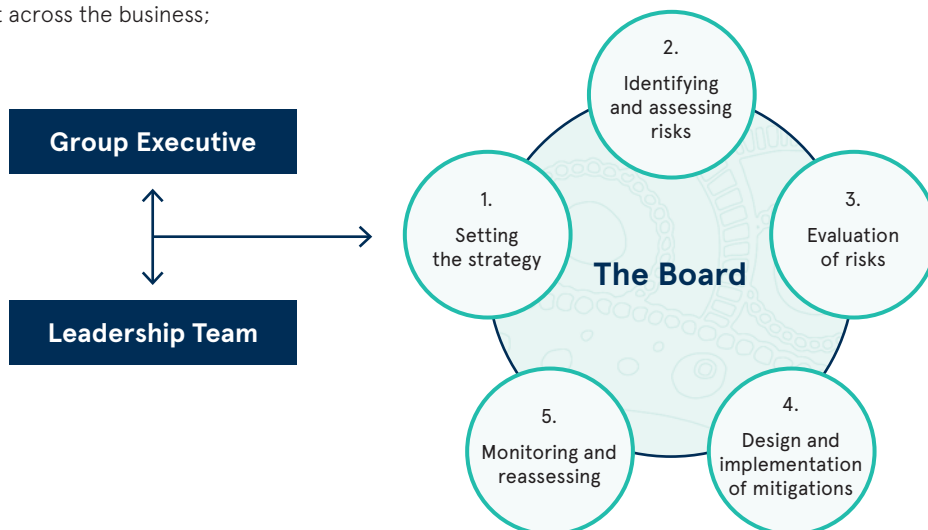
- to understand the business risks that the Group faces and to create and manage a register of these risks, documenting the decisions taken and judgments made;
- to ensure that the risk appetite of the Board is fully understood by those who are responsible for managing risk across the business;
- to ensure that mitigating actions and controls are aligned to the risk appetite of the Board;
- to ensure that risks are appropriately managed or mitigated and to ensure that, where appropriate, risk is mitigated through insurance;
- to control systematic risks within the organisation by maintaining and improving a system of internal controls to manage risks in decision making, legal contract management and the processing of financial transactions;
- to confirm and communicate the Group's policy on risk management;
- to establish and promote the importance of risk management across the business;

- to define what risk is and establish an understanding of when risk reaches an unacceptable level and how it may be mitigated;
- to establish a methodology for risk identification, mitigation, monitoring and reporting; and
- to assign responsibility as relevant for risk management and reporting.

As part of the Group risk strategy, the Audit Committee appointed a Group Risk Manager in 2016 to manage the level of risk within the Group.








### Operational risk management

- The quality team meets monthly to review all aspects of quality management across the business.
- Operational meetings between the finance team and all major divisions of the Company take place to review the progress of all key projects.
- The Leadership Team meets at least once a week and holds monthly strategy meetings to identify areas of risk and to communicate these to the Board as appropriate.
- The Audit Committee meets regularly during the year and consideration of the risk management plan, risk register and adequacy of actions taken to mitigate risk are considered at its meetings.
- The Audit Committee reports regularly to the full Board during the year. Risks and the adequacy of actions taken to mitigate them are considered at the Board meetings.









## Principal risks and uncertainties and risk management continued

### Principal risks and uncertainties

Risk description	Change	Reason for change	Further mitigation
<b>Norgine fails to achieve Feraccru® potential in Europe</b>		New risk due to dependency on Norgine to commercialise Feraccru® in Europe.	Senior management participates in Joint Management Committee with Norgine's management.
<b>Failure to achieve US approval of Feraccru®</b>		New risk to reflect the New Drug Application under review by the FDA.	Senior management is responding promptly to questions raised by the FDA during review process.
<b>Dependency on a single product</b>		This risk has been replaced by two risks: <ul style="list-style-type: none"> <li>• that Norgine does not achieve Feraccru®'s potential in Europe; and</li> <li>• that the US NDA is unsuccessful.</li> </ul>	
<b>Disruption to product supply</b>		Shield has further progressed its programme to validate a second supplier of Drug Substance and Drug Product for Feraccru® during the year.	The programme to successfully complete this validation process will be carefully managed.
<b>Delays in local reimbursement</b>		This risk has reduced following completion of the commercial licensing agreement with Norgine B.V.	The Group will continue to monitor this risk as it enters new markets.
<b>Reliance on wholesalers</b>		Licensing agreement with Norgine has reduced the level of risk.	Management of supply changes to effectively monitor patient supply.
<b>Non-compliance with regulatory requirements (e.g. GxP)</b>		No significant change noted.	The Group has an established quality team in place to address this risk.



Key  No change  Increased  Decreased

Risk description	Change	Reason for change	Further mitigation
<b>Delays in clinical study enrolment</b>		The Group's H2H and PK studies completed enrolment during the year.	Enrolment into planned future trials will be carefully monitored.
<b>Failure to protect IP</b>		One patent under challenge from Teva but management is confident the patent is robust.	Management fully engaged in defence of patent.
<b>Ability to attract and retain key staff and members of the management team</b>		No significant change noted.	The HR team continues to focus on remuneration arrangements designed to attract and retain key staff, following a significant reduction in headcount during 2018.
<b>Availability of finance and sources of capital at a reasonable cost</b>		The completion of a licence agreement for the commercialisation of Feraccru® during the year provided an upfront payment of £11.0 million, with the potential for significant additional milestone and royalty payments to follow.	Communication with shareholders and analysts regarding the potential value of the Group's assets. Additional actions to enhance the commercial worth of Feraccru®.
<b>Failure to commercialise PT20</b>		PT20 has a carrying value of £21.5 million in intangible assets which is at risk if PT20 is not commercialised.	The Group plans to carry out formulation work in 2019 which would facilitate a Phase III clinical study in later years.
<b>Possibility of disorderly Brexit</b>		Recent political events present the possibility of a disorderly Brexit.	The Group has strategically located inventory in continental Europe, has a key supplier of the drug located in continental Europe and has conducted Brexit planning with its commercial partner Norgine.



## Board of Directors



**CARL STERRITT**  
Chief Executive Officer  
and founder

### Tenure

Ten years

### Skills and experience

With approximately 20 years of management and executive level experience in pharmaceutical development and commercialisation in both large and small company settings, Carl has led the Company as its CEO since he founded the Group in 2008.

Previously, Carl held senior management roles at United Therapeutics and Encysive Pharmaceuticals, working on innovative therapies for the treatment of pulmonary arterial hypertension. Carl joined United Therapeutics to establish the company's European operations in preparation for the marketing approval of Remodulin®, running the subsidiary for six years. In collaboration with physicians in Germany, he was responsible for and holds patents related to United Therapeutics' decision to develop and commercialise treprostinil, now successfully commercialised in the US as Tyvaso™. Carl was instrumental in the successful commercial launch of Thelin™ and the rapid growth of Encysive's European operations. Carl founded Shield Therapeutics after Encysive was acquired by Pfizer Inc. for more than \$300 million.



**JAMES KARIS**  
Non-Executive Chairman

### Tenure

Three 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 BS in Management and Economics from Purdue University and an 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

Three years

### Skills and experience

Peter has over 25 years' experience in international M&A deals, company turnarounds, licensing transactions and financing activities with particular experience in chemical and healthcare industries. He is currently CEO of Apeiron Biologics. Peter was CFO of Medigene AG between 2012 and 2016 and supported the turnaround process by out-licensing marketed and legacy products and enhancing shareholder value with a large international investor base. Prior to that he was CFO of Wilex AG, having orchestrated its IPO in 2006 and concluded subsequent partnering deals and acquisitions. 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 Accelerate Partners, supporting private and listed companies and advising venture capital and private equity firms, and is a Non-Executive Director of Expedeon AG.

### Committee membership

**A N**





**ROLF HOFFMANN**  
Non-Executive Director

#### Tenure

Nine months

#### 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, sits on the boards of Genmab AG, EUSA Pharma Inc., Trigemina Inc. and Paratek Pharmaceuticals Inc.

#### Committee membership

**N** **R**



**HANS PETER HASLER**  
Non-Executive Director

#### Tenure

Five months

#### Skills and experience

Hans joined the Board of Shield Therapeutics plc in July 2018. His prior experience includes roles as COO, Elan Corporation, and several senior positions at Biogen, Inc., including Chief Operations Officer. Previously, Hans 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 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

On 8 March 2018 the London Stock Exchange published its revised rules for AIM quoted companies. Rule 26 now requires that AIM listed companies apply a recognised corporate governance code on a comply or explain basis. As a company whose shares are admitted to trading on AIM, Shield Therapeutics plc is required to comply with the AIM Rules for Companies. The Board recognises the importance of sound corporate governance and the disclosures below set out the Company's application of the UK Corporate Governance Code (2016), as well as reasons for any departures from the Code.

### 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
<b>Chairman</b>	James Karis <sup>(i)</sup>	Member of Remuneration and Nomination Committee.
<b>Chairman</b>	Andrew Heath <sup>(ii)</sup>	Chairman of Nomination Committee. Member of Remuneration Committee.
<b>CEO</b>	Carl Sterritt	
<b>Independent NED</b>	Peter Llewellyn-Davies	Chairman of Audit Committee. Member of Nomination Committee.
<b>Independent NED</b>	Rolf Hoffmann <sup>(iii)</sup>	Chairman of Remuneration Committee. Member of Nomination Committee.
<b>Independent NED</b>	Hans Peter Hasler <sup>(iv)</sup>	Chairman of Nomination Committee. Member of Audit Committee.

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

(ii) Resigned 27 June 2018

(iii) Appointed 6 April 2018

(iv) Appointed 26 July 2018

### 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 delegates authority as appropriate to its Committees and members of the Group's management.

The Board holds meetings at least five times a year, with additional ad hoc meetings as required. In addition, the Board and full management team meet for a strategy day at least once a year to discuss the medium to long term aspirations of the Group. A full briefing pack is circulated to the Board for review prior to each meeting.



## Effectiveness continued

### Composition of the Board continued

On 22 January 2019 James Karis was appointed as Company Chairman, 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. 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 subject to annual re-election and are re-elected at the first Annual General Meeting following their appointment. 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:

2018 meetings	Number of meetings	Attendance
Main Board	13	All Directors attended
Audit Committee	4	All Committee members attended
Remuneration Committee	3	All Committee members attended
Nomination Committee	2	All Committee members attended
Board strategy day	1	All Directors and executive management team members attended

## Board evaluation

### Progress against our areas of focus

Area of focus	Progress in 2018
<b>Succession planning</b>	The Board considers the adequacy and appropriateness of its composition, that of its Committees and the management team of the Company in order to fill any potential gaps.
<b>Induction</b>	All new Board members receive a comprehensive induction, including the opportunity to meet management and shareholders and a briefing from the Company's Nominated Advisor.
<b>Terms of reference</b>	The Board considers annually the appropriateness of its terms of reference and those of its Committees.

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 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 48.11% of Shield's issued share capital). Peter Llewellyn-Davies was put forward for election by the largest shareholder, W. Health LP. However, whilst as aforementioned, W. Health LP does have the right under the relationship agreement to appoint a representative to the Board. He was appointed independently and does not in any way represent W. Health LP. Hans Peter Hasler, a Non-Executive Director of the Company, until January 2018, served as a Director of AOP, which is a commercial partner of Shield and an affiliate of MaRu, which is itself a significant shareholder in Shield. The Board believes him to be independent as he no longer serves as a member of AOP's Board and does not represent its interests. Additionally, he had no day-to-day interactions with Shield during his time with AOP.



### Board evaluation continued

#### Progress against our areas of focus continued

Some Non-Executive Directors hold small shareholdings in the Company amounting to <0.1% of the Company's total share capital. The Board composition complies with the Code as applicable to smaller companies in terms of the number of independent Non-Executive Directors.

#### Appointments to the Board

The Nomination Committee is comprised of the Chairman and the other Non-Executive Directors who are all considered independent. During the year Rolf Hoffmann and Hans Peter Hasler were appointed as Directors of the Company. Their appointment followed a recommendation to the Board made by the Company's Nomination Committee. The Nomination Committee gave consideration to their skills and experience in comparison to the requirements of the roles prior to their recommendation. 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.

The Audit Committee has considered the following significant risks considered in the report of the external auditor.

Significant risks	Responses
Recoverable amounts of intangible assets	Value in use calculations have been reviewed and sensitivities considered in assessing their appropriateness.
Capitalisation of development costs	The criteria under IFRS for the capitalisation of development costs and application of the Group capitalisation policy have been reviewed against development costs capitalised.
Recoverability of investments in subsidiaries	Value in use calculations have been reviewed and sensitivities considered in assessing their appropriateness.
The impact of uncertainties due to the UK exiting the European Union	The Committee has confirmed that appropriate planning has been undertaken in response to risks presented by Brexit, including the strategic location of inventory ahead of Brexit and liaison with the Group's commercial partner Norgine.
Going concern	Forecasts until December 2020 have been reviewed in order to conclude on the going concern status.

### 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.

#### Financial and business reporting

Prior to approval of the Company's annual and interim reports the Board considers the going concern position of the Company and confirms the Company's ability to continue as a going concern for a period of at least twelve months from the date of their approval. 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.

The annual report includes an explanation of the Company's business model and strategy, together with an assessment of its delivery against its objectives.

#### 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. Further descriptions of the Audit Committee's activities in this area are provided in the audit and risk report on page 26.

The Directors confirm that their assessment of the principal risks facing the Group was robust. Based upon the robust assessment of the principal risks facing the Group and their stress testing-based assessment of the Group's prospects, all of which are described above, the Directors have a reasonable expectation that the Group will be able to continue in operation and meet its liabilities as they fall due over the 22-month period from the year end, subject to the assumptions described above.



## Accountability continued

### Audit Committee and auditor

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 26.

### Viability statement

In accordance with the provisions in the UK Corporate Governance Code, the Directors have assessed the viability of the Group over a 22-month period from 31 December 2018. The Directors' assessment has been made with reference to the Group's strategy, its cash resources and the principal risks as described in the annual report. Pages 18 and 19 of the annual report show how the principal risks are being managed and mitigated.

Whilst the Directors have no reason to believe the Group will not be viable over a longer period, a 22-month period is considered appropriate as there is reasonable visibility of the commercial options available to the Group over that period. This period provides the Board with an appropriate degree of confidence whilst still providing a longer term outlook.

The process involved considering the sensitivity of the forecasts to a number of key assumptions and also consideration of the key assumptions underlying the forecasts and their reasonableness. In making their assessment, the Directors have undertaken a sensitivity analysis of its forecast cash flows and liquidity. The key assumptions underpinning the assessment during the period are as follows:

- Commercialisation strategy of out-licensing in additional territories;
- Pursuit of FDA approval for Feraccru® in the US;
- Success of licensing agreement with Norgine in Europe; and
- Stable cost base in terms of central costs.

The forecasts were prepared on a prudent basis and therefore exclude potential revenue arising from entry into new geographical markets during the period.

The principal plausible stress tests are:

- Lower than expected growth and market sales;
- Delays in the US launch of Feraccru® or out-licensing in additional territories; and
- Delay of launch in additional EU5 territories.

Based on the assessment and stress testing, the Directors have a reasonable expectation that the Group will be able to continue in operation and meet its liabilities as they fall due over a 22-month period from 1 January 2019.

## 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.

## Relations with shareholders

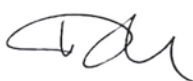
The Executive and Non-Executive Directors proactively engage with key shareholders and analysts during the course of the year, including the provision of investor briefing calls and meeting opportunities following the release of annual and interim results and fundraises.

## 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 attend the meeting and 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 and voting at meetings is conducted based on a poll.

The Company intends to send the Notice of the Annual General Meeting to shareholders at least 20 working days before the meeting. Previously this was not the case, as prior to the adoption of the Code the Company was not required to do so.

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

2 April 2019



**PETER LLEWELLYN-DAVIES**  
Audit Committee Chairman

### The Audit Committee

Whilst the Board has ultimate responsibility for the review and approval of the annual and interim reports, and for risk management, certain aspects are delegated to the Audit Committee, including:

- 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;
- Review of 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 2018. Its key activities included:

#### Risk management

- Review and approval of the 2018 updated Group risk management plan;
- Consideration and approval of the Group's corporate sign-off limits;
- Review of findings from internal controls testing performed as part of the external audit and consideration of any recommendations from the Group's external auditor;
- Consideration of whistleblowing arrangements and the Committee's role in this;

#### Financial reporting

- Review and approval of the Group's accounting policies;
- Review of the interim and annual financial statements, including review and challenge of the key judgments made in their preparation;

- Review of the work of the external auditor and matters requiring discussion following the 2018 audit;
- Advising the Board that, taken as a whole, the annual report and accounts are fair, balanced and understandable;
- Review of the basis for the going concern statement in the annual and interim reports;

#### External audit

- Recommendation to the Board to approve the reappointment of KPMG LLP as external auditor;
- Review and approval of the annual audit plan;
- Review of the independence, objectivity, performance and effectiveness of the auditor; and
- Approval of the Group audit fees and any non-audit services provided by the external auditor.

#### External audit

The Group's external auditor, KPMG LLP, is engaged to provide its independent opinion on the Group's financial statements. The terms of reference and findings of the auditor have been reviewed by the Audit Committee as part of the approval process for the 2018 annual report and accounts. The Group maintains a segregation between its external auditor and other advisors, with Ernst & Young LLP appointed as the Group's tax advisor and Deloitte LLP appointed as remuneration consultant, 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 has a tenure of four years. There are no current plans to retender the audit.

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 Audit Committee considers the requirement for an internal audit function on an annual basis, taking account of the scale and complexity of the Group's activities, number of employees, cost benefits, any issues identified in management's assessment of controls during the period and the adequacy of other management information provided. 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.

A handwritten signature in dark ink, appearing to read 'Peter Llewellyn-Davies'.

**Peter Llewellyn-Davies**  
Audit Committee Chairman  
2 April 2019





**ROLF HOFFMANN**  
Remuneration Committee Chairman

On behalf of the Board I am pleased to present the Directors' remuneration report for the year ended 31 December 2018. 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 Chairman from James Karis following the latter's appointment as Company Chairman on 22 January 2019. The Committee meets at least once a year and met three times during the course of 2018. 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.

Deloitte LLP has acted as an external advisor 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 stretching 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 stretching individual and corporate performance conditions.	Further alignment between Executive Directors and shareholders is achieved by our application of minimum shareholding guidelines.

### Executive remuneration in 2018

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 Bonus Share Plan and Retention and Performance Share Plan during the year. Further details are provided on pages 30 and 31.

### Looking forward to 2019

The Remuneration Committee is currently considering the final details of the Directors' remuneration for 2019. The Executive Directors' bonus opportunity and share options award opportunity for 2019 is expected to be up to 100% of salary and 125% of salary respectively, with each award subject to the achievement of performance conditions.

### Board changes

On 27 June 2018 Andrew Heath resigned as Chairman. No bonus was paid to him during the year and no share options were awarded or forfeited on his resignation. A contractual payment of £25,000, amounting to three months of fees, was paid in relation to his loss of office.



## Directors' remuneration report continued

### 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
<b>Fixed remuneration</b>		
<b>Basic salary</b>		
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: <ul style="list-style-type: none"> <li>• Salary increases awarded to the wider workforce;</li> <li>• Group performance;</li> <li>• Role and experience;</li> <li>• Individual performance; and</li> <li>• Competitive environment.</li> </ul>	Salary increases will generally be in line with salary increases to other employees, but may be adjusted to take account of: <ul style="list-style-type: none"> <li>• Promotion;</li> <li>• Change in scope of role;</li> <li>• Realignment with the market; and</li> <li>• 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).</li> </ul>
<b>Benefits</b>		
To provide a competitive range of benefits as part of total remuneration.	Executive Directors currently receive: <ul style="list-style-type: none"> <li>• Car allowance; and</li> <li>• Private medical insurance.</li> </ul>	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.
<b>Retirement benefits</b>		
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 2019 have been set at 12% of salary.
<b>Variable remuneration</b>		
<b>Annual bonus</b>		
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 2017 bonus was deferred under the Bonus Share Plan arrangements described below.	The maximum bonus opportunity is 100% of base salary.



## Executive Directors' remuneration policy continued

Element and purpose	Operation	Maximum opportunity
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### 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 2018 financial year. The plan is subject to malus and clawback provisions.	The maximum award in respect of any financial year is 125% of base salary.  Awards are made based on an assessment of the Executive Directors' performance and cover a twelve-month period from grant.  The current performance condition is based on the achievement of four corporate strategic objectives during 2018. Achievement of each objective entitles the recipient to 25% of the total award. The Committee will review and set performance conditions for future awards.
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The Company does not currently invite shareholders to approve new long term incentive schemes and significant changes to existing schemes.

#### 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
Carl Sterritt	CEO	12 months	Subject to annual reappointment at AGM
James Karis	NED (Chairman of Remuneration Committee)	3 months	Subject to annual reappointment at AGM
Peter Llewellyn-Davies	NED (Chairman of Audit Committee)	3 months	Subject to annual reappointment at AGM
Rolf Hoffmann	NED (Chairman of Nomination Committee)	1 month	Subject to annual reappointment at AGM
Hans Peter Hasler	NED	1 month	Subject to annual reappointment at AGM

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 report continued

### Directors' remuneration

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

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

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

A termination payment of £25,000 was paid to Andrew Heath following his resignation during the year, in lieu of his three months' period of notice. All amounts noted are included in the tabular disclosures above.

#### Directors' remuneration – year ended 31 December 2017

Name	Salary/fees £000	Benefits £000	Bonus £000	Pensions £000	Total remuneration 2017 £000
<b>Executive Directors</b>					
Carl Sterritt	300	43	–	–	343
Joanne Estell	103	6	–	12	121
Richard Jones	17	3	–	–	20
<b>Non-Executive Directors</b>					
Andrew Heath	100	–	–	–	100
James Karis	41	–	–	–	41
Peter Llewellyn-Davies	44	–	–	–	44
	<b>605</b>	<b>52</b>	<b>–</b>	<b>12</b>	<b>669</b>

No payments were made to past Directors.

No gains were made on the exercise of share options during the year and no awards of share options vested during the year.

No Director waived any emoluments in respect of the year.

### Bonus Share Plan options granted in 2018

The Bonus Share Plan was introduced by the Company in May 2018 in order to defer the cash cost to the Company of senior management bonuses until 31 May 2019. Settlement of awards under the plan are made in the form of either cash or shares of an equivalent value.

Bonus Share Plan options were granted in the year to the Executive Directors as follows:

Name	Number of options	Vesting date
Carl Sterritt	317,184	31 May 2019*

\* The award to Carl Sterritt was to be settled via either a cash payment of £80,882 or the issue of the lower of 317,184 shares or shares with a value of £80,882 at the vesting date. The award was cash settled during 2018 at the Company's discretion, once sufficient cash was available to do so.

If exercised, share options would have had a nominal exercise price of £0.015 per share. No amounts were paid on grant. No performance conditions were attached to the awards, as these had already been achieved at the time of the issue of the awards.

In total 899,203 options were awarded to senior management and 512,876 had been settled in cash by the year end.



### Retention and Performance Share Plan (RPSP) options granted in 2018

During the year the Company established the Retention and Performance Share Plan (RPSP) to incentivise the Executive Directors and senior management and in order to align their interests more closely with those of shareholders.

The first awards during 2018 included the following awards to the Executive Directors.

Name	Number of options	Vesting date
Carl Sterritt	970,867	31 December 2020

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 2018 financial year, with a proportion of the award earned for the achievement of each objective. Attainment of the objectives is measured on 31 December 2018 and options vest two years thereafter.

In total awards were made over 3,939,577 options, of which 2,059,830 had been forfeited or exercised by the year end, leaving 1,879,747 outstanding.

### Retention Share Plan (RSP)

Various other senior management were granted 251,776 options under the Retention Share Plan during the year, conditional on their continued employment with the Group until the vesting date. At the year end 99,286 of these options had vested, 90,123 had been forfeited and 161,653 remained in issue.

### Long Term Incentive Plan (LTIP)

967,549 options held by the Executive Directors and senior management under the LTIP lapsed during the year after the associated performance conditions were not met or staff left employment. At the year end 627,026 options remained in issue.

### Company Share Option Plan (CSOP)

280,690 options held by the Executive Directors and other employees under the CSOP lapsed during the year and 667,164 were granted. At the year end 558,132 options remained in issue. Of this amount 44,962 may be exercised in place of LTIP options held by the participant only, as part of tax efficient arrangements associated with the LTIP scheme. They are therefore considered to be non-dilutive and the dilutive number of options in issue at the year end was 513,170.

### 2018 annual bonus

The Executive Director was awarded a bonus of £202,000 in respect of 2018. A bonus payment of £81,000 was also awarded during the year in respect of 2017.

### 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 2018.

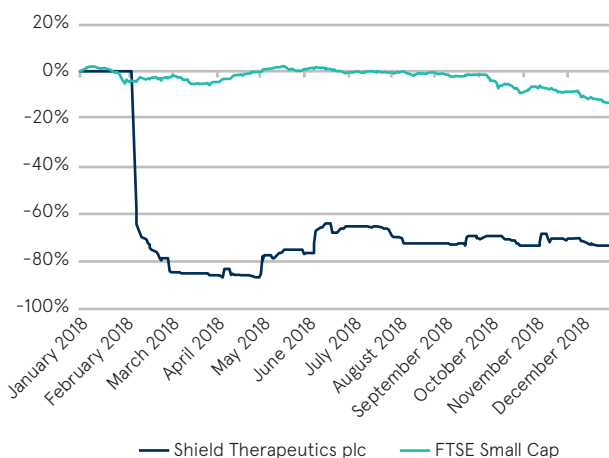
Name	Shares at 31 December 2018	% of share capital
Carl Sterritt	10,075,261	8.73%
James Karis	36,667	0.03%
Peter Llewellyn-Davies	10,000	0.01%

At 31 December 2018 Carl Sterritt had 976,948 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 2018 was £0.305. The highest mid-market price of the Ordinary Shares during the year was £1.125 and the lowest price was £0.155.



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

**Rolf Hoffmann**  
**Remuneration Committee Chairman**  
 2 April 2019



## Directors' report

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 2018.

### Principal activities

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

### 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 are provided in Note 22. Further details of additional share capital issued during the prior year are provided in Note 22. 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 24.

### 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 £1.8 million.

The Directors do not recommend the payment of a dividend in respect of the year ended 31 December 2018.

### 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  
James Karis  
Andrew Heath (resigned 27 June 2018)  
Peter Llewellyn-Davies  
Rolf Hoffmann (appointed 6 April 2018)  
Hans Peter Hasler (appointed 26 July 2018)

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 21 to the financial statements.

### Corporate governance report

The Company's corporate governance report can be found on pages 22 to 25 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	48.11%
MaRu AG*	10.76%
Carl Sterritt	8.73%
Richard Griffiths and family	7.79%
Christian Schweiger	4.85%
Universities Superannuation Scheme	4.38%

\* Formerly held by Irorph GmbH

## 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 at Stephenson Harwood, 1 Finsbury Circus, London EC2M 7SH, at 10.00am on Thursday 13 June 2019.

By order of the Board



### Carl Sterritt

Chief Executive Officer

2 April 2019

## 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 judgements 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.

The Directors have decided to prepare voluntarily a Directors' remuneration report in accordance with Schedule 8 to The Large and Medium-sized Companies and Groups (Accounts and Reports) Regulations 2008 made under the Companies Act 2006, as if those requirements applied to the Company. The Directors have also decided to prepare voluntarily a corporate governance statement as if the Company were required to comply with the Listing Rules and the Disclosure Guidance and Transparency Rules of the Financial Conduct Authority in relation to those matters.

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



**Carl Sterritt**  
Chief Executive Officer  
2 April 2019



## 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 2018 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 2018 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

### 2. Material uncertainty related to going concern

#### Going concern

We draw attention to Note 2 on page 49 to the financial statements which indicates that the cash resources of the Group will cease to be sufficient after June 2020 in the absence of further funding received from the continued commercialisation of the Group's Feraccru® asset, the success and timing of which are uncertain.

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.

Our opinion is not modified in respect of this matter.

#### The risk

#### Disclosure quality

There is little judgement involved in the Directors' conclusion that risks and circumstances described in Note 2 to the financial statements represent a material uncertainty over the ability of the Group and Company to continue as a going concern for a period of at least a year from the date of approval of the financial statements.

However, clear and full disclosure of the facts and the Directors' rationale for the use of the going concern basis of preparation, including that there is a related material uncertainty, is a key financial statement disclosure and so was the focus of our audit in this area. Auditing standards require that to be reported as a key audit matter.

#### Our response

Our procedures included:

#### Assessing transparency

- We assessed the completeness and accuracy of the matters disclosed in the going concern disclosure with reference to the audit findings from our review of the Group's cash projections and our understanding of the status of the Group's strategies to further commercialise the Group's drug assets. We assessed whether the going concern disclosure was consistent with our understanding and that the material uncertainty was clearly disclosed.

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:** £0.6 million (2017: £0.7 million)  
Group financial statements as a whole 4.3% (2017: 3.3%) of loss before tax

**Coverage** 100% (2017: 100%) of Group loss before tax

#### Key audit matters vs 2017

Recurring risks		
Recoverable amounts of intangibles		▲
Capitalisation of development costs		◀▶
Recoverability of investments in subsidiaries		◀▶
<b>Event driven</b>	<b>New:</b> The impact of uncertainties due to the UK exiting the European Union on our audit	▲



## Independent auditor's report continued

to the members of Shield Therapeutics plc

### 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:

	The risk	Our response
<p><b>The impact of uncertainties due to the UK exiting the European Union on our audit</b></p> <p>Refer to pages 18 and 19 (principal risks) and page 14 (Chief Executive Officer's statement and financial review)</p>	<p><b>Unprecedented levels of uncertainty</b></p> <p>All audits assess and challenge the reasonableness of estimates, in particular as described in the recoverable amount of intangibles and recoverability of parent company's investment in subsidiaries below, and related disclosures and the appropriateness of the going concern basis of preparation of the financial statements (see above). All of these depend on assessments of the future economic environment and the Group's future prospects and performance.</p> <p>In addition, we are required to consider the other information presented in the annual report including the principal risks disclosure and the viability statement and to consider the Directors' statement that the annual report and financial statements 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.</p> <p>Brexit is one of the most significant economic events for the UK and at the date of this report its effects are subject to unprecedented levels of uncertainty of outcomes, with the full range of possible effects unknown.</p>	<p>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:</p> <p><b>Our Brexit knowledge</b></p> <ul style="list-style-type: none"><li>• 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.</li></ul> <p><b>Sensitivity analysis</b></p> <ul style="list-style-type: none"><li>• When addressing the recoverable amount of intangibles and recoverability of parent company's investment in subsidiaries 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.</li></ul> <p><b>Assessing transparency</b></p> <ul style="list-style-type: none"><li>• As well as assessing individual disclosures as part of our procedures on the recoverable amount of intangibles and recoverability of parent company's investment in subsidiaries, 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.</li></ul> <p>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.</p>



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

	The risk	Our response
<p><b>Group: Recoverable amount of intangibles</b> (£31.0 million; 2017: £30.0 million)</p> <p><i>Refer to pages 52-53 (accounting policy) and pages 60-61 (financial disclosures)</i></p>	<p><b>Forecast-based valuation</b></p> <p>These intangible assets relate to the Group's two drug products and their valuation is a significant estimate at risk of irrecoverability 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).</p> <p>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.</p> <p>The risk has increased due to increased uncertainty in the future cash flows.</p> <p>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.</p> <p>The effect of these matters is that, as part of our risk assessment, we determined that the value in use of £31.0 million 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 14) disclose the sensitivity estimated by the Group.</p>	<p>Our procedures included:</p> <ul style="list-style-type: none"> <li>• <b>Control operation:</b> We tested the controls over the forecasts prepared for the intangible assets, including annual approval and challenge of those forecasts by the Directors.</li> <li>• <b>Our sector experience:</b> We evaluated the assumptions used, in particular those relating to forecast receipts from licensees and the discount rate applied to discount the cash flows.</li> <li>• <b>Benchmarking assumptions:</b> Compared the Group's assumptions to externally derived data in relation to key inputs such as projected market growth, royalty rates and discount rates.</li> <li>• 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.</li> <li>• <b>Sensitivity analysis:</b> Performed breakeven analysis on certain of the assumptions noted above.</li> <li>• <b>Comparing valuations:</b> Compared the sum of the discounted cash flows to the Group's market capitalisation to assess the overall reasonableness of those cash flows and considered the reasons for the current variance, including reference to analyst forecasts.</li> <li>• <b>Assessing transparency:</b> 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 valuation of intangibles.</li> </ul>

## Independent auditor's report continued

to the members of Shield Therapeutics plc

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

	The risk	Our response
<p><b>Group: Capitalisation of development costs</b> (£3.0 million; 2017: £3.2 million)</p> <p><i>Refer to pages 52–53 (accounting policy) and pages 60–61 (financial disclosures)</i></p>	<p><b>Effects of irregularities</b> The incentive to misstate research and development expenditure, whether 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.</p>	<p>Our procedures included:</p> <ul style="list-style-type: none"><li>• <b>Control design:</b> Evaluated the Group's process for capitalising and expensing research and development costs.</li><li>• <b>Tests of detail:</b> For a sample of costs both capitalised and expensed during the year assessed them against the capitalisation criteria.</li></ul>
<p><b>Parent company: Recoverability of parent company's investment in subsidiaries</b> (£103.7 million; 2017: £103.0 million)</p> <p><i>Refer to pages 50–51 (accounting policy) and pages 61–62 (financial disclosures)</i></p>	<p><b>Forecast-based valuation</b> The carrying amount of the parent company's investments in subsidiaries is significant and at risk of irrecoverability due to the carrying amount being in excess of the Company's market capitalisation.</p> <p>The effect of these matters is that, as part of our risk assessment, we determined that the value in use of £103.7 million 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.</p>	<p>Our procedures included:</p> <ul style="list-style-type: none"><li>• <b>Test of detail:</b> 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 range of the applicable intangible assets.</li><li>• <b>Assessing transparency:</b> 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 valuation of investments.</li></ul>



#### 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 £600,000, determined with reference to a benchmark of Group loss before tax, normalised by averaging over the last three years due to fluctuations in the business cycle, of £13.9 million, of which it represents 4.3% (2017: 3.3% of Group loss before tax).

Materiality for the parent company financial statements as a whole was set at £37,000 (2017: £35,000), determined with reference to a benchmark of loss before tax, of which it represents 2.4% (2017: 4.5%).

We agreed to report to the Audit Committee any corrected or uncorrected identified misstatements exceeding £30,000, in addition to other identified misstatements that warranted reporting on qualitative grounds.

Of the Group's five (2017: five) reporting components, we subjected three (2017: three) to full scope audits for Group purposes and two (2017: two) to specified risk-focused audit procedures. The latter were not individually financially significant enough to require a full scope audit for Group purposes, but did present specific individual risks that needed to be addressed.

The components within the scope of our work accounted for the percentages illustrated opposite. The Group reporting covered 100% (2017: 100%) of the total profits and losses that made up Group loss before tax.

The Group team carried out all of the work on the five reporting components. We used component materialities, which range from £3,000 to £450,000 (2017: £3,000 to £630,000), having regard to the mix of size and risk profile of the Group across the components.

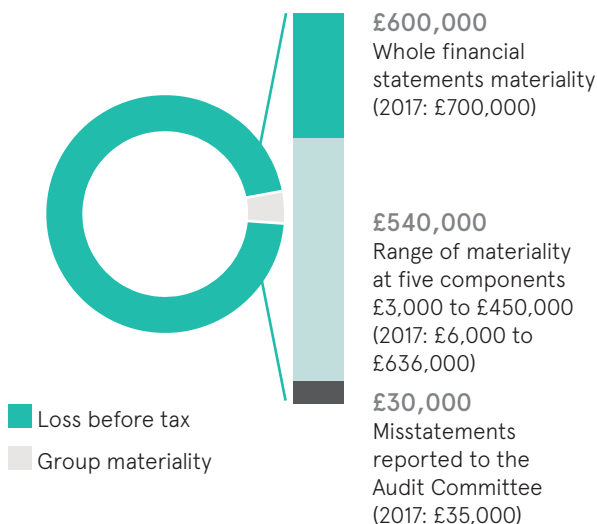
#### Normalised loss before tax

£13.9 million  
(2017: £21.0 million)

#### Group materiality

£600,000

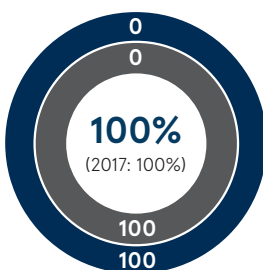
(2017: £700,000)



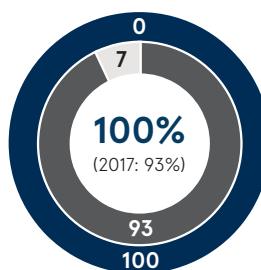
#### Group revenue



#### Group loss before tax



#### Group total assets



- Full scope for Group audit purposes 2018
- Specified risk-focused audit procedures 2018
- Full scope for Group audit purposes 2017
- Specified risk-focused audit procedures 2017



## Independent auditor's report continued

to the members of Shield Therapeutics plc

### 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.

#### Disclosures of principal risks and longer-term viability

Based on the knowledge we acquired during our financial statements audit, other than the material uncertainty related to going concern referred to above, we have nothing further material to add or draw attention to in relation to:

- The Directors' confirmation within the viability statement on page 25 that they have carried out a robust assessment of the principal risks facing the Group, including those that would threaten its business model, future performance, solvency and liquidity;
- The principal risks and uncertainties disclosures describing these risks and explaining how they are being managed and mitigated; and
- The Directors' explanation in the viability statement of how they have assessed the prospects of the Group, over what period they have done so and why they considered that period to be appropriate, and their statement as to whether they have a reasonable expectation that the Group will be able to continue in operation and meet its liabilities as they fall due over the period of their assessment, including any related disclosures drawing attention to any necessary qualifications or assumptions.

Our work is limited to assessing these matters in the context of only the knowledge acquired during our financial statements audit. As we cannot predict all future events or conditions and as subsequent events may result in outcomes that are inconsistent with judgments that were reasonable at the time they were made, the absence of anything to report on these statements is not a guarantee as to the Group's and Company's longer-term viability.

#### Corporate governance disclosures

We are required to report to you if:

- We have identified material inconsistencies between the knowledge we acquired during our financial statements audit and the Directors' statement that they consider that the annual report and financial statements 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; or
- The section of the annual report describing the work of the Audit Committee does not appropriately address matters communicated by us to the Audit Committee.

We have nothing to report in these respects.

### 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](http://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.

**Nick Plumb (Senior Statutory Auditor)**  
for and on behalf of KPMG LLP, Statutory Auditor  
Chartered Accountants  
Quayside House  
110 Quayside  
Newcastle upon Tyne  
NE1 3DX  
2 April 2019

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

for the year ended 31 December

	Notes	2018 £000	2017 £000
Revenue	5	<b>11,881</b>	637
Cost of sales		<b>(311)</b>	(155)
<b>Gross profit</b>		<b>11,570</b>	482
Operating costs – selling, general and administrative expenses	7	<b>(12,438)</b>	(16,722)
Operating loss before research and development expenditure		<b>(868)</b>	(16,240)
Research and development expenditure	6	<b>(4,300)</b>	(4,711)
<b>Operating loss</b>		<b>(5,168)</b>	(20,951)
Financial income	10	<b>50</b>	15
Financial expense	10	<b>(35)</b>	(58)
<b>Loss before tax</b>		<b>(5,153)</b>	(20,994)
Taxation	12	<b>3,359</b>	1,406
<b>Loss for the year</b>		<b>(1,794)</b>	(19,588)
<b>Attributable to:</b>			
Equity holders of the parent		<b>(1,794)</b>	(19,588)
<b>Other comprehensive income</b>			
Items that are or may be reclassified subsequently to profit or loss:			
Foreign currency translation differences – foreign operations		<b>4</b>	(41)
<b>Total comprehensive expenditure for the year</b>		<b>(1,790)</b>	(19,629)
<b>Attributable to:</b>			
Equity holders of the parent		<b>(1,790)</b>	(19,629)
<b>Total comprehensive expenditure for the year</b>		<b>(1,790)</b>	(19,629)
<b>Earnings per share</b>			
Basic and diluted loss per share	11	<b>£(0.02)</b>	£(0.17)



## Group balance sheet

at 31 December

	Notes	2018 £000	2017 £000
<b>Non-current assets</b>			
Intangible assets	14	30,957	29,961
Property, plant and equipment	13	8	13
		<b>30,965</b>	29,974
<b>Current assets</b>			
Inventories	16	109	125
Trade and other receivables	17	1,031	1,572
Current tax asset	12	1,500	–
Cash and cash equivalents	18	9,776	13,299
		<b>12,416</b>	14,996
<b>Total assets</b>		<b>43,381</b>	44,970
<b>Current liabilities</b>			
Trade and other payables	19	(2,548)	(3,501)
Other liabilities	20	(403)	(262)
		<b>(2,951)</b>	(3,763)
<b>Total liabilities</b>		<b>(2,951)</b>	(3,763)
<b>Net assets</b>		<b>40,430</b>	41,207
<b>Equity</b>			
Share capital	22	1,746	1,746
Share premium	23	88,338	88,338
Merger reserve	23	28,358	28,358
Currency translation reserve	23	36	32
Retained earnings	23	(78,048)	(77,267)
<b>Total equity</b>		<b>40,430</b>	41,207

These financial statements were approved by the Board of Directors on 2 April 2019 and were signed on its behalf by:



**Carl Sterritt**

Director

Company registered number: 09761509





## Company balance sheet

at 31 December

	Notes	2018 £000	2017 £000
<b>Non-current assets</b>			
Investments	15	<b>103,697</b>	102,980
		<b>103,697</b>	102,980
<b>Current assets</b>			
Trade and other receivables	17	<b>35,824</b>	33,826
Cash and cash equivalents	18	<b>9,003</b>	11,807
		<b>44,827</b>	45,633
<b>Total assets</b>		<b>148,524</b>	148,613
<b>Current liabilities</b>			
Trade and other payables	19	<b>(685)</b>	(301)
Other liabilities	20	<b>(81)</b>	–
<b>Total liabilities</b>		<b>(766)</b>	(301)
<b>Net assets</b>		<b>147,758</b>	148,312
<b>Equity</b>			
Share capital	22	<b>1,746</b>	1,746
Share premium	23	<b>88,338</b>	88,338
Merger reserve	23	<b>117,323</b>	117,323
Retained earnings	23	<b>(59,649)</b>	(59,095)
<b>Total equity</b>		<b>147,758</b>	148,312

These financial statements were approved by the Board of Directors on 2 April 2019 and were signed on its behalf by:



**Carl Sterritt**  
Director

Company registered number: 09761509



## Group statement of changes in equity

for the year ended 31 December

	Issued capital £000	Share premium £000	Warrants reserve £000	Merger reserve £000	Currency translation reserve £000	Retained earnings £000	Total £000
Balance at 1 January 2017	1,622	77,963	2,760	28,358	73	(62,380)	48,396
Loss for the year	—	—	—	—	—	(19,588)	(19,588)
Other comprehensive income:							
Foreign currency translation differences	—	—	—	—	(41)	—	(41)
Total comprehensive expense for the year	—	—	—	—	(41)	(19,588)	(19,629)
<b>Transactions with owners, recorded directly in equity</b>							
Share issue – exercise of Warrants	108	10,235	(2,760)	—	—	2,760	10,343
Share issue – placing	15	—	—	—	—	1,381	1,396
Share issue – subscription	1	140	—	—	—	—	141
Equity-settled share-based payment transactions	—	—	—	—	—	560	560
Balance at 31 December 2017	1,746	88,338	—	28,358	32	(77,267)	41,207
Loss for the year	—	—	—	—	—	(1,794)	(1,794)
Other comprehensive income:							
Foreign currency translation differences	—	—	—	—	4	—	4
Total comprehensive expense for the year	—	—	—	—	4	(1,794)	(1,790)
<b>Transactions with owners, recorded directly in equity</b>							
Equity-settled share-based payment transactions	—	—	—	—	—	1,013	1,013
<b>Balance at 31 December 2018</b>	<b>1,746</b>	<b>88,338</b>	<b>—</b>	<b>28,358</b>	<b>36</b>	<b>(78,048)</b>	<b>40,430</b>

## Company statement of changes in equity

for the year ended 31 December

	Issued capital £000	Share premium £000	Warrants reserve £000	Merger reserve £000	Retained earnings £000	Total £000
Balance at 1 January 2017	1,622	77,963	2,760	117,323	(63,013)	136,655
Loss for the year	–	–	–	–	(783)	(783)
Total comprehensive expense for the year	–	–	–	–	(783)	(783)
<b>Transactions with owners, recorded directly in equity</b>						
Share issue – exercise of Warrants	108	10,235	(2,760)	–	2,760	10,343
Share issue – placing	15	–	–	–	1,381	1,396
Share issue – subscription	1	140	–	–	–	141
Equity-settled share-based payment transactions	–	–	–	–	560	560
Balance at 31 December 2017	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)
<b>Transactions with owners, recorded directly in equity</b>						
Equity-settled share-based payment transactions	–	–	–	–	1,013	1,013
<b>Balance at 31 December 2018</b>	<b>1,746</b>	<b>88,338</b>	<b>–</b>	<b>117,323</b>	<b>(59,649)</b>	<b>147,758</b>



## Group statement of cash flows

for the year ended 31 December

	2018 £000	2017 £000
<b>Cash flows from operating activities</b>		
Loss for the year	(1,794)	(19,588)
Adjustments for:		
Depreciation and amortisation	2,354	2,437
Equity-settled share-based payment expenses	1,013	560
Financial income	(50)	(15)
Financial expense	35	17
Unrealised foreign exchange losses	4	39
Income tax	(3,359)	(1,406)
	<b>(1,797)</b>	<b>(17,956)</b>
Decrease in inventories	16	293
Decrease/(increase) in trade and other receivables	541	(171)
Decrease in trade and other payables	(953)	(409)
Increase in other liabilities	141	101
Financial income	50	15
Financial expense	(35)	(17)
Income tax received	1,859	1,993
<b>Net cash flows from operating activities</b>	<b>(178)</b>	<b>(16,151)</b>
<b>Cash flows from investing activities</b>		
Acquisitions of intangible assets	(346)	(235)
Capitalised development expenditure	(2,999)	(3,173)
<b>Net cash flows from investing activities</b>	<b>(3,345)</b>	<b>(3,408)</b>
<b>Cash flows from financing activities</b>		
Proceeds of Warrants exercise	—	10,792
Proceeds of placing	—	1,500
Proceeds of subscription	—	144
Share issue costs	—	(556)
<b>Net cash flows from financing activities</b>	<b>—</b>	<b>11,880</b>
Net decrease in cash	(3,523)	(7,679)
Cash and cash equivalents at 1 January	13,299	20,978
<b>Cash and cash equivalents at 31 December</b>	<b>9,776</b>	<b>13,299</b>

## Company statement of cash flows

for the year ended 31 December

	2018 £000	2017 £000
<b>Cash flows from operating activities</b>		
Loss for the year	(1,567)	(783)
Adjustments for:		
Equity-settled share-based payment expenses	296	148
Financial income	(426)	(15)
	(1,697)	(650)
Increase in trade and other receivables	(1,998)	(19,721)
Increase in trade and other payables	465	14
Financial income	426	15
<b>Net cash flows from operating activities</b>	<b>(2,804)</b>	<b>(20,342)</b>
<b>Cash flows from financing activities</b>		
Proceeds of Warrants exercise	—	10,792
Proceeds of placing	—	1,500
Proceeds of subscription	—	144
Share issue costs	—	(556)
<b>Net cash flows from financing activities</b>	<b>—</b>	<b>11,880</b>
Net decrease in cash	(2,804)	(8,462)
Cash and cash equivalents at 1 January	11,807	20,269
<b>Cash and cash equivalents at 31 December</b>	<b>9,003</b>	<b>11,807</b>





## Notes (forming part of the financial statements)

for the year ended 31 December

### 1. General information

Shield Therapeutics plc (the "Company") is incorporated in England and Wales as a public limited company. The Company trades on the London Stock Exchange's AIM, having been admitted on 26 February 2016.

The Company is domiciled in England and the registered office of the Company is at Northern Design Centre, Baltic Business Quarter, Gateshead Quays NE8 3DF.

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

Subsidiaries and their countries of incorporation are presented in Note 15.

### 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, unless otherwise stated, been applied consistently to all periods presented in these financial statements. The financial statements are prepared on the historical cost basis except for derivative financial instruments that are stated at their fair value. The functional currency of the Company is GBP. The consolidated financial statements are presented in GBP and all values are rounded to the nearest thousand (£000), except as otherwise indicated.

#### Company income statement

As permitted by Section 408 of the Companies Act 2006, the Company has not presented its own income statement. The loss for the financial year per the accounts of the Company was £1.6 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 £9.8 million of cash. Since the year end, the Group has achieved a successful Head-to-Head study, resulting in a milestone receivable of €2.5 million under the current European out-licensing agreement with Norgine.

The Directors have considered the funding requirements of the Group through the preparation of detailed cash flow forecasts for the period to December 2020. Under current business plans the current cash resources will extend to the third quarter of 2020. Based on this, additional funding is expected to be required by the third quarter of 2020 in order to support the Group's going concern status. The Directors are considering further commercialisation out-licensing opportunities for Feraccru<sup>®</sup>, in particular in the USA and China. 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 royalty finance underpinned by the existing European out-licensing agreement with Norgine, are likely to be available to the Group. However, there can be no guarantee that any of these opportunities will be successfully concluded.

Based on the above factors the Directors believe that it remains appropriate to prepare the financial statements on a going concern basis. However, the above factors give rise to a material uncertainty which may cast 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 2018.

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

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

#### Foreign currency

Transactions in foreign currencies are translated to the Group's functional currency at the foreign exchange rate ruling at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies at the balance sheet date are retranslated to the functional currency at the foreign exchange rate ruling at the balance sheet date. Foreign exchange differences arising on translation are recognised in the statement of profit and loss. Non-monetary assets and liabilities that are measured in terms of historical cost in a foreign currency are translated using the exchange rate at the date of the transaction. Non-monetary assets and liabilities denominated in foreign currencies that are stated at fair value are retranslated to the functional currency at foreign exchange rates ruling at the dates the fair value was determined.



## Notes (forming part of the financial statements) continued

for the year ended 31 December

### 2. Accounting policies continued

#### Foreign currency continued

The assets and liabilities of foreign operations, including goodwill and fair value adjustments arising on consolidation, are translated to the Group's presentation currency, Sterling, at foreign exchange rates ruling at the balance sheet date.

The revenues and expenses of foreign operations are translated at an average rate for the year where this rate approximates to the foreign exchange rates ruling at the dates of the transactions.

Exchange differences arising from this translation of foreign operations are reported as an item of other comprehensive income and accumulated in the currency translation reserve.

#### Financial instruments

##### (i) Recognition and initial measurement

Trade receivables are initially recognised when they are originated. All other financial assets and financial liabilities are initially recognised when the Company becomes a party to the contractual provisions of the instrument.

A financial asset (unless it is a trade receivable without a significant financing component) or financial liability is initially measured at fair value plus, for an item not at Fair Value Through Profit or Loss (FVTPL), transaction costs that are directly attributable to its acquisition or issue. A trade receivable without a significant financing component is initially measured at the transaction price.

##### (ii) Classification and subsequent measurement

###### Financial assets

###### (a) Classification

On initial recognition, a financial asset is classified as measured at: amortised cost; Fair Value through Other Comprehensive Income (FVOCI) – debt investment; FVOCI – equity investment; or FVTPL.

Financial assets are not reclassified subsequent to their initial recognition unless the Company changes its business model for managing financial assets in which case all affected financial assets are reclassified on the first day of the first reporting period following the change in the business model.

A financial asset is measured at amortised cost if it meets both of the following conditions:

- It is held within a business model whose objective is to hold assets to collect contractual cash flows; and
- Its contractual terms give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding.

On initial recognition of an equity investment that is not held for trading, the Company may irrevocably elect to present subsequent changes in the investment's fair value in OCI. This election is made on an investment-by-investment basis.

All financial assets not classified as measured at amortised cost or FVOCI as described above are measured at FVTPL.

Investments in subsidiaries are carried at cost less impairment.

###### Cash and cash equivalents

Cash and cash equivalents comprise cash balances and call deposits.

###### (b) Subsequent measurement and gains and losses

Financial assets at FVTPL – these assets (other than derivatives designated as hedging instruments) are subsequently measured at fair value. Net gains and losses, including any interest or dividend income, are recognised in profit or loss.

Financial assets at amortised cost – these assets are subsequently measured at amortised cost using the effective interest method. The amortised cost is reduced by impairment losses. Interest income, foreign exchange gains and losses and impairment are recognised in profit or loss. Any gain or loss on derecognition is recognised in profit or loss.

###### Financial liabilities and equity

Financial instruments issued by the Company are treated as equity only to the extent that they meet the following two conditions:

- (a) They include no contractual obligations upon the Company to deliver cash or other financial assets or to exchange financial assets or financial liabilities with another party under conditions that are potentially unfavourable to the Company; and
- (b) Where the instrument will or may be settled in the Company's own equity instruments, it is either a non-derivative that includes no obligation to deliver a variable number of the Company's own equity instruments or is a derivative that will be settled by the Company exchanging a fixed amount of cash or other financial assets for a fixed number of its own equity instruments.



## 2. Accounting policies continued

### Financial instruments continued

#### (ii) Classification and subsequent measurement continued

##### Financial liabilities and equity continued

To the extent that this definition is not met, the proceeds of issue are classified as a financial liability. Where the instrument so classified takes the legal form of the Company's own shares, the amounts presented in these financial statements for called up share capital and share premium account exclude amounts in relation to those shares.

Financial liabilities are classified as measured at amortised cost or FVTPL. A financial liability is classified as at FVTPL if it is classified as held for trading, it is a derivative or it is designated as such on initial recognition. Financial liabilities at FVTPL are measured at fair value and net gains and losses, including any interest expense, are recognised in profit or loss. Other financial liabilities are subsequently measured at amortised cost using the effective interest method. Interest expense and foreign exchange gains and losses are recognised in profit or loss. Any gain or loss on derecognition is also recognised in profit or loss.

Where a financial instrument that contains both equity and financial liability components exists these components are separated and accounted for individually under the above policy.

##### *Intra-group financial instruments*

Where the Company enters into financial guarantee contracts to guarantee the indebtedness of other companies within its Group, the Company considers these to be insurance arrangements and accounts for them as such. In this respect, the Company treats the guarantee contract as a contingent liability until such time as it becomes probable that the Company will be required to make a payment under the guarantee.

#### (iii) Impairment

The Company recognises loss allowances for expected credit losses (ECLs) on financial assets measured at amortised cost, debt investments measured at FVOCI and contract assets (as defined in IFRS 15).

The Company measures loss allowances at an amount equal to lifetime ECL, except for other debt securities and bank balances for which credit risk (i.e. the risk of default occurring over the expected life of the financial instrument) has not increased significantly since initial recognition, which are measured as twelve-month ECL.

Loss allowances for trade receivables and contract assets are always measured at an amount equal to lifetime ECL.

When determining whether the credit risk of a financial asset has increased significantly since initial recognition and when estimating ECL, the Company considers reasonable and supportable information that is relevant and available without undue cost or effort. This includes both quantitative and qualitative information and analysis, based on the Company's historical experience and informed credit assessment and including forward-looking information.

The Company assumes that the credit risk on a financial asset has increased significantly if it is more than 30 days past due.

The Company considers a financial asset to be in default when:

- The borrower is unlikely to pay its credit obligations to the Company in full, without recourse by the Company to actions such as realising security (if any is held); or
- The financial asset is more than 90 days past due.

Lifetime ECLs are the ECLs that result from all possible default events over the expected life of a financial instrument.

Twelve-month ECLs are the portion of ECLs that result from default events that are possible within twelve months after the reporting date (or a shorter period if the expected life of the instrument is less than twelve months).

The maximum period considered when estimating ECLs is the maximum contractual period over which the Company is exposed to credit risk.

##### Measurement of ECLs

ECLs are a probability-weighted estimate of credit losses. Credit losses are measured as the present value of all cash shortfalls (i.e. the difference between the cash flows due to the entity in accordance with the contract and the cash flows that the Company expects to receive). ECLs are discounted at the effective interest rate of the financial asset.

##### Credit-impaired financial assets

At each reporting date, the Company assesses whether financial assets carried at amortised cost and debt securities at FVOCI are credit impaired. A financial asset is "credit impaired" when one or more events that have a detrimental impact on the estimated future cash flows of the financial asset have occurred.



## Notes (forming part of the financial statements) continued

for the year ended 31 December

### 2. Accounting policies continued

#### Financial instruments continued

##### (iii) Impairment continued

###### Write-offs

The gross carrying amount of a financial asset is written off (either partially or in full) to the extent that there is no realistic prospect of recovery.

###### Inventories

Inventories are stated at the lower of cost and net realisable value. Cost is determined using standard costing techniques. The cost of finished goods comprises raw materials, direct labour, other direct costs and related production overheads. 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.

###### Intangible assets

##### Research and development

Expenditure on research activities is recognised as an expense in the statement of profit and loss.

Expenditure on development activities directly attributable to an intangible asset is capitalised when the following conditions are met:

- It is technically feasible to complete the product so that it will be available for use;
- Management intends to complete the product and use or sell it;
- There is an ability to use or sell the product;
- It can be demonstrated how the product will generate probable future economic benefits;
- Adequate technical, financial and other resources to complete the development and to use or sell the product are available; and
- The expenditure attributable to the product during its development can be reliably measured.

The Group considers that Marketing Authorisation Approval (MAA) regulatory approval in the relevant jurisdiction confirms these criteria.

Internally developed intangible assets are recorded at cost and subsequently measured at cost less accumulated amortisation and accumulated impairment losses.

Capitalised directly attributable development costs include clinical trial costs, Chemistry, Manufacturing and Controls (CMC) costs and contractor costs. Internal salary costs have not been capitalised as they are not considered to directly relate to bringing the asset to its working condition and employee costs are not allocated by project. Costs relating to clinical trials, such as the Head-to-Head study, are only capitalised once Marketing Authorisation has been received and prior to this point are instead expensed as research and development expenditure.

Expenditure in relation to patent registration and renewal of current patents is capitalised and recorded as an intangible asset. Registration costs are continually incurred as the Group registers these patents in different countries. Patent assets are stated at cost less accumulated amortisation and accumulated impairment losses. Capitalisation ceases when the related project concludes.

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

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

##### Impairment of assets

An impairment review is carried out annually for assets not yet in use. An impairment review is carried out for assets being amortised or depreciated when a change in market conditions and other circumstances indicates that the carrying value may not be recoverable. The recoverable amount is the higher of an asset's fair value less costs to sell and value in use.



## 2. Accounting policies continued

### Intangible assets continued

#### Impairment of assets continued

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

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.

Depreciation on 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

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.

#### Revenue

Revenue is net invoice value after the deduction of value-added tax and other sales taxes. Deductions are made for product returns based on historical experience.

The Group has two revenue streams, being revenue associated with the sale of goods and revenue arising under milestone payments included in licensing agreements.

Revenue is recognised in the consolidated statement of profit and loss and other comprehensive income when control of goods passes to the customer. This is deemed to occur when the customer collects and loads the product, resulting in the legal transfer of title.

Milestone payments under licensing agreements are recognised as revenue in the consolidated statement of profit and loss when related performance obligations are met, as defined in the licensing agreement, unless the Group has substantial ongoing performance obligations associated with the milestone still to deliver and the payment is not fixed or non-refundable.

The Norgine contract is assessed to be a right to use licence, on the grounds that the Group's post-deal activity is not expected to significantly enhance the value of the asset to Norgine, and includes three types of performance obligation:

- execution of the licence – revenue is recognised at a point in time upon signature of the agreement;
- event-based milestones such as successful completion of clinical trials and achievement of sales thresholds – these comprise variable consideration and, as such, revenue is only recognised when it is highly probable that no revenue will be reversed in the future. No revenue has been recognised in respect of these performance obligations in the year; and
- sales-based royalties – these are attributable to the licence and revenue is recognised when the subsequent sale or usage occurs.

#### Norgine licence agreement

Revenue is recognised at a point in time. The Norgine contract has been assessed as containing a right to use licence as opposed to a right to access and therefore revenue is recognised at a point in time. If the licence were right to access, revenue would have been recognised over the life of the agreement. The contract also contains performance obligations with variable consideration. No amounts have been recognised in relation to these performance obligations in the year as management have judged that it is not highly probable that any revenue recognised would not be reversed in future periods since the outcome of the events is uncertain.

#### Expenses

##### Financial income and expense

Financing expenses comprise interest payable, finance charges on shares classified as liabilities and net foreign exchange losses that are recognised in the income statement (see foreign currency accounting policy). Financing income comprises interest receivable on funds invested, dividend income and net foreign exchange gains.

Interest income and interest payable are recognised in profit or loss as they accrue, using the effective interest method. Dividend income is recognised in the income statement on the date the entity's right to receive payments is established. Foreign currency gains and losses are reported on a net basis.



## Notes (forming part of the financial statements) continued

for the year ended 31 December

### 2. Accounting policies continued

#### 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.

#### Share-based payments

The Group operates equity-settled, share-based compensation plans, under which the entity receives services from employees as consideration for equity instruments (options) of the Group. The fair value of the employee services received in exchange for the grant of the options is recognised as an expense. The total amount to be expensed is determined by reference to the fair value of the options granted:

- Including any market performance conditions;
- Excluding the impact of any service and non-market performance vesting conditions; and
- Including the impact of any non-vesting conditions.

Non-market performance and service conditions are included in assumptions about the number of options that are expected to vest. The total expense is recognised over the vesting period, which is the period over which all of the specified vesting conditions are to be satisfied.

In addition, in some circumstances employees may provide services in advance of the grant date and therefore the grant date fair value is estimated for the purposes of recognising the expense during the period between the service commencement period and the grant date.

#### Share-based payments

The grant by the Company of options over its equity instruments to the employees of subsidiary undertakings in the Group is treated as a capital contribution. The fair value of employee services received, measured by reference to the grant date fair value, is recognised over the vesting period as an increase to investments in subsidiary undertakings, with a corresponding credit to equity in the parent entity accounts.

### 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 judgments, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognised in the period in which the estimate is revised if the revision affects only that period or in the period of the revision and future periods if the revision affects both current and future periods. The significant judgments and estimates which may lead to material adjustment in the next accounting period are:

#### Going concern

Following the receipt of the £11.0 million upfront milestone payment on signing the licence agreement with Norgine and the preparation of detailed cash flow forecasts, the Directors are of the opinion that the Group has sufficient working capital for its present requirements, that is for at least twelve months from the date of this report. The Directors therefore consider it appropriate to adopt the going concern basis of accounting in preparing the financial statements.

#### Valuation of intellectual property acquired with Phosphate Therapeutics Limited – £21.5 million

The valuation of intellectual property acquired with Phosphate Therapeutics Limited in 2016 is based on cash flow forecasts for the underlying business and an assumed appropriate cost of capital and other inputs in order to arrive at a value in use for the asset. The realisation of its value is ultimately dependent on regulatory approval and successful commercialisation of the asset. Work on the development of a suitable commercial formulation of the drug product is ongoing. In the event that commercial returns are lower than current expectations this may lead to an impairment. See Note 14 for sensitivity analysis of key assumptions in this valuation.

#### Development expenditure

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



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

#### Valuation of intellectual property associated with Feraccru® – intangible assets of £9.5 million; investments in Company balance sheet of £76.9 million

The valuation of intellectual property associated with Feraccru® (including patents, development costs and the Company's investment in Shield TX (Switzerland) AG) is based on cash flow forecasts for the underlying business and an assumed appropriate cost of capital and other inputs in order to arrive at a fair value for the asset. The realisation of its value is ultimately dependent on the successful commercialisation of the asset. An agreement was reached during the year with a strategic commercial partner for the asset in Europe. An upfront payment of £11.0 million was received as part of the agreement, with the potential for significant additional milestone payments and royalties to follow. In the event that commercial returns are lower than current expectations or partner or alternative funding is not available this may lead to an impairment. No impairment has been recognised to date. 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.

From 1 January 2018 the Company adopted IFRS 15 Revenue from contracts with customers. The Company has also adopted IFRS 9 Financial instruments. No adjustments have been required as a consequence of these standards' adoption, as the impact is immaterial. There are no other new or amended standards which impact the Group in the year.

At the balance sheet date the following standards, amendments and interpretations were in issue but not yet effective. The Group has not early adopted any of these standards, amendments and interpretations.

- IFRS 16 Leases.

The Group is continuing to assess the impact of IFRS 16 and expects from an initial assessment that the impact on the financial statements will not be material.

### 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® 2018 £000	PT20 2018 £000	Central and unallocated 2018 £000	Total 2018 £000	Feraccru® 2017 £000	PT20 2017 £000	Central and unallocated 2017 £000	Total 2017 £000
Revenue	11,881	–	–	11,881	637	–	–	637
Operating profit/(loss)	2,009	(1,904)	(5,273)	(5,168)	(16,718)	(2,047)	(2,186)	(20,951)
Financial income				50				15
Financial expense				(35)				(58)
Tax				3,359				1,406
Loss for the year				(1,794)				(19,588)

## Notes (forming part of the financial statements) continued

for the year ended 31 December

### 5. Segmental reporting continued

The revenue analysis in the table below is based on the country of registration of the fee-paying party. £11.1 million (2017: £Nil) of revenue is derived from milestone payments from commercial partners. The remainder of revenue is derived from the sale of goods. All revenue in 2017 related to the sale of goods.

	Year ended 31 December 2018 £000	Year ended 31 December 2017 £000
UK	171	70
Europe	11,710	567
	<b>11,881</b>	<b>637</b>

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

	Year ended 31 December 2018 £000	Year ended 31 December 2017 £000
Customer A	11,025	–
Customer B	516	497
Customer C	126	93
Other customers	214	47
	<b>11,881</b>	<b>637</b>

As at 31 December 2018	Feraccru® £000	PT20 £000	Central and unallocated £000	Total £000
Segment assets	12,643	21,627	9,111	43,381
Segment liabilities	(2,068)	(57)	(826)	(2,951)
<b>Total net assets</b>	<b>10,575</b>	<b>21,570</b>	<b>8,285</b>	<b>40,430</b>
Depreciation, amortisation and impairment	435	1,919	–	2,354
Capital expenditure	–	–	–	–
Capitalised development costs	2,999	–	–	2,999

As at 31 December 2017	Feraccru® £000	PT20 £000	Central and unallocated £000	Total £000
Segment assets	9,623	23,451	11,896	44,970
Segment liabilities	(3,570)	(16)	(177)	(3,763)
<b>Total net assets</b>	<b>6,053</b>	<b>23,435</b>	<b>11,719</b>	<b>41,207</b>
Depreciation, amortisation and impairment	421	2,016	–	2,437
Capital expenditure	–	–	–	–
Capitalised development costs	3,173	–	–	3,173

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



## 6. Expenses and auditor's remuneration

	Year ended 31 December 2018 £000	Year ended 31 December 2017 £000
Loss for the year has been arrived at after charging:		
Research and development expenditure	4,300	4,711
Fees payable to Company's auditor and its associates for the audit of parent company and consolidated financial statements	34	29
Fees payable to Company's auditor and its associates for other services:		
The audit of Company's subsidiaries	26	23
Corporate finance transactions	50	—
Tax compliance services	3	2
Other services	10	5

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

Operating costs are comprised of:

	Year ended 31 December 2018 £000	Year ended 31 December 2017 £000
Selling costs	3,495	9,133
General administrative expenses	6,589	5,152
Depreciation and amortisation	2,354	2,437
	<b>12,438</b>	<b>16,722</b>

## 8. Staff numbers and costs

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

	Number of employees	
	2018 Number	2017 Number
R&D	5	6
Medical	4	6
Commercial	8	17
Finance and administration	8	18
	<b>25</b>	<b>47</b>

The number of staff employed by the Group at 31 December 2018 was 15 (31 December 2017: 50).

The aggregate payroll costs of these persons were as follows:

	2018 £000	2017 £000
Wages and salaries	4,308	5,150
Share-based payments (see Note 24)	1,213	560
Other employee benefits	117	272
Pensions	138	206
	<b>5,776</b>	<b>6,188</b>

## Notes (forming part of the financial statements) continued

for the year ended 31 December

### 9. Directors' remuneration

	2018					2017				
	Salary/fees £000	Bonus £000	Taxable benefits £000	Pensions £000	Total £000	Salary/fees £000	Bonus £000	Taxable benefits £000	Pensions £000	Total £000
Carl Sterritt	301	283	58	—	642	300	—	43	—	343
Joanne Estell	—	—	—	—	—	103	—	6	12	121
Richard Jones	—	—	—	—	—	17	—	3	—	20
Andrew Heath	75	—	—	—	75	100	—	—	—	100
James Karis	43	—	—	—	43	41	—	—	—	41
Peter Llewellyn-Davies	46	—	—	—	46	44	—	—	—	44
Rolf Hoffmann	43	—	—	—	43	—	—	—	—	—
Hans Peter Hasler	17	—	—	—	17	—	—	—	—	—
	<b>525</b>	<b>283</b>	<b>58</b>	<b>—</b>	<b>866</b>	<b>605</b>	<b>—</b>	<b>52</b>	<b>12</b>	<b>669</b>

The aggregate of remuneration and amounts receivable under long term incentive schemes of the highest paid Director was £Nil (2017: £Nil).

No Directors exercised share options in the year (2017: none). One Director received shares or share options under long term incentive schemes in the year (2017: two).

£60,000 was paid to third parties in respect of Director services (2017: £Nil), relating to the services of Rolf Hoffmann and Hans Peter Hasler.

A termination payment of £25,000 was paid to Andrew Heath following his resignation during the year, in lieu of his three months' period of notice.

All amounts noted are included in the tabular disclosures above.

#### Related party transactions

The Group has no disclosable related party transactions other than key management compensation.

Key management compensation information is as follows:

	2018 £000	2017 £000
Wages and salaries	2,075	2,133
Share-based payments	1,018	556
Other employee benefits	104	139
Pensions	77	106
	<b>3,274</b>	<b>2,934</b>

### 10. Financial income and expenses

	Year ended 31 December 2018 £000	Year ended 31 December 2017 £000
<b>Financial income</b>		
Net foreign exchange gains	30	—
Total interest income on financial assets measured at amortised cost	20	15
	<b>50</b>	<b>15</b>

	Year ended 31 December 2018 £000	Year ended 31 December 2017 £000
<b>Financial expense</b>		
Net foreign exchange losses	—	(41)
Total interest expense on financial liabilities measured at amortised cost	(22)	—
Bank charges	(13)	(17)
	<b>(35)</b>	<b>(58)</b>





## 11. Loss per share

	2018			2017		
	Loss £000	Weighted shares 000	Loss per share £	Loss £000	Weighted shares 000	Loss per share £
Basic and diluted	<b>(1,794)</b>	<b>116,426</b>	<b>(0.02)</b>	(19,588)	112,358	(0.17)

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

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

The diluted loss per share is identical to the basic loss per share in both years, as potential dilutive shares are not treated as dilutive since they would reduce the loss per share. At the date of approval of the report 3,104,186 of share options were in issue under the Company's LTIP, CSOP, Bonus Share Plan, Retention and Performance Share Plan (RPSP) and Retention Share Plan (RSP), which are considered non-dilutive and potentially provide 3,104,186 additional Ordinary Shares (approximately 2.7% of the current share capital). The level of options exercisable under the LTIP is dependent on the achievement of targets against the Compound Annual Growth Rate in the Company's share price over the vesting period.

## 12. Taxation

Recognised in the income statement:

	Year ended 31 December 2018 £000	Year ended 31 December 2017 £000
Current income tax	<b>1,500</b>	—
Current income tax – adjustments in respect of prior years	<b>1,859</b>	1,406
Deferred tax	—	—
Total tax credit	<b>3,359</b>	1,406

Reconciliation of total tax credit:

	Year ended 31 December 2018 £000	Year ended 31 December 2017 £000
Loss for the year	<b>(1,794)</b>	(19,588)
Taxation	<b>3,359</b>	(1,406)
Loss before tax	<b>(5,153)</b>	(20,994)
Standard rate of corporation tax in the UK	<b>19%</b>	19.25%
Tax using the UK corporation tax rate	<b>(979)</b>	(4,041)
Expenses not deductible for tax purposes	<b>281</b>	111
R&D tax credits – current year	<b>1,500</b>	—
Adjustments in respect of prior years	<b>1,859</b>	1,408
Unrelieved tax losses carried forward and other temporary differences not recognised for deferred tax	<b>682</b>	3,928
Total tax credit	<b>3,359</b>	1,406

### 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. This will reduce the Group's future current tax charge accordingly. The deferred tax assets and liabilities at 31 December 2018 have been calculated based on this rate.



## Notes (forming part of the financial statements) continued

for the year ended 31 December

### 12. Taxation continued

#### 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.

	2018 £000	2017 £000
Unutilised Swiss tax losses to carry forward	11,110	16,187
Potential deferred tax asset thereon	1,387	2,020
Unutilised German tax losses to carry forward	26	109
Potential deferred tax asset thereon	4	16
Unutilised UK tax losses to carry forward	20,114	34,320
Potential deferred tax asset thereon	3,419	5,637
<b>Total potential deferred tax asset</b>	<b>4,810</b>	<b>7,673</b>

The current asset of £1.5 million at 31 December 2018 (2017: £Nil) relates to the anticipated R&D tax credit claim in respect of the 2018 financial year.

### 13. Property, plant and equipment

Group	2018 £000	2017 £000
<b>Cost</b>		
1 January	29	29
Additions	—	—
31 December	29	29
<b>Accumulated depreciation</b>		
1 January	16	10
Charge for the period	5	6
31 December	21	16
<b>Net book value</b>	<b>8</b>	<b>13</b>

The Company had no property, plant and equipment (2017: £Nil).

### 14. Intangible assets

Group	Patents and trademarks £000	Feraccru® development costs £000	Phosphate Therapeutics licences £000	Total £000
<b>Cost</b>				
Balance at 1 January 2017	1,440	2,639	27,047	31,126
Additions – externally purchased	235	—	—	235
Additions – internally developed	—	3,173	—	3,173
Balance at 31 December 2017	1,675	5,812	27,047	34,534
Additions – externally purchased	346	—	—	346
Additions – internally developed	—	2,999	—	2,999
<b>Balance at 31 December 2018</b>	<b>2,021</b>	<b>8,811</b>	<b>27,047</b>	<b>37,879</b>
<b>Accumulated amortisation</b>				
Balance at 1 January 2017	325	115	1,702	2,142
Charge for the period	92	327	2,012	2,431
Balance at 31 December 2017	417	442	3,714	4,573
Charge for the period	71	427	1,851	2,349
<b>Balance at 31 December 2018</b>	<b>488</b>	<b>869</b>	<b>5,565</b>	<b>6,922</b>
<b>Net book value</b>				
<b>31 December 2018</b>	<b>1,533</b>	<b>7,942</b>	<b>21,482</b>	<b>30,957</b>
31 December 2017	1,258	5,370	23,333	29,961



#### 14. Intangible assets continued

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

##### Feraccru®

- The value in use has been calculated based on out-licensing income which expires in 2035, being the current patent life of the asset.
- Anticipated sales are based on a third party assessment provided to the Company.
- A discount factor of 15% in Europe, reflecting the Marketing Authorisation already obtained for the drug and commercial progress to date, and 20% in the US, reflecting the higher perceived risks of commercialisation pre-FDA approval.

##### Phosphate Therapeutics Limited

- The value in use has been calculated based on out-licensing income which expires in 2029, being the current patent life of the asset.
- Anticipated sales are based on a third party assessment provided to the Company.
- A discount factor of 15%, reflecting the inherent uncertainty attached to obtaining Marketing Authorisation for the drug and an anticipated out-licensing business model.

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

	2018 £000	2017 £000
Feraccru®	9,475	6,628
Phosphate Therapeutics Limited	21,482	23,333
	<b>30,957</b>	29,961

Management has identified that if the discount rate was changed as follows this would result in the recoverable amount in respect of the assets reducing so as to equal their carrying amount.

	Feraccru® Europe	Feraccru® US	Phosphate Therapeutics Limited
Discount rate	58%	300%	25%

The Company has no intangible assets (2017: £Nil).

#### 15. Investments

Company	2018 £000	2017 £000
<b>Cost</b>		
1 January	163,380	162,968
Additions	717	1,912
Disposals	—	(1,500)
31 December	<b>164,097</b>	163,380
<b>Accumulated impairment</b>		
1 January and 31 December	<b>(60,400)</b>	(60,400)
<b>Net book value</b>		
31 December	<b>103,697</b>	102,980
1 January	<b>102,980</b>	102,568

Additions and disposals of £1.5 million in the prior year relate to the incorporation and dissolution of Snow Jersey Limited (see notes below).

Other additions of £0.7 million (2017: £0.4 million) relate to investments during the year arising due to share-based payments costs in respect of Group share-based payments arrangements.

## Notes (forming part of the financial statements) continued

for the year ended 31 December

### 15. Investments continued

The Group's equity interests were as follows:

#### At 31 December 2018 and 31 December 2017

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

Snow Jersey Limited, a company registered in Jersey and held 100% directly by the Company, was incorporated on 2 June 2017 and dissolved on 3 August 2017, as part of a cash box structure used to facilitate the placing undertaken during the prior year (see Note 22).

The registered office address of Shield Therapeutics (DE) GmbH is c/o Lambsdorff Rechtsanwälte PartGmbH, 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 at 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 value in use has been calculated based on out-licensing income which expires in 2035, being the current patent life of the asset.
- Anticipated sales are based on a third party assessment provided to the Company.
- A discount factor of 15% in Europe, reflecting the Marketing Authorisation already obtained for the drug and commercial progress to date, and 20% in the US, reflecting the higher perceived risks of commercialisation pre-FDA approval.

#### Phosphate Therapeutics Limited

- The value in use has been calculated based on out-licensing income which expires in 2029, being the current patent life of the asset.
- Anticipated sales are based on a third party assessment provided to the Company.
- A discount factor of 15%, reflecting the inherent uncertainty attached to obtaining Marketing Authorisation for the drug and an anticipated out-licensing business model.

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

	2018 £000	2017 £000
Shield TX (Switzerland) AG	76,933	76,216
Phosphate Therapeutics Limited	26,764	26,764
	<b>103,697</b>	102,980

Management has identified that if the discount rate was changed as follows this would result in the recoverable amount in respect of the assets reducing so as to equal their carrying amount.

	Shield TX (Switzerland) AG – European market	Shield TX (Switzerland) AG – US market	Phosphate Therapeutics Limited
Discount rate	37%	100%	20%



## 16. Inventories

Group	2018 £000	2017 £000
Raw materials	34	105
Finished goods	75	20
	<b>109</b>	125

The cost of inventories recognised as an expense and included in cost of sales was £161,000 (2017: £81,000). Cost of sales includes royalties payable to Vitra Pharmaceuticals Limited.

The Company had no inventories (2017: £Nil).

## 17. Trade and other receivables

	Group		Company	
	2018 £000	2017 £000	2018 £000	2017 £000
Trade receivables	256	51	—	—
Other receivables	206	478	58	39
Prepayments	569	1,043	14	21
Amounts due from Group undertakings	—	—	35,752	33,766
	<b>1,031</b>	1,572	<b>35,824</b>	33,826

At the year end no trade receivables were past due or impaired (2017: £Nil).

## 18. Cash and cash equivalents

	Group		Company	
	2018 £000	2017 £000	2018 £000	2017 £000
Cash at bank and in hand	9,776	13,299	9,003	11,807

## 19. Trade and other payables

	Group		Company	
	2018 £000	2017 £000	2018 £000	2017 £000
Trade payables	22	1,802	—	87
Accruals	2,526	1,699	685	214
	<b>2,548</b>	3,501	<b>685</b>	301

## 20. Other liabilities

	Group		Company	
	2018 £000	2017 £000	2018 £000	2017 £000
Taxation and social security	202	227	—	—
Other payables	201	35	81	—
	<b>403</b>	262	<b>81</b>	—

## 21. Risk management

The Group is exposed to a variety of risks such as market risk, credit risk, foreign currency risk and liquidity risk. The Group's principal financial instruments are:

- Financial liabilities measured at amortised cost; and
- Trade and other receivables, trade and other payables, and cash and short term deposits arising directly from operations.

This note provides further detail on financial risk management and includes quantitative information on the specific risks.



## Notes (forming part of the financial statements) continued

for the year ended 31 December

### 21. Risk management continued

#### Fair values

The carrying values of financial assets and liabilities reasonably approximate their fair values.

#### Market risk

Market risk is the risk that the fair value of future cash flows of a financial instrument will fluctuate because of changes in market prices. Market risk comprises three types of risk: interest rate risk, currency risk and credit risk.

The Group's exposure is currently primarily to the financial risk of changes in foreign currency exchange.

#### Sensitivity analysis

The Group recognises that movements in certain risk variables (such as foreign exchange rates) might affect the value of its loans and also the amounts recorded in its equity and its profit and loss for the period. Therefore the Group assessed the following risks:

#### Foreign currency risk

The following tables consider the impact of several changes to the spot £/Euro and £/USD exchange rates of +/-5%. If these changes were to occur the tables below reflect the impact on loss before tax. Only the impact of changes in Euro and US Dollar denominated balances have been considered as these are the most significant non-GBP denominations used by the Group.

		Effect on loss before tax	
		Year ended	Year ended
		31 December	31 December
		2018	2017
		£000	£000
EUR	Change in GBP vs. EUR rate		
	+5.00%	(214)	(437)
USD	+5.00%	(108)	(197)
	-5.00%	108	197

		Effect on equity	
		Year ended	Year ended
		31 December	31 December
		2018	2017
		£000	£000
EUR	Change in GBP vs. EUR rate		
	+5.00%	(214)	(442)
USD	+5.00%	(108)	(197)
	-5.00%	108	197

#### Liquidity risk

Cash flow is regularly monitored and the relevant subsidiaries are aware of their working capital commitments. The Group reviews its long term funding requirements in parallel with its long term strategy, with an objective of aligning both in a timely manner.

The table below summarises the maturity profile of the Group's undiscounted financial liabilities at 31 December 2018 and 2017.

	On demand £000	Less than one year £000	Between two and five years £000	More than five years £000	Total £000
<b>Liquidity risk – 31 December 2018</b>					
<b>Financial liabilities</b>					
Trade and other payables	–	–	–	–	–
<b>Liquidity risk – 31 December 2017</b>					
<b>Financial liabilities</b>					
Trade and other payables	–	1,802	–	–	1,802



## 21. Risk management continued

### Liquidity risk continued

The table below summarises the maturity profile of the Company's undiscounted financial liabilities at 31 December 2018 and 31 December 2017.

	On demand £000	Less than one year £000	Between two and five years £000	More than five years £000	Total £000
<b>Liquidity risk – 31 December 2018</b>					
Financial liabilities					
Trade and other payables	–	–	–	–	–
<b>Liquidity risk – 31 December 2017</b>					
Financial liabilities					
Trade and other payables	–	87	–	–	87

### Credit risk

Credit risk is the risk that a counterparty will not meet its obligations under a financial instrument leading to a financial loss. The Group is primarily exposed to credit risk from its financing activities in relation to its deposits with banks and financial institutions. There is considered to be no material credit risk associated with receivables. The Group's maximum exposure is shown at Note 17.

Credit risk from balances with banks and financial institutions is managed by depositing with reputable financial institutions, from which management believes the risk of loss to be remote. The Group's maximum exposure to credit risk for the components of the statement of financial position is the carrying amounts of cash at bank and in hand.

## 22. Share capital

	2018 Number 000	£000	2017 Number 000	£000
At 1 January	116,426	1,746	108,135	1,622
Exercise of Warrants	–	–	7,194	108
Issuance of shares pursuant to placing	–	–	1,000	15
Issuance of shares pursuant to subscription	–	–	97	1
<b>At 31 December</b>	<b>116,426</b>	<b>1,746</b>	<b>116,426</b>	<b>1,746</b>

### Fundraising

During the prior year the Company raised gross proceeds of £12.4 million through the combination of an exercise of Warrants, institutional placing and subscription for shares. Details of these transactions are provided below.

#### Exercise of Warrants

As part of the listing process 11,666,658 Warrants were issued to participants in the placing, which traded under the ticker STXW. The Warrants were scheduled to expire at 30 June 2017.

During June 2017 7,193,766 Warrants were exercised at a strike price of £1.50, raising gross proceeds of £10.8 million. The remaining 4,472,892 Warrants lapsed at 30 June 2017.

#### Placing

On 28 June 2017 the Company issued an additional 1,000,000 Ordinary Shares to participants in a placing, raising gross proceeds of £1.5 million. The placing was undertaken by means of a cash box structure. Consequently relief was available under s612 of the Companies Act 2006 from recording share premium and the difference between net proceeds and the nominal value of shares issued was transferred to retained earnings.

#### Subscription

On 28 June 2017 the Company's Directors and senior management subscribed to an issue of 96,669 Ordinary Shares, raising gross proceeds of £145,000.

Expenses of £0.5 million were incurred in the course of the exercise of Warrants, placing and subscription.



## Notes (forming part of the financial statements) continued

for the year ended 31 December

### 23. 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.

### 24. Share-based payments

The Group grants rights to the parent entity's equity instruments to certain employees, which are accounted for as equity-settled or cash-settled in the consolidated financial statements.

#### Long Term Incentive Plan (LTIP)

The Group operates a share option scheme for the Executive Directors of the Company and the Group's senior management team. The scheme is intended to attract, retain and incentivise participants, whilst encouraging higher standards of performance and aligning the objectives of the senior management team with those of shareholders. The plan was established in February 2016 as part of the IPO process.

The total expense recognised for share-based payments, in relation to the LTIP, in the Group's financial statements during the year was £540,000 (2017: £541,000).

The terms and conditions of grants are as follows:

Grant date	Method of settlement accounting	Number of instruments	Vesting date	Contractual life of options	Remaining contractual life of options
March 2016	Equity	1,773,581	February 2019	February 2026	8 years
July 2016	Equity	80,000	July 2019	July 2026	8 years
September 2016	Equity	253,144	September 2019	February 2026	8 years
July 2017	Equity	1,683,877	July 2020	July 2027	9 years

The vesting of awards under the LTIP is conditional on the achievement of a performance target, based on the Compound Annual Growth Rate (CAGR) in the Company's share price. CAGR is measured against the target based on the increase in the price from the first day of the year to the last day of the year over each discrete year in the performance period.

The March 2016 and September 2016 awards vest as follows:

- One-third on 25 February 2017, one-third on 25 February 2018 and one-third on 25 February 2019 in the event of a CAGR of 11.7% in the Company's share price.

The July 2016 awards vest as follows:

- One-third on 25 July 2017, one-third on 25 July 2018 and one-third on 25 July 2019 in the event of a CAGR of 11.7% in the Company's share price.

The July 2017 awards vest as follows:

- One-third on 31 December 2017, one-third on 31 December 2018 and one-third on 31 December 2019 in the event of a CAGR in the Company's share price of at least 9.6%. A growth of 9.6% results in a minimum entitlement for each participant. The percentage growth triggering maximum entitlement varies by participant, but in no case exceeds 19.6%.



## 24. Share-based payments continued

### Long Term Incentive Plan (LTIP) continued

The number of share options are as follows:

	Number of options	
	Year ended 31 December 2018	Year ended 31 December 2017
Outstanding at the beginning of the year	1,594,575	1,523,393
Granted during the year	—	1,683,877
Forfeited/lapsed during the year	(967,549)	(1,612,695)
Outstanding at the end of the year	627,026	1,594,575
Exercisable at the end of the year	—	—

The fair value of services received in return for share options granted is measured by reference to the fair value of share options granted. The fair value of the services received is measured using a Monte Carlo valuation model. Measurement inputs and assumptions are as follows:

	July 2017	March 2016	July 2016	September 2016
Weighted average share price	£0.69	£0.79	£0.75	£0.60
Exercise price	£0.015	£0.015	£0.015	£0.015
Expected volatility	44%	44%	43%	44%
Expected option life	3 years	3 years	3 years	3 years
Expected dividends	Nil	Nil	Nil	Nil
Risk-free interest rate (based on UK government bonds)	0.37%	0.6%	0.17%	0.16%
Fair value at measurement date	£0.69	£0.79	£0.75	£0.60

The expected volatility is based on the historical volatility of quoted companies in a similar market environment.

The exercise of share options is conditional on a CAGR in the Company's share price as illustrated above.

### Company Share Option Plan (CSOP)

The Group operates a share option scheme which is able to issue both HMRC-approved and unapproved options to employees of the Group. The scheme is intended to attract, retain and incentivise participants, whilst encouraging higher standards of performance and aligning the objectives of employees with those of shareholders. The plan was established in February 2016 as part of the IPO process.

The total expense recognised for share-based payments, in relation to the CSOP, in the Group's financial statements during the year was £21,000 (2017: £19,000).

The terms and conditions of grants are as follows:

Grant date	Method of settlement accounting	Number of instruments	Vesting date	Contractual life of options	Remaining contractual life of options
July 2017	Equity	288,610	July 2020	July 2027	9 years
May 2018	Equity	600,000	May 2021	May 2028	10 years
October 2018	Equity	67,164	October 2021	October 2028	10 years

Of the 288,610 share options issued to CSOP participants in July 2017, 60,034 were issued to participants in the LTIP scheme and 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. 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.

## Notes (forming part of the financial statements) continued

for the year ended 31 December

### 24. Share-based payments continued

#### Company Share Option Plan (CSOP) continued

The number of share options is as follows:

	Number of options	
	Year ended 31 December 2018	Year ended 31 December 2017
Outstanding at the beginning of the year	171,658	–
Granted during the year	667,164	288,610
Forfeited/lapsed during the year	(280,690)	(116,952)
Outstanding at the end of the year	558,132	171,658
Exercisable at the end of the year	–	–

The fair value of services received in return for share options granted is measured by reference to the fair value of share options granted. The fair value of the services received is measured using a Black Scholes valuation model. Measurement inputs and assumptions are as follows:

	October 2018	May 2018	July 2017
Weighted average share price	£0.09	£0.09	£0.47
Exercise price	£0.255	£0.255	£1.575
Expected volatility	51%	51%	44%
Expected option life	3 years	3 years	3 years
Expected dividends	Nil	Nil	Nil
Risk-free interest rate (based on UK government bonds)	0.86%	0.86%	0.04%
Fair value at measurement date	£0.09	£0.09	£0.47

The expected volatility is based on the historical volatility of quoted companies in a similar market environment.

#### Retention Share Plan (RSP)

The Group operates a share option scheme for the Executive Directors of the Company and the Group's senior management team. The scheme is intended to attract, retain and incentivise participants, whilst encouraging higher standards of performance and aligning the objectives of the senior management team with those of shareholders.

The total expense recognised for share-based payments, in relation to the RSP, in the Group's financial statements during the year was £161,000 (2017: £Nil). There are no vesting conditions associated with the awards other than continued employment with the Group at the vesting date.

The terms and conditions of grants are as follows:

Grant date	Method of settlement accounting	Number of instruments	Vesting date	Contractual life of options	Remaining contractual life of options
January 2018	Equity	99,286	December 2018	January 2028	9 years
January 2018	Equity	152,490	December 2019	January 2028	9 years

The number of share options are as follows:

	Number of options	
	Year ended 31 December 2018	Year ended 31 December 2017
Outstanding at the beginning of the year	–	–
Granted during the year	251,776	–
Forfeited/lapsed during the year	(90,123)	–
Outstanding at the end of the year	161,653	–
Exercisable at the end of the year	99,286	–





## 24. Share-based payments continued

### Retention Share Plan (RSP) continued

The fair value of services received in return for share options granted is measured by reference to the fair value of share options granted. The fair value of the services received is measured using a Black Scholes valuation model. Measurement inputs and assumptions are as follows:

	January 2018	January 2017
Weighted average share price	£1.13	£1.11
Exercise price	£0.015	£0.015
Expected volatility	40%	44%
Expected option life	1 year	2 years
Expected dividends	Nil	Nil
Risk-free interest rate (based on UK government bonds)	0.5%	0.5%
Fair value at measurement date	£1.13	£1.11

The expected volatility is based on the historical volatility of quoted companies in a similar market environment.

### Retention and Performance Share Plan (RPSP)

The Group operates a share option scheme for the Executive Directors of the Company and the Group's senior management team and staff. The scheme is intended to attract, retain and incentivise participants, whilst encouraging higher standards of performance and aligning the objectives of the senior management team with those of shareholders.

The total expense recognised for share-based payments, in relation to the RPSP, in the Group's financial statements during the year was £291,000 (2017: £Nil).

The terms and conditions of grants are as follows:

Grant date	Method of settlement accounting	Number of instruments	Vesting conditions	Vesting date	Contractual life of options	Remaining contractual life of options
May 2018	Equity or cash	846,777	Employment at 31 December 2018. Achievement of four corporate performance conditions.	December 2018	May 2028	9 years
May 2018	Equity	2,692,800	Entitlement is scaled back by 25% for every condition not met. 50% vest based on continued employment at 1 January 2019, 25% based on continued employment at 1 April 2019 and 25% based on continued employment at 1 July 2019.	December 2020	May 2028	9 years
October 2018	Equity	400,000		July 2019	May 2028	9 years

The number of share options are as follows:

	Number of options	
	Year ended 31 December 2018	Year ended 31 December 2017
Outstanding at the beginning of the year	—	—
Granted during the year	3,939,577	—
Forfeited/lapsed during the year	(1,490,111)	—
Exercised during the year	(569,719)	—
Outstanding at the end of the year	1,879,747	—
Exercisable at the end of the year	—	—

## Notes (forming part of the financial statements) continued

for the year ended 31 December

### 24. Share-based payments continued

#### Retention and Performance Share Plan (RPSP) continued

The remaining contractual life of options is one year. The fair value of services received in return for share options granted is measured by reference to the fair value of share options granted. The fair value of the services received is measured using a Monte Carlo valuation model in respect of the May 2018 equity-based award and a Black Scholes model in respect of the October 2018 equity-based award. Measurement inputs and assumptions are as follows:

	October 2018	May 2018
Weighted average share price	£0.32	£0.03
Exercise price	£0.015	£0.015
Expected volatility	42%	51%
Expected option life	1 year	3 years
Expected dividends	Nil	Nil
Risk-free interest rate (based on UK government bonds)	0.86%	0.83%
Fair value at measurement date	£0.32	£0.03

The expected volatility is based on the historical volatility of quoted companies in a similar market environment.

The May 2018 award of 846,777 options was eligible for settlement on either a cash or equity basis and therefore qualified as a compound financial instrument. As the option was structured so that each alternative had the same value the award was valued based on the fair value of the debt element. As the options vested within one year the fair value of the debt was undiscounted.

#### Bonus Share Plan (BSP)

The Group operates a share option scheme for the Executive Directors of the Company and the Group's senior management team. The scheme is intended to defer the cash cost to the Company of senior management bonuses.

The total expense recognised for share-based payments, in relation to the BSP, in the Group's financial statements during the year was £200,000 (2017: £Nil). There are no performance conditions associated with the award.

The terms and conditions of grants are as follows:

Grant date	Method of settlement accounting	Number of instruments	Vesting date	Contractual life of options	Remaining contractual life of options
May 2018	Equity or cash	899,203	May 2019	May 2028	9 years

The number of share options are as follows:

	Number of options	
	Year ended 31 December 2018	Year ended 31 December 2017
Outstanding at the beginning of the year	—	—
Granted during the year	899,203	—
Forfeited/lapsed during the year	(512,876)	—
Outstanding at the end of the year	386,327	—
Exercisable at the end of the year	—	—

The BSP award was eligible for settlement on either a cash or equity basis and therefore qualified as a compound financial instrument. As the option was structured so that each alternative had the same value the award was valued based on the fair value of the debt element. A discount rate of 12% was applied in arriving at the fair value of the debt.



## 25. Capital and leasing commitments

The Group and parent company had no material capital commitments at either the current or prior period end.

The future aggregate minimum lease payments under non-cancellable operating leases are as follows:

	Group		Company	
	2018 £000	2017 £000	2018 £000	2017 £000
Less than one year	150	467	—	—
One to five years	—	—	—	—
More than five years	—	—	—	—
	150	467	—	—

The lease expense in respect of the year was £462,000 (2017: £418,000).

## 26. 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.

	2018 £000	2017 £000
Cash and cash equivalents	9,776	13,299

## 27. Post balance sheet events

None noted.

## Glossary

<b>CHF</b>	Chronic heart failure
<b>CKD</b>	Chronic kidney disease
<b>EU5</b>	Five largest EU markets (France, Germany, Italy, Spain and the UK)
<b>FDA</b>	US Food and Drug Administration
<b>GFR</b>	Glomerular Filtration Rate
<b>H2H</b>	AEGIS-Head-to-Head clinical study
<b>Hb</b>	Haemoglobin
<b>IBD</b>	Inflammatory Bowel Disease
<b>ID</b>	Iron Deficiency
<b>IDA</b>	Iron Deficiency Anaemia
<b>IV</b>	Intravenous
<b>NDA</b>	New Drug Application (US)
<b>PDUFA</b>	Prescription Drug User Fee Act (US)
<b>WHO</b>	World Health Organization



## Advisors

### **Nominated advisor and broker**

Peel Hunt LLP  
120 London Wall  
London  
EC2Y 5ET

### **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



Produced by

**designportfolio**





**SHIELD**  
THERAPEUTICS PLC

Improving Lives Together

**London**

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

t +44 (0)207 186 8500  
e [info@shieldtx.com](mailto: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](mailto:info@shieldtx.com)