shield therapeutics

Shield Therapeutics plc
Annual report and accounts 2022

Our pathway to growth

We deliver innovative specialty pharmaceuticals that address a significant unmet need for patients suffering from iron deficiency, with or without anaemia. Our lead product Accrufer® (ferric maltol) is broadly indicated for use in adults across multiple therapeutics categories.

Investment case

1

Large US defined market

~20 million individuals with anaemia[1]

13.4 million annual oral iron prescriptions (OTC)

2

FDA approved potential best in class solution

Accrufer®, an FDA approved therapy, oral iron solution with minimal (<5%) gastrointestinal adverse reactions* and discontinuations[2]

3

Viatris collaborative sales agreement

Increase Accrufer® adoption and revenues

100-person combined sales team to call on 12,000+ HCPs

4

Unmet need

Conventional irons (OTC) have poor tolerability and high discontinuation rates mainly due to gastrointestinal side effects

5

Experienced team

Senior leadership team has extensive US commercial experience building brands and launching new products

6

Strong resources and significant revenue potential

Recent fundraise of US$35.1 million allows potential to cash flow breakeven by year end 2024

US$2.3 billion market opportunity**

Patent coverage through to mid-2030s

* Adverse reaction based on individual events.
** Market opportunity is an estimate only, prepared by Shield and based on a number of assumptions made by Shield.

1. As estimated by Shield based on a population of c.313 million and the study as set out in Hong Le C, et al. PLoS One. 2016;11(11): e0166635.
2. Accrufer® (ferric maltol) Prescribing Information. Austin, TX: Shield Therapeutics, 2019. Revised 02/22.

Financial highlights

- Revenue of £4.5 million (2021: £1.5 million)
- Loss for the year of £40.4 million (2021: £19.7 million) after impairment loss of £14.7 million (2021: nil)
- Net cash at year end of £2.8 million (2021: £12.1 million)
- New convertible shareholder loan for £8.2 million (or US$10.0 million)

Group revenue

£4.5m

(2021: £1.5m)

Operating loss before impairment and R&D expenditure

£24.6m

(2021: £19.5m)

Cash and short-term deposits at year end

£2.8m

(2021: £12.1m)

Operational highlights

- Collaborative sales agreement with Viatris for Accrufer® in the US
- Exclusive licence agreement with KYE Pharmaceuticals and submission of NDS in Canada
- Regulatory pathway and timelines for Accrufer® approval in Republic of Korea
- Launch of new corporate brand and website
- Extension of shelf-life of Accrufer® to 48 months

Post-period highlights

- Equity placing and open offer for £16.4 million, equal to US$20.1 million (net)
- Amendment to convertible shareholder loan providing an additional £8.2 million (or US$10.0 million)
- Fully funded to support operations through to expected cash flow break even by end of 2024

→ **For more information on our business and all our latest news and press releases, visit us at: www.shieldtherapeutics.com. Follow Shield on Twitter @ShieldTx**

Delivering innovation to address significant unmet needs in the treatment of iron deficiency, with or without anaemia

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

Shield's proprietary lead product, Accrufer®/Feraccru®, has been approved for use in the US, the EU, the UK, Australia and Switzerland. The product has patent coverage until the mid-2030s. The Group launched Accrufer® in the US with an exclusive, multi-year collaboration agreement with Viatris Inc. Feraccru® is commercialised in the UK and European Union by Norgine B.V., that also have the marketing rights in Australia and New Zealand. Shield also has an exclusive licence agreement with Beijing Aosaikang Pharmaceutical Co., Ltd., for the development and commercialisation of Accrufer®/Feraccru® in China, Hong Kong, Macau and Taiwan, with Korea Pharma Co., Ltd. for the Republic of Korea, and with KYE Pharmaceuticals Inc. for Canada.

Corporate history and milestones

2023

2023
Completion of US$20m (£16m) equity raise

Amendment of convertible shareholder loan to increase balance to US$20m

2022
Licence Agreement in Canada for Accrufer® with KYE Pharmaceuticals

Execution of convertible shareholder loan of US$10m from AOP Health

Execution of Collaborative Sales Agreement for Accrufer® in US with Viatris

2021
Completion of US$38m (£27m) equity raise

US Launch of Accrufer®

2020
Licence Agreement in China for Feraccru® with ASK Pharma

Licence Agreement in Korea for Accrufer® with Korea Pharma

2019
FDA approves Accrufer® for treatment of iron deficiency in adults

2018
Licence Agreement in Europe, Australia and New Zealand for Feraccru® with Norgine

Completion of Phase III study in CKD (US NDA enabling)

2016
Issuance of marketing authorisation for Feraccru® by EMA

Admission to London Stock Exchange's AIM Market

2013
Completion of Phase III study in IBD (EU MAA-enabling)

2011
VC funding with investment from W Health (Inventages)

2010
Commitment by first corporate investor (AOP Health)

Acquisition of ST10 asset from Vitra Pharma

2008
Shield Therapeutics Limited formed and registered in the UK

2008

Strategic collaboration announced with Viatris Inc.

Shield Therapeutics and Viatris sign Collaborative Sales Agreement for Accrufer® in the United States (December 2022)

Key terms of agreement include:

- Upfront payment: Shield will receive a US$5 million one-time payment
- Milestone payments: Viatris will pay Shield a series of sales milestones up to a total of US$30 million, linked to annual net sales ranging from US$100 million to US$250 million
- Revenue split and marketing costs: Shield and Viatris will share revenues and marketing expenses following an agreed upon split between them, with Shield retaining a slightly higher percentage of each. Companies will pay for their own respective sales force and related selling costs

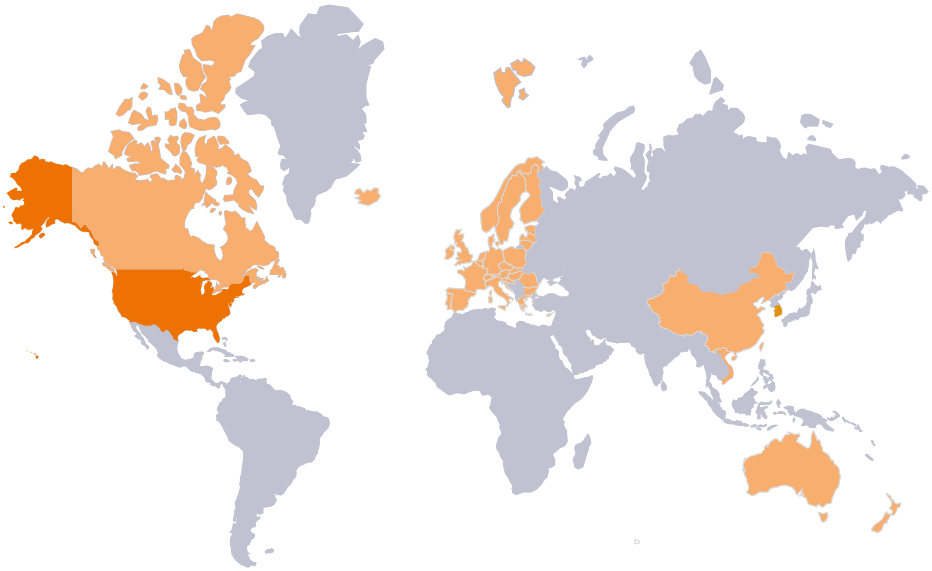
"We are excited that through our Global Healthcare Gateway® we have become the Partner of Choice® for Shield to support the commercialisation of Accrufer® in the US and thus expand access to those living with iron deficiency. This collaboration is a great opportunity to leverage our commercial capabilities while furthering Viatris' mission to empower people worldwide to live healthier at every stage of life."

Jose Cotarelo
Head of North America, Viatris

→ Read more on pages 4 and 5

Global partnerships continue to progress

Deals include upfronts, milestones and double-digit royalties



United States	EU & other	Canada	Republic of Korea	China & other
Co-commercial agreement, Dec 2022	Call points re-focused to women's health/GPs	Approval expected mid-2023	Final regulatory study underway	Enrolling Phase 3

Significant progress has been made during 2022, transforming the Group

Hans Peter Hasler
Chairman

Greg Madison
Chief Executive Officer

We have made tremendous progress as an organisation and 2022 was an important and transformational year for our Company across many different areas. We have secured an important co-commercialisation agreement with Viatris, which dramatically expands the commercial resources for our product Accrufer® in the US. With a much larger field sales organisation (100 dedicated sales people collectively vs 30-person contract sales team in 2022), plus additional resources on the marketing and payer/reimbursement side, we believe this represents a significant growth opportunity for Accrufer® prescriptions and revenues. In addition, we completed a financing of the Company at year end 2022, providing the necessary financial capital to expand our operations in conjunction with the Viatris agreement, and, based on our financial models, allowing us to potentially reach cash flow break-even by year end 2024. It was a challenging year for the financial markets, and we were very pleased to have these transactions concluded at the end of the year. Following these events, 2023 becomes a year of execution across a number of key areas, first and foremost the expansion of our field teams, which we expect to conclude by 1 May 2023.

We believe the activities and foundation created in 2022 set us up for a strong 2023 and beyond.

United States

There were 25,200 prescriptions written for Accrufer® (ferric maltol) in the US during 2022, with significant growth seen every single quarter throughout the year. Our efforts to increase awareness leading to first time prescribers of Accrufer® accelerated during the year, thanks to the efforts of our field-based team of approximately 25 people. In the fourth quarter alone, we generated just under 9,400 prescriptions of Accrufer® with just a 22-person field-based team, and the 9,400 represented about 37% of our total 2022 prescriptions, setting us up with positive momentum in 2023. On the payer side, we continued to expand our payer coverage, ending up at 100 million lives that were covered by their health plans for Accrufer®, representing approximately 40% of all available lives.

Iron deficiency, with or without anaemia, continues to be a prevalent issue in the US, with over 13 million prescriptions of oral iron written every year, the vast majority over the counter (OTC) iron. Physicians and patients alike routinely comment on the challenges associated with these irons, namely around poor effectiveness driven by tolerability, discontinuations and lack of efficacy. As a result, health care providers (HCPs) have relatively unfavourable impressions of oral irons. As the only FDA approved oral iron to treat iron deficiency regardless of the aetiology, we are in a unique and competitive position to change the way physicians think about oral iron.

Throughout the year, we stated that while we were happy with the progress we had made with our small team, we needed to scale up our business in order to maximise the opportunity for Accrufer®. The key areas we identified were: 1) larger field sales team; 2) increase our marketing strategy, with focus on digital marketing; and 3) expand patient access and payer coverage. We evaluated several options and determined that the optimal pathway for Shield to accomplish this goal would be to find a strong partner in the US to co-commercialise and promote Accrufer®. After a detailed and extensive process, we identified Viatris as an ideal partner.

In December, we signed a multi-year, exclusive co-commercialisation agreement with Viatris, which will dramatically expand the commercial resources for Accrufer®. We believe this collaboration will result in an acceleration of awareness, prescriptions and revenues which can potentially allow Shield to be cash flow positive by the end of 2024. This agreement increases the amount of field sales representatives from 22 in Q4 2022 to 100 by 1 May 2023. This increases the number of HCPs the collective team can call on, from approximately 3,300 in 2022 to over 12,000 in 2023 once these new sales representatives are fully trained and in the field. We should also see a benefit from smaller geographies resulting in increased opportunities for our field sales team to engage with HCPs. Importantly, Accrufer® will be the only product promoted by this combined sales force, resulting in 100% of its focus and effort.

Shield and Viatris, through a shared budget model, can also deepen our resources in critical areas such as digital marketing, direct to consumer and payer access. Viatris has a full and dedicated team speaking with payers on an everyday basis, and it will be involved in our goal to further expand our patient access.

The partnership with Viatris is off to a great start. We have already begun the work on the sales force expansion and expect to have our full team of 100 sales representatives hired and trained by 1 May 2023. As this new team begins calling on its high volume HCPs, we firmly believe that we will start seeing the effects of its efforts during the second half of 2023.

> "The work done sets the Company up for both short- and long-term success."

Company culture

Our people in the organisation are a source of pride. We have put together an outstanding team of individuals that are focused on achieving our goals and our mission "to improve lives together".

Empowerment

We develop an open and trusting environment that requires accountability and responsibility at all levels.

Will to succeed

Results oriented environment that values resilience in overcoming challenges. Encourage a "learning culture" that celebrates success and learns from failures.

Collaboration

Our success is driven by teamwork, trust, transparency and our ability to work together to find the optimal solutions.

Agility

While moving with a clear purpose, we want to prepare for the unexpected and adapt quickly to change and the changing environment.

Chairman and Chief Executive Officer's joint statement continued

> "There were 25,200 prescriptions written for Accrufer® in the US during 2022 with significant growth seen."

Europe/Australia

Norgine, our partner with responsibility for Europe and Australia, saw 10% growth in Feraccru® volume during 2022. Germany now represents approximately 59% of the total unit sales of Feraccru® for Norgine. There remains a significant opportunity for Feraccru® in key markets such as Germany and the UK; however, there is work to be done in order to maximise the value. The area of opportunity lies in women's health. OB/GYN clinicians are consistently high prescribers of oral iron products for their patients with iron deficiency. We will continue to work with Norgine in helping shift its focus to this important customer segment.

Global partnerships and development

We also saw continued progress working with our external partners across the globe to bring ferric maltol to patients with iron deficiency in new markets. In Canada, our partner KYE Pharmaceuticals filed for regulatory approval with Health Canada in 2022, and we expect full approval in the second half of 2023. ASK Pharma, our partner in China, continues to enrol patients in the Phase 3 clinical study. COVID-19 has continued to plague many parts of China, and has had a significant impact on enrolment for this study, pushing back the expected timeline for completion. Lastly, our partner in the Republic of Korea, Korea Pharma, gained clarity and feedback from authorities on the regulatory and clinical pathway to gain approval for ferric maltol. A single pharmacokinetic (PK) study will be required for submission of an NDA, and that study will begin in 2023.

Separately, our paediatric study, a requirement of both the EMA and FDA, continues to enrol patients. This study has patients ranging from 12 months to 17 years of age, and if successful, would pave the way for an expansion of the approved label, opening up another potential patient population for ferric maltol.

One last important achievement in 2022 was the approval by the FDA of our extension to our product shelf life for Accrufer® from 36 to 48 months. This extension provides us with tremendous flexibility within our supply chain.

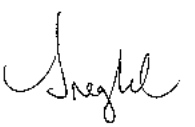
Our people and culture

Our teams across the Group have made outstanding contributions to the Company's progress during the year. We operate with a small yet highly skilled and dedicated group of people here at Shield, who are passionate about the opportunity to change the way iron deficiency, with or without anaemia, is treated. We have been able to recruit and hire a highly talented team, which embodies the values here at Shield – collaboration, agility, will to succeed and empowerment. We are excited to add over 50 new full-time employees here at Shield as part of our commercial expansion, and we are focused on providing all of the necessary resources to continue their development and investing in their futures.

Outlook

With the progress made in 2022, we are very optimistic about our outlook in 2023 and beyond. Early in the year, there will be tremendous focus on scaling up our organisation, particularly with recruiting, hiring and training our newly expanded field sales team, which we expect to complete by 1 May 2023. We believe the newly expanded commercial organisation and resources have the potential to dramatically increase our awareness, level of prescriptions and revenues as the team hits its stride in the second half of 2023. With financing and commercial resources in place, we are very confident and excited about the immediate and long-term opportunities for the Group.

Hans Peter Hasler
Chairman
5 May 2023



Greg Madison
Chief Executive Officer
5 May 2023

"I enjoy the commercial challenge of launching new brands, while also focusing on building and transforming the organisation as we look ahead."

Q&A

With Greg Madison
Chief Executive Officer

Q. How do you feel about Shield's achievements – both strategically and operationally – over the course of last year?

A. I am very proud of the progress that we made during 2022. It starts with a smart, driven, passionate and collaborative team and we have that and then some here at Shield. We are not large and ask a lot of our people, and they define a "high performance team". We did a lot of "fixing" commercially at the end of 2021 going into 2022, and the new leadership team really delivered with strong growth quarter over quarter despite being limited on the budget side. Now, with Viatris as a strong partner on our side, along with the new funding, we are in a position to accelerate the launch of our product Accrufer(R) in a much more robust way. There is a lot more work to done, but our team is ready to take it on.

Q. How would you describe your experience so far with Viatris, Shield's new co-promote partner in the US?

A. Our experience thus far with Viatris has been excellent, and we feel very good about having it as our partner for co-commercialisation of Accrufer® in the US. From the early stages of discussion, we were very aligned on the opportunity for Accrufer® to disrupt the oral iron market for patients with iron deficiency, with or without anaemia. We have a shared view of the market, the strategic imperatives and the key levers for success which makes running the business a cohesive task. On the intangible side, I'm very impressed with the level of communication, collaboration and sharing of ideas that I've seen at all levels of the organisation. At a recent training programme, one couldn't tell apart the sales teams from Shield and the sales teams from Viatris as we approach our Accrufer® business from a joint perspective. I'm confident we have the right partner.

Q. What are your plans for the Company for the next year and beyond?

A. The first step is to scale up our business in support of the recently signed co-commercialisation deal with Viatris. We started the year by hiring 16 sales representatives from our 22-person contract sales team into Shield in January, and we need to recruit, hire and train 34 additional sales people along with 4 Regional Sales Managers and have them all hired and trained by 1 May 2023. While it may not sound like a lot, it's a big lift and we need to ensure we have the right people and support systems in place to become a business with over 80 employees and larger field presence. Next year is all about execution and performance, especially as the new team gets up and running in the second half of 2023, and that goes for both Shield and our new partner in the US. Outside of the US, it's supporting our global partners in their launch (Canada) or ensuring the clinical studies that can lead to approval be done as efficiently as possible (China, Korea). Lastly, we will continue working with Norgine to identify ways to increase performance and adoption of Feraccru® in key markets.

→ **Read more on pages 8 and 9**

The US Accrufer® opportunity; To become the oral iron treatment of choice

The iron deficiency, with or without anaemia market, is large and well-defined as described elsewhere. Most of this market is flooded with oral ferrous salt products that comprise 90% of the prescriptions written for this condition in the US. The conventional or traditional oral iron salt, mostly ferrous-based, products are known for their poor adherence and tolerability mostly based on the gastrointestinal adverse effects.

These ferrous salts dissociate prior to intestinal uptake and the inefficient absorption of iron results in residual free iron in the gastrointestinal tract causing a high level of adverse events to oral iron treatments. These gastrointestinal adverse effects and lack of tolerability of the conventional or traditional iron products, creates an unsatisfactory cycle of switches and discontinuations that ranges from 40-60%.

Accrufer® (ferric maltol) is a novel formulation of oral iron designed to treat iron deficiency with minimal gastrointestinal adverse reactions, as demonstrated during clinical trials. Additionally, Accrufer® was well tolerated with a less than 5% discontinuation rate. Therefore, Accrufer® has the potential to play a major role in this undertreated high-growth iron deficiency market.

Iron deficiency prevalence in the US

In the US, ~20 million patients are at risk of iron deficiency, with or without anaemia, across multiple therapeutic areas. These include:

Women's health

One in five US women of childbearing age are at risk of iron deficiency, with many experiencing heavy uterine or post-partum bleeding.

Gastrointestinal disorders

Iron deficiency affects up to three-quarters of patients with inflammatory bowel disease (IBD).

Chronic kidney disease (CKD)

There are 37 million CKD patients (dialysis and non-dialysis) in the US. Around 50% of these patients are at risk, while roughly 2.5 million patients have Stage 3 or Stage 4 CKD with iron deficiency anaemia.

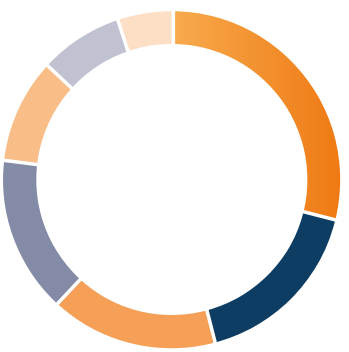
Oncology

Between 32–60% of cancer patients are at risk; those with solid tumours and haematological malignancies are particularly susceptible.

Cardiology

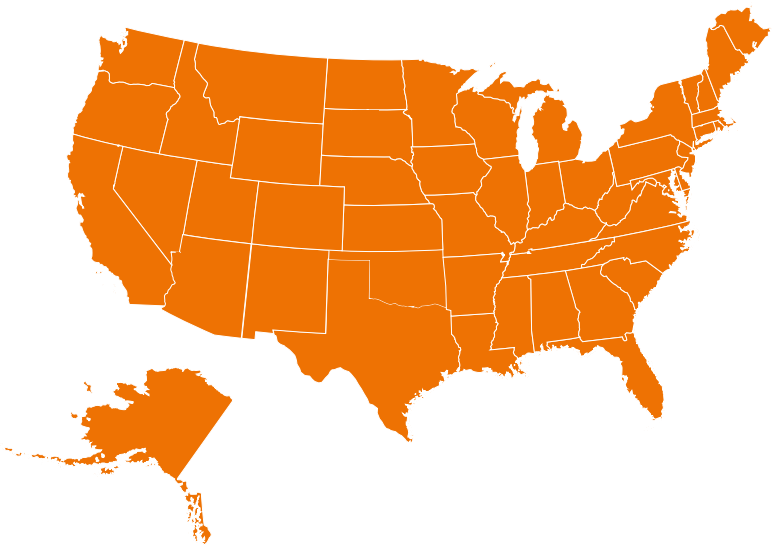
Iron deficiency may also affect around 17% of Chronic Heart Failure (CHF) patients.

Iron Deficiency Anaemia – Addressable Market by Therapeutic Area



Sources: Global Data, European Medical Journal, Daiichi Sankyo annual report, LEK Consulting, CDC, EVOLUTION research and assumptions.

A market ripe for disruption



> We believe Accrufer® has the potential to be the oral iron treatment of choice for patients with ID/IDA. Over the last year, we set out to substantially increase product adoption, sales growth, physician awareness and generate positive clinical experience and expand payer coverage."

Greg Madison
CEO of Shield Therapeutics

Patients with anaemia (actively diagnosed and treated)

~20m

US market opportunity for iron deficiency

US$2.3bn

Prescriptions per year (majority OTC iron)

13.4m

Patent protection in US until

mid-2030s

Accrufer®/Feraccru® (ferric maltol) Effective and well tolerated

Accrufer®/Feraccru® is a novel, oral iron replacement therapy for the treatment of iron deficiency, with or without anaemia, and addresses a significant need for patients, namely tolerability. Accrufer®/Feraccru® is broadly indicated for use in adults across multiple therapeutic categories.

Composition and mechanism of action

- Accrufer®/Feraccru® is formulated as a capsule of ferric maltol containing 30mg iron which is taken twice daily.
- Ferric maltol is a tightly bound iron complex which shields the ferric iron and avoids dissociation until it reaches the duodenum where iron is normally absorbed.
- Ferric maltol avoids dissociation in the stomach, and allows it to be well tolerated as shown in our clinical trials, with individual adverse reactions <5%.
- Unabsorbed ferric maltol passes through the digestive system as an unaltered complex and is excreted.

Accrufer®/Feraccru® offers an efficacious and well tolerated oral iron replacement therapy option for the treatment of iron deficiency, with or without anaemia.

Adverse reactions by preferred term[1]

	Ferric maltol 30mg BID (n = 175)	Placebo BID (n = 120)
Body system adverse reaction: GI		
Flatulence	**4.6%**	**0.0%**
Diarrhoea	**4.0%**	**1.7%**
Constipation	**4.0%**	**0.8%**
Faeces discoloured	**4.0%**	**0.8%**
Abdominal pain	**2.9%**	**2.5%**
Nausea	**1.7%**	**0.8%**
Vomiting	**1.7%**	**0.0%**
Abdominal discomfort	**1.1%**	**0.0%**
Abdominal distension	**1.1%**	**0.0%**

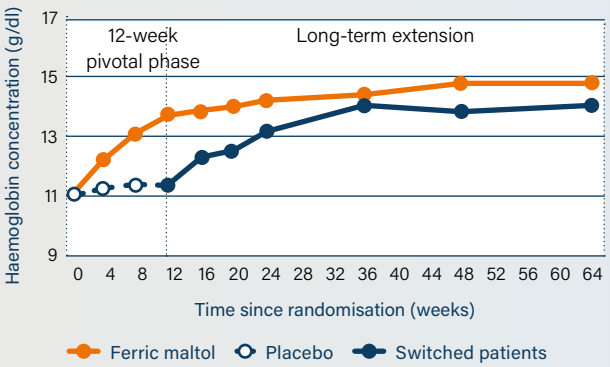
1. Accrufer® (ferric maltol) prescribing information. Austin, TX: Shield Therapeutics, 2021.

Clinical studies have demonstrated efficacy, tolerability and safety

- The Phase III pivotal studies in patients suffering from inflammatory bowel disease (IBD) and chronic kidney disease (CKD) with iron deficiency anaemia were used for regulatory approval in the US, the EU, the UK, Australia and Switzerland. These studies demonstrated that Accrufer®/Feraccru®:
  - Improved haemoglobin (Hb) levels over the 12 and 16 weeks double-blinded phase;
  - Maintains Hb levels over 52–64 weeks during the long-term open label phase;
  - Increased ferritin and transferrin saturation (TSAT) levels at weeks 12 and 16 with steady levels within target range maintained over 52–64 weeks; and
  - Is shown to be well tolerated.

Pivotal studies in inflammatory bowel disease

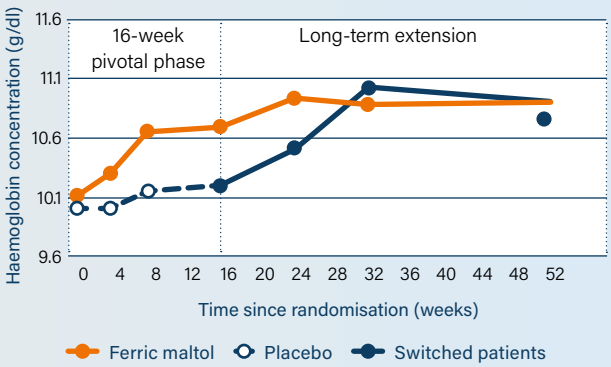
Absolute haemoglobin concentrations in patients over time[1,2]



1. Gasche C, et al. Inflamm Bowel Dis. 2015; 21(3):579–588
2. Schmidt C, et al. Aliment Pharmacol Ther. 2016; 44(3):259–270

Pivotal study in chronic kidney disease

Absolute haemoglobin concentrations in patients over time[3]



3. Pergola PE, et al. Am J Kidney Dis. 2021:S0272-6386(21)00624-7

Paediatric clinical study

Continued progress with enrolment in the US/UK study evaluating Accrufer® for children aged one month to 17 years with IDA.

- In the second half of 2021, we initiated the FORTIS clinical study in the US and the UK.
- The study will evaluate the tolerability, safety and efficacy of ferric maltol oral suspension versus ferrous sulfate oral liquid in children and adolescents aged two to seventeen years with iron deficiency anaemia, with a single-arm study in infants aged one month to less than two years.
- A pharmacokinetic study in healthy volunteers has confirmed that the paediatric ferric maltol suspension formulation is therapeutically interchangeable with the approved adult ferric maltol capsule formulation.

"We continue to work with the FDA and the European Medicines Agency to address the unmet medical need for a paediatric oral iron formulation by making available an effective, well tolerated and palatable oral iron product in a form suitable for infants through to adolescents."

Dr Jackie Mitchell
VP Quality, Clinical and Regulatory Affairs

How we create value

To make Accrufer® the oral iron of choice

Why patients and writers choose Accrufer®

Unmet need and unsatisfied market:
Other available oral iron treatments are driven by gastrointestinal related adverse events and minimal efficacy, resulting in a highly unsatisfied market with little to no innovation among oral iron therapies over the past two decades.

Effectiveness with tolerability:
Due to its unique maltol formulation and mechanism of action, delivering elemental iron to the small intestine, Accrufer® effectively treats iron deficiency with a lower dose of iron and results in <5% individual adverse reactions and treatment discontinuations.

Acceptable cost to patients:
Through agreements with most of the large commercial payer organisations, State-run Medicaid plans, plus available patient assistance programmes, ~100 million patients in the US have access to Accrufer® at a minimal out-of-pocket cost.

Our resources

A. FDA- and EMA-approved potential best-in-class solution
Accrufer®, an FDA approved therapy, oral iron solution with minimal (<5%) individual gastrointestinal adverse reactions and discontinuations.

B. Collaborative commercial partnership in US
Commercial partnership with Viatris expands commercial footprint and resources for Accrufer® in the US with 100-person combined sales team, calling on 12,000+ HCPs.

C. Dedicated and committed global licence partner
Dedicated global licence partner works with local regulatory authorities in various jurisdictions to make our product available to even more patients around the world.

D. Experienced and solution-driven team of professionals
Team of highly skilled, experienced and diverse employees drives the overall performance of the business. We continue to invest into our people by hiring new talent and targeted development.

What we do

Drive US prescription demand

With a combined and dedicated sales force of 100 representatives, we are planning to call on 12,000+ targeted high-prescribing HCPs with a significant focus on Women's Health and General Practitioners to drive prescription demand and increase US market share.

Educate physicians and patients

Our experts frequently present at medical conferences and various other events to educate physicians, payers and patients about iron deficiency anaemia to create awareness about this under-served therapeutic area and to illustrate available treatment options.

Support global licence partner

We are working closely with our global licence partner to support their efforts to obtain regulatory approval for Accrufer®/Feraccru® and, in the case of Europe and the UK, assist our partner Norgine with the execution of their commercialisation plan.

Manage life cycle of our product

We continue to invest in our product and initiated a clinical study in the US and the UK to evaluate the tolerability, safety and efficacy of ferric maltol oral suspension versus ferrous sulfate oral liquid in children and adolescents aged two to seventeen years with iron deficiency anaemia, with a single-arm study in infants aged one month to less than two years. Additionally, we recently increased the accessibility and user-friendliness of Accrufer® by expanding the shelf life from 36 to 48 months.

How we create value for stakeholders

Patients:
We aim to provide our patients with an effective, well tolerated and convenient therapy, which has a good safety profile and which is affordable.

Healthcare professionals:
HCPs rely on the quality of our product, our expertise and our trusted partnerships to deliver the best care for their patients.

Investors:
We create value for our shareholders through increased prescription demand, revenue growth and profitability.

Employees:
We offer our employees the opportunity to grow careers and make a real difference to the business.

→ Read more about stakeholder engagement on page 18

Progressing with our strategy

Our strategic pillars

1

Make Accrufer® the brand leader in oral iron therapy in the US

- Redefine expectations of oral iron therapy
- Increase brand awareness
- Build Accrufer® advocates
- Raise patient awareness
- Minimise patient barriers to access

Achievements

- Annual US Accrufer® sales volume of more than 25,000 prescriptions
- Broad reimbursement coverage with +100 million patients in US
- Agreement with Viatris Inc. on co-commercialisation of Accrufer® in US

Future outlook

- Increase of US sales force to 100 dedicated sales representatives
- Targeting of +12,000 high-prescribing Health Care Professionals

Link to risk

1 2 3 4 5 6 7

Link to KPIs

1 3 4 5 6

2

Accelerate global adoption of Accrufer®/Feraccru®

- Increase adoption and payer reimbursement in Europe
- Assist current licence partner in obtaining regulatory approvals
- Identify potential partners in new markets and territories

Achievements

- Increase in net sales of Feraccru® in Europe by c.10% versus prior year
- Completion of out-licensing agreement in Canada and acceptance of New Drug Submission (NDS) by Health Canada paving way for future approval
- Confirmation of regulatory path in Korea to support New Drug Application (NDA)

Future outlook

- Further progress in net sales of Feraccru® in Europe with expansion of call reach into Women's Health practitioners in Germany
- Approval by Health Canada in H2:2023

Link to risk

1 2 3 5 7

Link to KPIs

2 3 4 6

3

Identify expansion opportunities for our business

- Seek to expand indication to include paediatric patients
- Explore alternative dosing regimens and other life cycle management opportunities
- Identify in-licensing opportunities that leverage our infrastructure and fit strategically to grow our business

Achievements

- Start of enrolment in US/UK study evaluating Accrufer® for children aged one month to 17 years with IDA
- FDA approval of increase in shelf life of Accrufer® from 36 to 48 months

Future outlook

- Complete enrolment for paediatric study in H1:2024
- Receipt of results from paediatric study in H2:2024

Link to risk

1 2 3 5 7

Link to KPIs

1 2 3 4 5

Link to risk

1. Dependency on commercial success of Accrufer®/Feraccru®
2. Need for additional financing if future revenues insufficient
3. Inability to meet regulatory requirements and obligations
4. Reliance on third-party contractors
5. Failure to protect intellectual property rights
6. Ability to attract and retain key staff and management team members
7. Adverse impact of economic, political and financial market conditions

→ Read more on page 24

Link to KPIs

1. US Accrufer® net revenue
2. Royalty and milestone revenue
3. Operating profit/(loss) before impairment and R&D expenditure
4. Cash and short-term deposits at year-end
5. US Accrufer® prescriptions
6. Headcount (average number of employees during year)

→ Read more on page 16

Shield Therapeutics and KYE Pharmaceuticals (KYE) enter into exclusive licence agreement for Accrufer® in Canada (January 2022)

KYE filed New Drug Submission (NDS) with Health Canada (July 2022)

Key Terms of Agreement include:

- Up to £1 million in upfront, development and sales milestones;
- Double-digit royalties on net sales;
- KYE Pharmaceuticals Inc. to be responsible for, and cover costs of all development and regulatory activity; and
- Shield will be responsible for all manufacturing and supply to the Canadian market.

Health Canada are expected to complete their regulatory review in mid-2023 and a successful outcome will allow KYE to market Accrufer® in Canada.

"Iron deficiency is highly prevalent worldwide and a public health concern in Canada. Accrufer® will be the first oral prescription-only therapy available in Canada to treat patients who continue to suffer from low iron despite attempts at treatment with currently available agents. This agreement is very much aligned with our strategy to bring innovative medicines to the people of Canada and KYE is proud to be partnering with Shield. We look forward to bringing Accrufer® to the Canadian market in the near future."

Doug Reynolds
President of KYE Pharmaceuticals

Measuring our performance

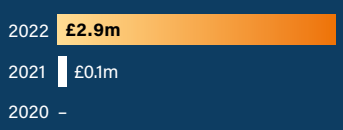
We track and monitor key performance indicators to assess how we deliver against our strategy.

Strategic focus

Financial

US Accrufer® net revenue

£2.9m



Why is it a KPI?

The Group measures US Accrufer® net revenue as a key financial metric to assess the progress of its commercial activities.

Performance

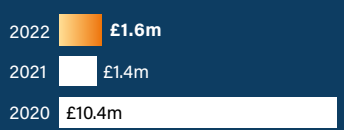
US Accrufer® net revenue is £2.9m and excludes an upfront payment of £4.2m (or US$5.0m), received from Viatris upon execution of the collaborative sales agreement. An amount of £0.7m (or US$0.8m) of that upfront payment was recorded in other operating income. The balance will be recognised in 2023.

Link to strategy

1 3

Royalty and milestone revenue

£1.6m



Why is it a KPI?

The Group measures royalty and milestone revenue from its global licence partner as a key financial metric.

Performance

Royalty revenue from Shield's licence partner in Europe increased by 48% from £0.9 million in 2021 to £1.4 million in 2022. In addition, the Group received an upfront of £0.2 million in 2022 from its new licence partner in Canada and £0.5 million in 2021 from its partner in the Republic of Korea.

Link to strategy

2 3

Operating profit/(loss) before impairment and R&D expenditure

£(24.6)m

Why is it a KPI?

The Group's operating profit/(loss) before impairment and R&D expenditure measures the overall financial performance of its commercial and operating activities during the period.

Performance

The operating losses in 2022 and 2021 were significantly impacted by the investments undertaken to establish the US commercial business. In 2020, the Group benefited from the upfront payment received by its licence partner in China.

Link to strategy

1 2 3

Link to Strategy

1. Make Accrufer® the brand leader in oral iron therapy in the US
2. Accelerate Global adoption of Accrufer®/Feraccru®
3. Identify expansion opportunities for our business

→ Read more on page 14

Non-Financial

Cash and short-term deposits at year end

£2.8m

Why is it a KPI?

Since the ongoing US commercialisation activities still require further investment and the business is not yet generating positive cash flows, the remaining cash balance is considered a key metric.

Performance

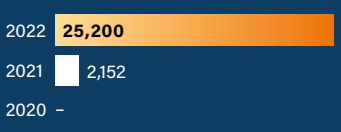
The Group closed 2022 with £2.8 million of cash, but it has since raised £16.4 million net proceeds from a fundraise completed in January 2023, plus £8.2 million (or US$10.0 million) cash through an extension of the existing convertible shareholder loan.

Link to strategy

1 2 3

US Accrufer® prescriptions

25,200



Why is it a KPI?

Sales volume of Accrufer® prescriptions is a key measure of brand awareness and patient accessibility.

Performance

The 2022 sales volume represents a nearly 12-fold increase from the prior year volume. The 9,324 dispenses in Q4 2022 represent 37% of the annual prescription volume and was achieved with only a limited sales force of c.22 representatives.

Link to strategy

1 3

Headcount (average number of employees during year)

28

Why is it a KPI?

Headcount is a key indicator of the Group's central cost control and the appropriateness of the Group's structure.

Performance

The Group's headcount has been tightly managed over the last several years to keep costs under control and any increases in headcount since 2020 are directly connected to the development of the US commercial activities.

Link to strategy

1 2

Engaging with our stakeholders

Our stakeholders help to shape our strategy and are critical to our success. We engage to ensure we manage expectations and promote trust and transparency across all our activities with a view to promoting mutually beneficial relationships.

Duty to promote the success of the Group

Shield's objective is to progress shareholder value through the continuing development and commercialisation of Accrufer®/Feraccru® with a focus on patients around the world who suffer from iron deficiency, with or without anaemia. This year, the Group has accomplished important milestones in achieving its objective to making Accrufer® the oral iron of choice. The operational and financial reviews within this Annual Report discuss these milestones in more detail.

Stakeholder engagement

The Board recognises its responsibility to take into consideration the needs and concerns of Shield's key stakeholders as part of its decision-making process. The table on page 19 illustrates how the Group engages with its stakeholders.

Section 172 statement on the discharge of Directors' duties

In compliance with the Companies Act 2006, the Board is required to act in accordance with a set of general duties. During the year ended 31 December 2022, the Board considers that it has individually and collectively acted in a way it considers, in good faith, would be most likely to promote the success of the Group for the benefit of its shareholders as a whole having regard to the six matters listed in Section 172(1)(a) to (f) of the Companies Act 2006. In order to achieve long-term success for the benefit of all shareholders, the Board recognises the importance of building and maintaining relationships with key stakeholders as well as considering the likely consequences of its decisions in the long term.

"As principal shareholder of Shield Therapeutics, AOP Health strongly believes in the potential of its lead product, Accrufer®/ Feraccru®, a non-salt-based oral therapy for iron deficiency in adults. We are therefore supporting the company's efforts to further expand its commercial footprint in the U.S. market."

Andreas Steiner
Group Chief Executive Officer of AOP Health International Management AG

Patients and Health Care Professionals (HCPs)

The principle of providing our patients an oral iron therapy which is well tolerated, effective, convenient, safe and affordable is critical to our strategy.

Key issues:
- Understanding needs of patients and HCPs
- Patient and HCP experience
- Maintain high standard of product offering

Our response:
- Sales representatives solicit feedback on their interactions with HCPs
- Medical Affairs engages and educates key opinion leaders and healthcare professionals
- Monitoring of internal and external data reports, e.g. repeat and new subscribers

Global licence partner

Shield's continuing engagement with its global licence partner allows it to provide the support required to serve our patients, health care providers and employees.

Key issues:
- Regulatory approval of our lead product in the jurisdictions of our licence partner is critical to advance the reach of our product
- Successful commercialisation by licence partner upon regulatory approval provides additional revenue streams to the Group

Our response:
- Direct engagement by senior members of management team and key partners and suppliers
- Regular business reviews with global licence partner

Investors

Investor support and loyalty by the shareholder base is vital for future growth and the long-term success of the Group.

Key issues:
- Reliable, timely and transparent information
- Access to key decision makers of the business

Our response:
- Issuance of regular business and trading updates
- Availability of meaningful information on corporate website www.shieldtherapeutics.com
- Periodic analyst and investor meetings by CEO and CFO
- Availability of Directors and senior management team at AGM

Our people

Our people are key to our success, and communication and engagement with the workforce is vital to the success of the business.

Key issues:
- Flexible work arrangement
- Competitive pay and benefits package
- Retention

Our response:
- Both remote and hybrid office work arrangements
- Third-party compensation surveys to ensure competitiveness in local markets
- Development of reward and recognition programmes and tools

Staying engaged, strengthening relationships, building trust

Our people and values anchor who we are as a Company and are the undercurrent of the programme offerings, initiatives and resources we are developing for our organisation.

Empowerment
We develop an open and trusting environment that requires accountability and responsibility at all levels.

Will to succeed
Results oriented environment that values resiliency in overcoming challenges. Encourage a "learning culture" that celebrates success and learns from failures.

Collaboration
Our success is driven by teamwork, trust and transparency and our ability to work together to find optimal solutions.

Agility
While moving with a clear purpose, we want to prepare for the unexpected and adapt quickly to change and the changing environment.

Believing strongly we are Better Together.

We have begun to integrate our two pillar organisations in the UK and US to ensure there is One Shield moving forward and aim to eliminate as many silos as possible, believing strongly we are Better Together.

We developed behaviour-based interview questions and a collaborative interview approach anchored in our Company values to ensure our key priority of building out our sales organisation secures talent we believe will be successful at Shield and allow us to retain and foster our culture.

Our reward and recognition strategy includes programmes designed to allow leaders and peers the ability to quickly recognize those who demonstrate our values in their day-to-day work and contributions.

Kate Armanetti
Senior Director, People and Culture

"At Shield, I am proud to lead alongside an experienced management team who is committed to success at every level of the organisation. Shield is an organisation that puts people first, an organisation that invests in employee growth and development. We promote a culture of passion, innovation, transparency and accountability. The team is excited to be building a best-in-class operational infrastructure to support global cross-functional teams."

Lorraine Nemyier
VP of Commercial Operations

Continuing growth momentum from a solid foundation

Hans-Peter Rudolf
Chief Financial Officer

"Cash resources are expected to be sufficient to support operations through to cash flow break even by end of 2024."

Revenue

Revenue in 2022 was £4.5 million (2021: £1.5 million), comprising £2.9 million net product revenues from Accrufer® sales in the US (2021: £0.1 million), £1.4 million royalty income from Feraccru® sales in Europe by Norgine (2021: £0.9 million) and £0.2 million upfront payment from KYE Pharmaceuticals on the signing of the Canadian license agreement (2021: £0.5 million from Korea Pharma on the signing of the Korean licence agreement).

The 25,200 prescriptions of Accrufer® sold in the US yielded net revenue of £2.9 million (2021: £0.1 million from 2,500 prescriptions). A significant number of the 2022 prescription sales are still subsidised through patient assistant programmes, resulting in a net average sales price of approximately US$135 per prescription in 2022.

In December 2022, the Group signed an exclusive, multi-year collaborative sales agreement for Accrufer® in the US with Viatris. This collaboration will result in a 100-person dedicated sales team (previously 30 contracted sales reps) which will promote Accrufer® to over 12,000 Health Care Professionals (HCPs) who write the majority of oral iron prescriptions. The Company received a £4.2 million (or US$5.0 million) upfront payment upon execution of the agreement. An amount of £0.7 million of that upfront payment was recorded in other operating income and the balance of £3.5 million will be recognized in 2023.

Royalty revenue from Norgine, Shield's license partner in Europe, increased from £0.9 million in 2021 to £1.4 million in 2022 on the back of a 10% increase in total packs sold. Germany now accounts for c.72% of the total net sales of Feraccru® in Europe, followed by the United Kingdom with c.17%. Norgine began expanding its call reach into Women's Health practitioners in Germany at the end of 2022, which is expected to have a further positive impact on future sales volumes.

Cost of sales

Cost of sales of £2.5 million (2021: £1.0 million) includes the manufacturing and shipping cost of the prescriptions sold in the US, the finished packs supplied to Norgine for sale in Europe and the 5% royalty payable to Vitra Pharmaceuticals Limited ("Vitra") on net sales, as well as 10% of the licence upfront received from KYE Pharmaceuticals.

Vitra was the original owner of the intellectual property underpinning Accrufer®/Feraccru® and, under the terms of the 2010 Asset Purchase Agreement, is entitled to receive either a 5% royalty on net sales or 10% of any licence upfront and sales milestones. For the Norgine licence covering European commercialisation, Vitra chose in 2018 to receive 5% on net sales whereas for the ASK Pharm agreement covering China, the Korea Pharma agreement covering the Republic of Korea and the KYE Pharmaceuticals agreement covering Canada, Vitra elected to receive 10% of the upfront and sales milestones instead of future sales royalties.

Selling, general and administrative expenses

Selling, general and administrative expenses were £27.3 million in 2022 (2021: £20.2 million). This increase is largely attributable to the continuing development of the commercial functions in the US during 2022 and the fact that these activities did not exist for the entire year 2021. Accordingly, the average number of persons employed by the Group increased from 23 in 2021 to 28 in 2022, with an increase from 10 to 12 staff directly related to the US commercial function.

Impairment of intangible assets

Following the completion of the collaborative sales agreement for Accrufer® in the United States with Viatris, the Group carried out a review of the recoverable amount of its intangible assets. As a result of this review, the Directors concluded that the Group should concentrate the use of its resources on the commercial development of Accrufer®/Feraccru® and the ongoing paediatric study.

Based on that conclusion, along with the limited remaining patent life of PT20, the Directors decided to write off the assets related to the Phosphate Therapeutics Limited business, resulting in an impairment loss of £14.7 million (2021: £Nil) in the Group's statement of profit and loss for the year ended 31 December 2022.

Research and development

The Group spent £2.9 million (2021: £2.5 million) on research and development. Of that total spend, £1.8 million (2021: £1.7 million) have been capitalised as additions to intangible assets, as management that it is probable that these costs will generate future economic benefits. The balance of £1.1 million (2021: £0.8 million) was expensed in the current year. All research and development expenditure are related to the ongoing paediatric study.

Financial income

Financial income of £0.7 million was reported in 2022 (2021: £0.4 million). This income was generated primarily through currency gains on the cash held in US Dollars.

Tax

The tax charge of £0.4 million compares with a tax credit of £0.2 million in 2021. The reason for the current year charge is an adjustment in respect of prior years' estimate.

Balance sheet

Intangible assets at 31 December 2022 were £11.8 million (31 December 2021: £26.9 million), comprised of £10.8 million (31 December 2021: £9.5 million) capitalised Feraccru® development costs, in particular the AEGIS-H2H study and the paediatric pharmacokinetic study and £1.0 million (31 December 2021: £1.3 million) capitalised Feraccru® patent and trademark cost, incurrent to strengthen the Group's intellectual property. All capitalised expenditure related to Phosphate Therapeutics licences have been written off in the current year.

Inventories are comparable to the prior year at £1.5 million (31 December 2021: £1.6 million).

Trade and other receivables increased from £2.9 million at 31 December 2021 to £5.4 million at 31 December 2022, reflecting the increase in trading volume in the US.

The current tax asset of £0.4 million at 31 December 2022 (31 December 2021: £0.6 million) relates to the anticipated R&D tax credit claim in respect of the 2022 and 2021 financial years.

Cash at 31 December 2022 was £2.8 million (31 December 2021: £12.1 million), which does not include the £16.4 million net of expenses from the equity fundraise, completed on 5 January 2023, and the £8.2 million (or US$10.0 million) from the increase in the convertible shareholder loan with AOP Health, drawn on 12 January 2023.

Non-current liabilities are comprised of the convertible shareholder loan from AOP Health, which is repayable by 31 December 2026. The fair value of the conversion feature of this loan, which will be revalued at each balance sheet date, has been separated from the value of the loan principal amount in accordance with IFRS 9. At 31 December 2022, the fair value of the conversion feature was £0.5 million and the remaining loan balance was £5.5 million. These balances do not yet reflect the additional £8.2 million (or US$10.0 million), which the Company drew down on 12 January 2023.

Trade and other payables increased from £3.5 million at 31 December 2021 to £9.5 million at 31 December 2022 as a result of the larger trading volume in the US. Additionally, the balance at 31 December 2022 includes £3.5 million (31 December 2021: £Nil) of the Viatris upfront payment, received in 2022, which will be recognised in 2023.

Cash flow

Net cash outflow in 2022 was £12.2 million, decreasing the cash on hand from £12.1 million at 31 December 2021 to £2.8 million at 31 December 2022, excluding a positive effect of exchange rate fluctuations on cash balances.

Net cash flows from operating activities was £18.2 million, comprised of £40.4 million loss for the year, adjusted for non-cash items of £17.8 million (including an impairment of intangible assets of £14.7 million, depreciation and amortisation of £2.4 million, share-based payments of £0.7 million, net financial income of £0.3 million and an income tax charge of £0.4 million) and net investments in increasing the Group's working capital of £4.4 million.

Net cash outflows from investing activities of £1.7 million are the result of capitalised development expenditure of £1.8 million and the acquisition of tangible assets of £0.1 million.

Net cash inflows from financing activities of £7.7 million are largely attributable to the net proceeds from the new convertible shareholder loan of £8.2 million.

Going concern

At 31 December 2022, the Group held £2.8 million in cash. Since year-end, the Group completed an equity fundraise which raised £16.4 million net of expenses, and it drew £8.2 million (or US$10.0 million) on the convertible shareholder loan with AOP Health in connection with an amendment to the original loan agreement, dated 1 August 2022, raising the Group's unaudited cash balance at 31 March 2023 to £19.2 million.

The Group is planning to use these funds to drive continuing growth in sales volumes of Accrufer® in the US. The Directors have considered the funding requirements of the Group through the preparation of detailed cash flow forecasts for the period to December 2024, including the prospective Accrufer® sales revenues and the related commercial operating costs. These forecasts show that the Group's monthly cash flows start to turn positive by the end of 2024 and that the recent fundraise should provide sufficient cash to allow the business to continue in operations for at least 12 months from the balance sheet date. The Directors have considered scenarios in which sales revenues fall below base case forecasts. In these circumstances mitigating actions such as reduction of discretionary selling and marketing expenditure could be taken to preserve cash. The Directors also believe that other forms of finance, such as debt finance or royalty finance are likely to be available to the Group.

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

Financial outlook

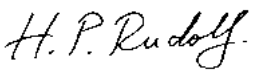
In December 2022, Shield signed an exclusive, multi-year collaborative sales agreement with Viatris, a global healthcare company, to co-commercialise Accrufer® in the US. The collaboration expands the commercial footprint and resources for Accrufer®, as the brand aspires to be the oral iron of choice in the US Market.

The collaboration will result in a 100-person sales team which will promote Accrufer® to over 12,000 HCPs that write the majority of oral iron prescriptions in the US. Shield and Viatris are each hiring a team of 50 dedicated sales professionals as part of the collaboration agreement. Shield's recruitment of the new sales team is well under way with 16 of the targeted 50 representatives already hired and trained and promoting Accrufer® in their respective territories. Shield is on track for its stated goal to have the field sales team hired and trained by 1 May 2023.

Each company is responsible for its own respective sales force and related selling costs. Shield and Viatris will share revenues and marketing expenses, with Shield retaining a slightly higher percentage of each.

With the support of the Viatris partnership, management estimates that Accrufer® has the potential to generate combined net product revenues in excess of US$150 million by the year ending 31 December 2025 and it expects the Group to turn cash flow positive by the end of 2024.

Annual operating expenses for Shield are expected to reach around US$45 million in the year ending 31 December 2023 and are expected to remain approximately at this level until the year ending 31 December 2025 assuming Accrufer® prescriptions and revenues build as expected. The costs of servicing interest on the convertible shareholder loan will be around £1.7 million (or US$2.0 million) per annum, however no interest is payable on the £8.2 million (or US$10.0 million) extension during 2023.



Hans-Peter Rudolf
Chief Financial Officer
5 May 2023

Managing our key risks in light of the Group's strategy and objectives

Risk Management Framework

The Board is responsible for risk management and reviewing the internal controls systems. It ensures that the key risks are understood and appropriately managed in light of the Group's strategy and objectives, and that an effective internal risk management process, including internal controls, is in place to identify, assess, minimise and manage significant risks. The internal control systems are designed to manage rather than eliminate the risk of failure to achieve business objectives and can only provide reasonable and not absolute assurance against material misstatement or loss. The Audit Committee oversees risk management on behalf of the Board.

The Group highlights potential financial and non-financial risks that may impact on the business as part of the risk management procedures in the form of a Risk Register. The Audit Committee periodically reviews the Risk Register and approves the addition or deletion of any risks, along with changes in the underlying risk assessment. There are ongoing processes for identifying, evaluating and mitigating the significant risks faced by the Group, which are reviewed on a regular basis.

The review process involves a review of each area of the business to identify material risks and the controls in place to manage these risks. The process is led by the Chief Financial Officer, together with the senior managers with responsibility for specific controls, and overseen by the Audit Committee. Where any significant weakness or failing is identified, implementation of appropriate remedial action is completed following approval by the Audit Committee.

Principal risks and uncertainties that could significantly impact the Group:

Key ↔ No change ↗ Increased ↘ Decreased N New risk

Risk description	Change	Potential impact
1. Dependency on commercial success of Accrufer®/Feraccru®	↔	The Group is dependent on one product for its short and medium-term success: Accrufer®/Feraccru® which has been out-licensed for commercialisation in a range of territories including Europe, China, Canada, Korea, Australia and New Zealand and will be marketed in the US pursuant to the Viatris Partnership. The Company is heavily dependent upon sales of Accrufer®/Feraccru® by its collaboration and licensing partners in those territories and the resultant revenues receivable by the Company. Further, regulatory approval is still required to be obtained for the product to be sold in China, Korea and Canada and this may not be obtained and the clinical trials required for such regulatory approval may not be successfully completed or may take materially longer than currently expected.
2. Need for additional financing if future revenues insufficient	↘	The Company has incurred losses since its inception and near-term losses are expected to increase as a result of the commercialisation of Accrufer® in the United States pursuant to the Viatris Collaboration Agreement. If Accrufer®/Feraccru® is not successfully commercialised in the US, Europe, China, Canada, Korea and other markets, the Company is unlikely to become profitable or produce a reasonable return, or any return, on investment. If the Company fails to generate sufficient revenues from its operations to fund its business objectives, additional financing will be required before it becomes self-sustaining, the terms of which may not be advantageous for existing shareholders.
3. Inability to meet regulatory requirements and obligations	↔	The Company operates in a highly regulated environment. Accrufer®/Feraccru®, along with any other products of the Company which may obtain regulatory approval, are subject to ongoing regulatory obligations. Regulatory authorities may impose significant restrictions on the indicated uses or marketing of Accrufer®/Feraccru® or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. In addition, product manufacturers and their facilities are subject to continual review and periodic inspections by the EMA, the FDA and other regulatory authorities for compliance with good manufacturing practices and good pharmacovigilance practices. If the Company or a regulatory agency discovers previously unknown problems with Accrufer®/Feraccru® or problems with a facility where Accrufer®/Feraccru® is manufactured, a regulatory agency may impose restrictions relative to Accrufer®/Feraccru® or the manufacturing facility, including requiring recall or withdrawal of Accrufer®/Feraccru® from the market or suspension of manufacturing which could severely limit the Company's ability to generate revenues. Whilst the Company maintains and operates suitable quality standards and practices including the audit of key suppliers and manufacturers, there is a risk that an inspection by a relevant regulatory authority may result in adverse findings that inhibit or disrupt the Group's product supply.

Principal risks and uncertainties and risk management continued

Principal risks and uncertainties that could significantly impact the Group: continued

Key: No change | Increased | Decreased | New risk

Risk description	Change	Potential impact
4. Reliance on third-party contractors	↔	The Company's business strategy utilises the expertise and resources of third parties in a number of areas including manufacturing and the conducting of clinical studies and the protection of the Group's intellectual property rights in various geographical locations. This strategy creates risks for the Company by placing critical aspects of the Company's business in the hands of third parties whom the Company must manage appropriately to fit in its best interest. The Group is also currently reliant on two contract manufacturers for the manufacture of Accrufer®/Feraccru®, although it is currently in the process of engaging an alternative supplier for both drug substance and the completed product.
5. Failure to protect intellectual property rights	↔	The Company has been granted, or has in-licensed rights under, a number of key patent families for Accrufer®/Feraccru® (or other proprietary rights), and patent applications are pending in multiple jurisdictions. The strength of patents in the pharmaceutical field involves complex legal and scientific questions and can be uncertain. Patents or other rights might not be granted under any pending or future applications filed or in-licensed by the Company and any claims allowed might not be sufficiently broad to protect the Group's technologies and products from competition. In addition, patents granted may be subjected to opposition or comparable proceedings lodged in various national and regional patent offices. These proceedings could result in the loss of a patent which has already been granted, or loss or reduction in the scope of one or more of the claims of the patent. Generic pharmaceutical manufacturers may successfully challenge some of the Company's patents and/or seek approval to market products which utilise the intellectual property involved in the development and manufacture of Accrufer®/Feraccru®. Competitors may also successfully design around key patents held by the Group, thereby avoiding a claim of infringement. Patents or other registrable rights might also be revoked for other reasons after grant. Competitors may have filed applications or been granted patents or obtained additional patents and proprietary rights that relate to and could be infringed by the Company's products. Any such failure to sufficiently protect the Company's proprietary intellectual property, resulting in additional competition from other third-party products could have a material adverse effect on the Company's business, prospects, financial condition and results of operations.

Risk description	Change	Potential impact
6. Ability to attract and retain key staff and management team members	⇔	The Company needs to attract and retain key personnel to conduct and grow its operations effectively. The Company's ability to compete in the highly competitive pharmaceutical industry depends upon its ability to attract and retain highly qualified employees. Many of the other pharmaceutical companies and academic institutions that it competes against for qualified personnel have greater financial and other resources and different risk profiles and a longer history in the industry than the Company does. The Company might not be able to attract or retain these key persons on conditions that are economically acceptable. The inability of the Company to attract and retain these key persons could have a material adverse effect on its business, earnings, financial situation and prospects and its relationships with its suppliers and key commercialisation partners.
7. Adverse impacts of economic, political and financial market conditions	⇔	The Company's operations may be adversely affected by general economic, political and financial market conditions. The Company and its operations will be susceptible to any economic downturn, the impact of Government policy, increased interest rates, exchange rate fluctuations, geo-political conditions (including the Ukraine-Russia conflict), volatility and/or price increases in the UK, the US and Europe and volatility in world markets. Global capital markets are seeing significant downturns and extreme volatility as both the Ukraine-Russia conflict and COVID-19 continue to have a sustained impact on business across the world. Such volatility and downturn could have an impact on the liquidity of the Ordinary Shares. Investors should be aware that if any of these issues continue for a sustained period of time, and should any of the risks identified above materialise, it could have a material adverse effect on the performance of the Company, the Company's earnings and returns to shareholders.

Hans Peter Hasler
Chairman
5 May 2023

Board of Directors

Greg Madison
Chief Executive Officer

Tenure
Two years

Skills and experience
Prior to joining Shield, Greg was the Chief Executive Officer at Melt Pharmaceuticals, a company developing a sublingual formulation of midazolam and ketamine, providing needle and opioid-free procedural sedation and analgesia. Prior to Melt Pharmaceuticals, Greg was Chief Executive Officer of Keryx Biopharmaceuticals from 2015 to 2018, where he led the transformation of the organisation from development stage to commercial stage focused on Auryxia®, an oral product for the treatment of hyperphosphatemia and iron deficiency anaemia, and ultimately leading to a merger with Akebia Therapeutics. In 2013 and 2014, Greg was Chief Commercial Officer at AMAG Pharmaceuticals where he was closely involved with Feraheme®, a leading intravenous product for the treatment of iron deficiency. From 2000-2012, Greg was at Genzyme Corporation, ultimately serving as Vice President and General Manager of Nephrology, where he led a division that had revenues in excess of US$1 billion, led by the world's leading phosphate binder, Renvela®. Greg began his career as a Sales Representative for Janssen Pharmaceuticals, a division of Johnson and Johnson.

External appointments
None.

Hans Peter Hasler
Non-Executive Chairman

Tenure
Five years

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

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

Peter Llewellyn-Davies
Non-Executive Director

Tenure
Seven years

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

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

Essential skills and experience our Board delivers:

	Healthcare	Financial	International	Commercial	Compliance
Greg Madison	✓		✓	✓	
Hans Peter Hasler	✓		✓		
Peter Llewellyn-Davies	✓	✓	✓		
Christian Schweiger	✓		✓		
Fabiana Lacerca-Allen	✓		✓		✓
Anders Lundstrom	✓		✓	✓	

Dr Christian Schweiger, MD, PhD
Non-Executive Director

Tenure
Three years

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

External appointments
Christian is the President of TACHRIS AG, Chairman of the board of Arxx Therapeutics, Non-Executive board member of AOP Orphan International AG and CEO of aidCURE AG.

Fabiana Lacerca-Allen
Non-Executive Director

Tenure
Two years

Skills and experience
Fabiana is currently Senior Vice President, Chief Compliance Officer at Aimmune Therapeutics based in San Francisco, California (a Nestlé Health Science Corporation since October 2020). She brings to Shield extensive experience in compliance having started and implemented compliance programmes at several major pharmaceutical companies including Merck, Sharp & Dohme, Bristol-Myers Squibb Company, Mylan Laboratories and Elan Pharmaceuticals. Fabiana was also a Non-Executive Director at ArthroCare Corporation, a publicly traded company in the medical device sector prior to its acquisition by Smith & Nephew in 2014. Fabiana holds a Master's in Law from the University of California, and a Doctor in Law and a Bachelor in Law from the Universidad de Buenos Aires. Fabiana is the recipient of several international recognitions and has been published extensively in areas of leadership and compliance.

External appointments
Fabiana is a Director of the Centre for Excellence in Life and member of Board of Directors of the American Red Cross Bay Area Chapter.

Anders Lundstrom
Non-Executive Director

Tenure
Two years

Skills and experience
Anders brings over 30 years of global pharmaceutical/biotech experience. He is currently Executive Vice President and Chief Commercial Officer at Banner Life Sciences where he is planning and executing a US launch of a novel treatment of multiple sclerosis. He has previously held senior commercial and general management roles in AstraZeneca, Biogen, Orexo AB, where he was President and Chief Executive Officer, EMD Serono, and Santhera Pharmaceuticals. Anders holds an MSc in Pharmacy from Uppsala University and a Diploma in Business Administration from IHM, Stockholm.

External appointments
Anders is a Director of Lexington Biopharma Consulting LLC.

Committee key

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

Senior Executive Team

Lucy Huntington-Bailey
General Counsel and Company Secretary

Tenure
Seven years

Skills and experience
Lucy has been the Group's Legal Advisor since August 2015 and was an integral member of the team working towards the successful admission of Shield Therapeutics to the AIM market in early 2016. Having worked previously at a boutique corporate law firm and prior to that an international US law firm in Singapore, Lucy brings to Shield a wealth of experience in the oil and gas sector as well as the pharmaceutical industry. Lucy was promoted to Senior In-House Counsel in December 2016, General Counsel in 2018 and is responsible for the management of the Group's legal team and all legal advice and services. Lucy was appointed by the Board of Directors to the role of Company Secretary in September 2017. Lucy is admitted as a Solicitor of the Senior Courts of England and Wales.

David Childs
VP Commercial Operations

Tenure
Twelve years

Skills and experience
David joined Shield Therapeutics in 2011 as Director of Manufacturing with the primary objective of creating a robust manufacturing process with multiple CMOs for the development and commercialisation of our lead medicine, Accrufer®. During his tenure David has also had a central role in developing and managing the Company's intellectual property, whilst more recently adding responsibility for the development of commercial alliances. Prior to joining Shield, David gained over 18 years of experience in chemical and pharmaceutical development at GlaxoSmithKline (GSK), where he led several successful projects and teams including the manufacturing elements of the successful Promacta® and Relovair® developments.

Dr Jackie Mitchell
VP Regulatory Affairs and Quality

Tenure
Twelve years

Skills and experience
Jackie has over 20 years' experience in regulatory affairs. She holds an MA in biochemistry from Lady Margaret Hall in Oxford, where she also obtained a doctorate in immunology and molecular biology. Following completion of her academic studies, Jackie spent a number of years working as a research scientist, including a period at Johns Hopkins School of Medicine in Baltimore, USA. Since moving into the pharmaceutical industry, Jackie has worked in regulatory affairs for large, medium and small pharmaceutical companies, including Boehringer Ingelheim, Abbott and Archimedes. She has been involved in a broad range of global, EU and national applications across many therapeutic areas and has led several major regulatory projects, including successful MAA and NDA submissions, including the NCEs Kaletra and Humira. Jackie has run the Group's regulatory activities since 2012.

Dr. José Menoyo obituary

Dr. José Alberto Menoyo, MD, Chief Medical Officer from September 2021 to January 2023, passed away suddenly on January 2, 2023. Though he slipped away from this earth quickly and quietly, his passionate, bold, and loving spirit remains with us. José, a native of Puerto Rico, completed his internal medicine residency and nephrology fellowship at Hahnemann University and Medical College of Pennsylvania. During medical training, he met his lifelong partner and husband, Dr. Eric Goldberg. After briefly working in clinical nephrology, José went on to exercise his ingenuity and clinical expertise in the pharmaceutical industry. He had over 25 years of experience in medicine affairs, drug development, and regulatory leadership across large and small publicly traded biopharmaceutical companies. He was most recently the Vice President and Chief Medical Officer for Shield Therapeutics PLC. Whether at the boardroom table or a dinner table with good friends and family, José was a beloved and valued presence, always engaging and energising. José (aka Papi, Jefe, Tio) filled the room with his deep voice and desire to connect with those around him. José was the devoted husband, partner, and best friend of 30 years to Dr. Eric Goldberg. Together they built a beautiful life, the centre of which is their miracle daughter, Alexa Paris Menoyo.

Committed to the highest standards of corporate governance

Hans Peter Hasler
Chairman

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

Leadership

The role of the Board

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

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

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

Effectiveness

Composition of the Board

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

Role	Name	Committee membership
Chairman	Hans Peter Hasler	Chair of Nomination Committee. Member of Remuneration Committee.
CEO	Greg Madison	
Independent NED	Peter Llewellyn-Davies	Chair of Audit Committee. Member of Nomination Committee.
NED	Dr Christian Schweiger	Member of Nomination Committee. Member of Remuneration Committee.
Independent NED	Fabiana Lacerca-Allen	Member of Audit Committee. Member of Nomination Committee.
Independent NED	Anders Lundstrom	Chair of Remuneration Committee. Member of Nomination Committee.

Corporate governance report continued

Effectiveness continued

Composition of the Board continued

No Director holds a directorship of a FTSE 100 company.

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

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

2022 meetings	Number of meetings	Attendance
Main Board	14	All Directors attended
Audit Committee	5	All Committee members attended
Remuneration Committee	2	All Committee members attended
Nomination Committee	0	All Committee members attended

Due to the significant matters facing the Company during 2022, the Board met more frequently during the second half of the year.

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

The Board recognises the importance of continually assessing how effectively they are performing against the objectives set annually. The Board carries out an internal evaluation on an annual basis of the Board and all subcommittees and the outcomes of the evaluation are dealt with by the main Board. These evaluations include a variety of factors, some of which are Board structure, strategy, financial reporting and internal audit and the role of the Chairperson.

Independence of Non-Executive Directors

A majority of the Company's Directors are Non-Executive Directors and Peter Llewellyn-Davies, Fabiana Lacerca-Allen and Anders Lundstrom 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 9.56% of Shield's issued share capital). Although Peter Llewellyn-Davies was put forward for election by W. Health, he was nevertheless appointed independently and does not represent W. Health.

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

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

Appointments to the Board

The Nomination Committee comprises the Chair and the other Non-Executive Directors. No new Directors were appointed during 2022.

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 36.

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

Information and support for Directors

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

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

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

Accountability

Composition of the Audit Committee

The Audit Committee comprises Peter Llewellyn-Davies and Fabiana Lacerca-Allen. Peter Llewellyn-Davies is Chair of the Committee and is considered to be independent and to have recent relevant financial experience, having previously held the role of CFO of other companies. During the year 2020 Hans Peter Hasler was a member of the Audit Committee.

As set out in the Company's last Annual Report, the Company recognised that the Chairman's continued membership of the Committee was not best practice and therefore he was replaced by Fabiana Lacerca-Allen. The Committee has written terms of reference, which are available for inspection on request to the Company Secretary. The activities of the Audit Committee, including those in relation to the Group's external auditor, are described in the audit and risk report on pages 34 and 35.

Risk management and internal control

The Board has overall responsibility for the adequacy of the Group's internal control arrangements and consideration of its exposure to risk. It approves and adopts the annual update to the Group's risk management plan, following recommendations made by the Audit Committee. The Directors have assessed the principal risks facing the Company and actions taken to mitigate them on pages 24 to 27 of the Annual Report.

Remuneration

The role of the Board and its Remuneration Committee in establishing a policy on Executive remuneration and an explanation of the level and components of remuneration are provided in the Directors' remuneration report on pages 36 to 41.

Governance and compliance

The Company's Compliance Program is guided by the Office of Inspector General's (OIG) Compliance Program Guidance for Pharmaceutical Manufacturers which outlines seven key elements of an effective compliance program. The Company's Corporate Compliance Committee, led by Fabiana Lacerca-Allen, defines, oversees, and validates the development, implementation, and continuous execution and improvement of the Company Compliance Program. The Committee's role is to support and hold the Compliance Team accountable for fulfilling the responsibilities with respect to the Company's Compliance Program. The Compliance Committee meets regularly and works with the department heads to implement and execute this program, adjusting as needed to reflect evolving business needs. In order to conduct business efficiently and operate with the highest ethical standards, Company Personnel must understand the policies, procedures, laws, regulations and ethical guidelines governing their day-to-day responsibilities, business functions, and behaviour. Conducting effective training and education promotes the understanding and awareness needed to detect and minimise instances of fraud, abuse and unlawful conduct. Through proper training and education, Company Personnel can help foster a culture of integrity, accountability, and respect here at Shield. All US employees have received a Code of Conduct and Compliance and Ethics Manual training.

The Company's culture is shaped by its values which align to the Company's corporate objectives which are set each year. The Board monitors the Company's objectives closely throughout the year and the Company through its People and Culture department, showcases recognition of good value behaviour.

General meetings

Details of the Annual General Meeting (AGM) are provided in the Directors' report on page 43. Separate resolutions are proposed at the AGM for each substantially separate issue and a resolution will be proposed for approval of the Annual Report. Proxy voting is available for general meetings of the Company.

Hans Peter Hasler
Chairman
5 May 2023

Monitoring risk and reporting

Peter Llewellyn-Davies
Audit Committee Chair

2022 membership and attendance

Peter Llewellyn-Davies

Fabiana Lacerca-Allen

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

The Audit Committee

The Audit Committee is a sub-committee of the Board with the responsibility to review all aspects of the financial reporting of the business and all aspects of internal control. The Committee represents the interests of our shareholders in relation to the integrity of information and the effectiveness of the audit processes in place.

The responsibilities of the Audit Committee include, but are not limited to:

- Evaluating the effectiveness of the Group's internal controls and risk management system and overseeing the process for managing risks across the Group, including review of the Group's corporate risk profile;
- Reviewing the integrity of the financial statements, including the Annual Report and the Half-Year Report;
- Reviewing and discussing with management the appropriateness of judgements involving the application of accounting principles and disclosures;
- Oversight of the Group's compliance with legal requirements and accounting standards and ensuring that an effective system of internal financial control is maintained;
- Monitoring the qualifications, expertise, resources and independence of the external auditor, as well as assessing the external auditor's performance and effectiveness; and
- Recommending the appointment or reappointment of the external auditor to the Board so that the Board may put the recommendation to the shareholders at the AGM.

Meetings of the Committee are held as required throughout the year. The regular meetings coincide with the review of the scope of the external audit and observations arising from their work in relation to internal control and to review the financial statements. The external auditor is invited to these meetings and meets with the Audit Committee at least once a year.

At its meeting, the Committee carries out a review of the year-end financial statements and of the audit, using as a basis the Report to the Audit Committee prepared by the external auditor and considering any significant accounting policies, any changes to them and significant estimates or judgements. Questions are asked of management of any significant or unusual transactions where the accounting treatment could be open to different interpretations.

During 2022 additional Committee meetings were held in relation to the appointment of a new external auditor as set out below.

Due to its size and structure, the Group does not have an internal audit function. This is a matter which the Committee reviews annually.

External auditor

The external auditor is required to give the Committee information about policies and processes for maintaining their independence and compliance regarding the rotation of audit partners and staff. The Committee considers all relationships between the external auditor and the Company to ensure that they do not compromise the auditor's judgement or independence, particularly with the provision of non-audit services.

KPMG LLP were originally appointed auditor to the Group in 2016. Following the completion of the 2021 external audit, they indicated that they would not be seeking re-election for the 2022 external audit, having served as auditor since the Company's initial public offering on the FTSE Alternative Investment Market (AIM).

The Audit Committee commenced an audit tender process in May 2022, having reviewed the current auditors of comparable companies which at that time were listed on the FTSE AIM 100 Index. The review identified six audit firms and initial informal pre-tender discussions were undertaken to identify which auditors would be suitable/able to participate in a formal audit tender process. This process led to a shortlist of two auditors who were then contacted under a formal Request for Proposal (RFP) process.

The RFP process undertaken sought to request information on the auditors covering several key areas:

- Credentials of the firm to support the Group's expanding US commercial business;
- Resource capacity to complete the year ended 31 December 2022 audit;
- Indicative fee proposals;
- Composition of the audit team and lead partner;
- Experiences of auditing similar sized healthcare and AIM-listed entities;
- Observations on existing accounting policies/treatments used by the Group; and
- Recent FRC feedback on the auditors' recent audits of AIM-listed entities.

The shortlisted auditors presented to the Audit Committee and the Committee subsequently reviewed the quality of the tender documents and presentations.

The Committee decided to appoint Mazars LLP, with Valerie Levi taking on the role of engagement partner. Mazars have completed the audit for the year ended 31 December 2022 and their appointment will be formally put before shareholders at the upcoming AGM.

Significant issues relating to the financial statements

The specific issues considered by the Audit Committee in the period under review, in relation to the financial statements, are shown below.

Use of judgements and estimates

In preparing the consolidated financial statements, the Group has made judgements and estimates that affect the application of the Group's accounting policies and the reported amounts of assets, liabilities, income and expenses. Actual results may differ from these estimates. Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to estimates are recognised prospectively.

Information about judgements and estimates made by the Group that have the most significant effects on the amounts recognised in the financial statements include:

Co-promote arrangement – The Group entered into a multi-year arrangement with Viatris to co-commercialise its lead product, Accrufer(R) (ferric maltol), in the United States. Upon execution of this agreement, the Group receive a one-time, non-refundable, upfront payment in the amount of £4.2 million (or US$5.0 million). This upfront payment serves as compensation for expenditure, which the Group incurs to expand and prepare it's operating functions and processes for the combined commercial activities. An amount of £0.7 million (or US$0.8 million), equal to such costs spent during 2022, has been recorded within other income of the consolidated statement of profit and loss and other comprehensive income for the year ended 31 December 2022. The balance of £3.5 million (or US$54.2 million) is expected to be recognised in the year ended 31 December 2023.

Share-based payments – Fair values used in calculating the amount to be expensed as a share-based payment is subject to a level of uncertainty. The Group is required to calculate the fair value of the cash-settled instruments granted to employees in terms of the share option schemes, and the share-based payment charges relating to empowerment transactions. These fair values are calculated by applying a valuation model, which is in itself judgmental, and takes into account certain inherently uncertain assumptions. The basis assumptions that are used in the calculation are explained further in note 23 of the financial statements.

Impairment – Impairment tests have been performed on the carrying amounts of the Group's intangible assets, investments in subsidiaries and property, plant and equipment. Key assumptions such as the amount and timing of future cash flow growth, discount rates and the achievement of future development milestones, underlie the recoverable amounts used in these impairment tests. Further information on the key assumptions used is disclosed in Note 13 Intangible assets.

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.

Peter Llewellyn-Davies
Audit Committee Chair
5 May 2023

Recognising the importance of shareholder engagement

Anders Lundstrom
Remuneration Committee Chair

2022 membership and attendance

Hans Peter Hasler

Anders Lundstrom

Christian Schweiger

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

On behalf of the Board of Directors, I am pleased to present the Directors' remuneration report for the year ended 31 December 2022. Although the Company is not subject to the reporting regulations of Main Market listed companies, the Remuneration Committee recognises the importance of shareholder engagement in relation to Executive remuneration.

Accordingly, the Committee has prepared this report as a matter of best practice and has taken account of those regulations in doing so.

Remuneration Committee membership and activities

The current members of the Remuneration Committee are Anders Lundstrom, Hans Peter Hasler and Dr Christian Schweiger; Anders Lundstrom has acted as chair of the Remuneration Committee since 18 June 2021 when he took over from Rolf Hoffmann.

The Committee meets at least once a year and met two times during the course of 2022. It has responsibility for:

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

Aon Solutions UK Limited has acted as external advisor to the Committee during the year.

The duties of the Committee are set out in the terms of reference, which are available on request from the Company Secretary. All decisions taken by the Remuneration Committee in 2022 were in accordance with the terms of reference and the Remuneration Committee exercised with appropriate commercial judgment.

The Remuneration Committee has concluded that the Remuneration Policies in place for the Company continue to be effective and appropriate to attract and retain high caliber individuals who help contribute to the Company's success.

With operations both within the UK and the US the Company continues to monitor market remuneration trends and works with advisors to ensure the Company is remaining competitive. Moving into 2023 it is anticipated that there will be an increasing focus on the US remuneration strategies in relation to the expansion of the Company's US workforce.

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

Executive remuneration in 2022

Base salary, bonus and share options for the Chief Executive Officer (CEO) were approved by the Remuneration Committee prior to the appointment of Greg Madison as CEO on 1 June 2021.

Awards were granted to the CEO under the Retention and Performance Share Plan during the year. Further details of these awards is provided on page 40.

Looking forward to 2023

The CEO's bonus opportunity and share options award opportunity for 2023 are expected to be up to 75% of salary and 100% of salary respectively, with each award subject to the achievement of the full year performance conditions and pro-rated for length of service during the year.

Board changes

There have been no Board changes during the course of 2022.

Executive Directors' remuneration policy

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

Element and purpose	Operation	Maximum opportunity
Fixed remuneration		
Basic salary		
To provide a competitive base salary for the market and size of the Company in order to attract and retain Executive Directors of a suitable calibre.	Usually reviewed annually, taking account of: ▪ Salary increases awarded to the wider workforce; ▪ Group performance; ▪ Role and experience; ▪ Individual performance; and ▪ Competitive environment.	Salary increases will generally be in line with salary increases to other employees, but may be adjusted to take account of: ▪ Promotion; ▪ Change in scope of role; ▪ Realignment with the market; and ▪ Development and performance in role (for example, if a new Director is appointed on a salary which is increased over time to a market-competitive level).
Benefits		
To provide a competitive range of benefits as part of total remuneration.	Executive Directors currently receive: ▪ Private medical insurance.	No overall maximum has been set, but the level of benefits provided is determined taking into account the overall cost to the Company. Other benefits may be provided to reflect individual circumstances, such as relocation expenses.
Retirement benefits		
To provide an appropriate level of retirement benefit (or cash allowance equivalent).	Executive Directors are eligible to participate in the Group defined contribution pension scheme and/or the Company safe harbour 401(k) retirement plan with Transamerica.	Contributions for 2022 and 2023 have been set at 12% of salary.
Variable remuneration		
Annual bonus		
Rewards performance over the financial year, including in relation to performance which supports the Company's longer-term objectives.	Awards for Executive Directors are based on performance, measured over the year to which they relate, and split between financial, strategic and individual objectives. The measures and weightings are determined each year to reflect the Company's strategic priorities.	The bonus opportunity is up to 75% of base salary. The Remuneration Committee may in its discretion award a bonus higher or lower than the target bonus of 75%.
Retention and Performance Share Plan (RPSP)		
To create alignment between Executive Directors' and shareholders' interests through the delivery of performance-based awards or onboarding recruitment awards.	Awards are made in the form of nominal cost or market value share options. Vesting is subject to the achievement of specific performance conditions for performance awards or for remaining in office in relation to onboarding recruitment options. The plan is subject to malus and clawback provisions.	For performance awards, awards are made based on an assessment of the Executive Directors' performance and cover a twelve-month period from grant. Achievement of each objective entitles the recipient to a percentage of the total award. The Committee will review and set performance conditions for future awards. For retention awards, awards are made based on a percentage of salary at the date of grant and will vest in equal tranches over a three-year period providing the Executive Director remains in office, or is not under notice, as at the dates of vesting. For recruitment awards, awards are made based on a percentage of salary at the time of onboarding and will vest twelve to thirty-six months from grant provided the Executive Director remains in office, or is not under notice, at the date of vesting.

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 AGM.

Name	Position	Notice period	Notes
Greg Madison	CEO	6 months	
Hans Peter Hasler	NED (Chairman, Chair of Nomination Committee)	3 months	Subject to annual reappointment at AGM
Peter Llewellyn-Davies	NED (Chair of Audit Committee)	3 months	Subject to annual reappointment at AGM
Anders Lundstrom	NED (Chair of Remuneration Committee)	3 months	Subject to annual reappointment at AGM
Fabiana Lacerca-Allen	NED	3 months	Subject to annual reappointment at AGM
Dr Christian Schweiger	NED	3 months	Subject to annual reappointment at AGM

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

Peter Llewellyn-Davies is engaged under a letter of appointment dated 18 January 2022 with a term of three years.

Anders Lundstrom is engaged under a letter of appointment dated 10 May 2021 with a term of three years.

Fabiana Lacerca-Allen is engaged under a letter of appointment dated 10 May 2021 with a term of three years.

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

Directors' remuneration (audited)

The tables below detail the total remuneration received by each Director during 2022 and 2021.

Name	Salary/fees £000	Benefits £000	Bonus £000	Pensions £000	Total remuneration 2022 £000
Executive Directors					
Greg Madison	**406**	**—**	**223***	**49**	**678**
Non-Executive Directors					
Hans Peter Hasler	**103**	**—**	**—**	**—**	**103**
Peter Llewellyn-Davies	**32**	**—**	**—**	**—**	**32**
Christian Schweiger	**45**	**—**	**—**	**—**	**45**
Anders Lundstrom	**51**	**—**	**—**	**—**	**51**
Fabiana Lacerca-Allen	**45**	**—**	**—**	**—**	**45**
	682	**—**	**223**	**49**	**954**

* The Remuneration Committee approved a bonus of £178,400 in respect of the CEO's achievement of his 2021 corporate and personal objectives. The Remuneration Committee agreed with the CEO to delay payment of the bonus until after the completion of additional financing was secured. The Remuneration Committee agreed that an additional 25% £44,600 would be paid in compensation of delayed payment.

Directors' remuneration – year ended 31 December 2021

Name	Salary/fees £000	Benefits £000	Bonus £000	Pensions £000	Total remuneration 2021 £000
Executive Directors					
Greg Madison[(i)]	218	—	—	26	244
Tim Watts[(ii)]	233	—	83	27	343
Non-Executive Directors					
Hans Peter Hasler[(iii)]	120	—	—	—	120
Peter Llewellyn-Davies[(iii)]	58	—	—	—	58
Rolf Hoffmann[(iii)]	26	—	—	—	26
Dr Christian Schweiger[(iv)]	50	—	—	—	50
Anders Lundstrom[(v)]	30	—	—	—	30
Fabiana Lacerca-Allen[(vi)]	26	—	—	—	26
	761	—	83	53	897

(i) Greg Madison was appointed as a Director on 18 June 2021.

(ii) Tim Watts resigned on 30 September 2021.

(iii) The fees for Hans Peter Hasler, Peter Llewellyn-Davies, Rolf Hoffmann and Dr Christian Schweiger each include the additional £10k for 2021 described on page 39.

(iv) Anders Lundstrom was appointed on 10 May 2021.

(v) Fabiana Lacerca-Allen was appointed on 10 May 2021.

No Director waived any emoluments in respect of the year.

Retention and Performance Share Plan (RPSP) options granted in 2022 (audited)

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

The awards during 2022 included the following awards to the CEO.

Name	Number of options	Vesting date
Greg Madison (performance award)	2,596,058	By 08 August 2023
Greg Madison (retention award)	2,596,058	By 08 August 2025

As at 31 December 2022, Greg Madison held 5,812,812 options. No other Director holds any options. No amounts were paid on grant.

2022 annual bonus (audited)

The CEO was awarded a bonus of £329,000 in respect of 2022 which was paid in April of 2023. This award reflects an additional 6% granted in recognition of the CEO's achievements surrounding the Viatris partnership and fundraising.

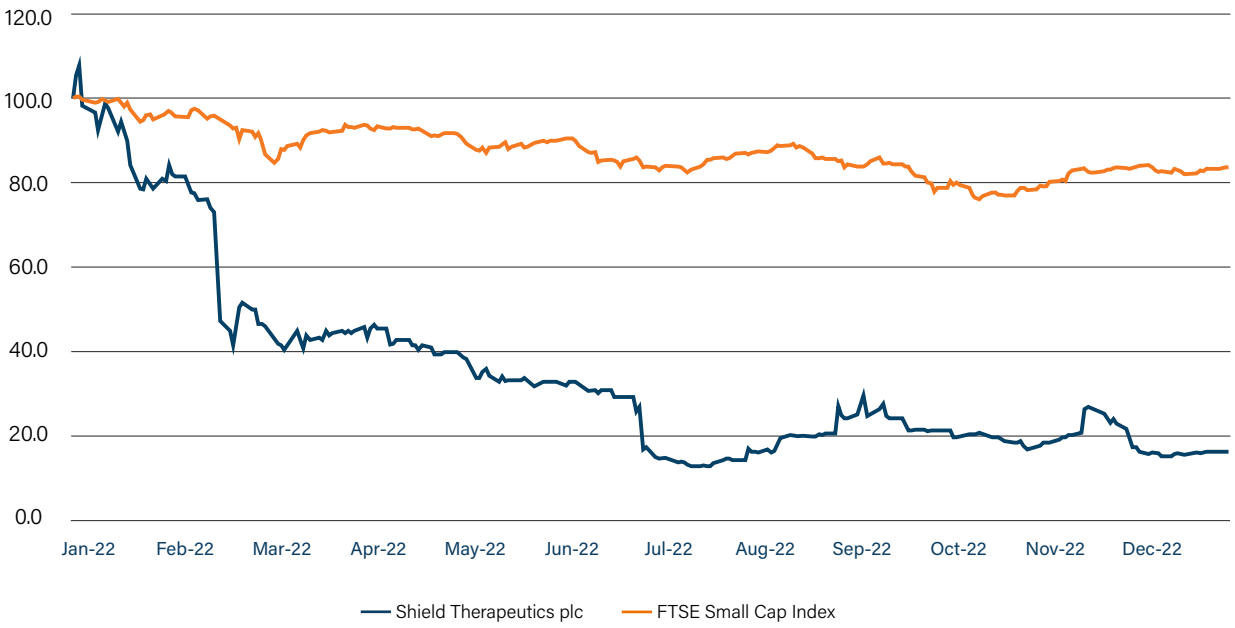
Directors' shareholdings

The table below discloses the interests of any Directors serving during the year in the shares of the Company at 31 December 2022.

Name	**Shares at 31 December 2022**	% of share capital	Shares at 31 December 2021	% of share capital
Greg Madison	**1,893,039**	0.32%	—	—
Dr Christian Schweiger	**11,651,713**	1.99%	5,665,580	2.62%
Hans Peter Hasler	**3,500,000**	0.60%	500,000	0.23%
Peter Llewellyn-Davies	**177,842**	<0.1%	20,000	0.00%
Fabiana Lacerca-Allen	**271,886**	<0.1%	—	—
Tim Watts	**—**	—	728,500	0.30%

Share performance graph

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



The mid-market price of the Ordinary Shares as at 31 December 2022 was £0.0705. The highest mid-market price of the Ordinary Shares during the year was £0.470 and the lowest price was £0.0560.

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

Anders Lundstrom
Remuneration Committee Chair
5 May 2023

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 2022.

Principal activities

Shield Therapeutics plc is a commercial stage specialty pharmaceutical company with a focus on addressing iron deficiency with its lead product Accrufer® (ferric maltol).

Strategic report

The strategic report is set out on pages 1 to 27. The Directors consider that the Annual Report and Accounts, taken as a whole, is fair, balanced and understandable.

Section 172 statement

Under Section 172 of the Companies Act 2006 the Directors have a duty to act in good faith in a way that is most likely to promote the success of the Company for the benefit of its members as a whole, having regard to the likely consequences of decisions for the long term, the interests of the Company's employees, the need to foster relationships with other key stakeholders, the impact on the community and the environment, maintaining a reputation for high standards of business conduct, and the need to act fairly between members of the Company.

Key decisions made by the Board during 2022 were related primarily to the commercialisation of Accrufer® in the US. This included:

- The exclusive, multi-year agreement with Viatris Inc. to co-commercialise Accrufer® (ferric maltol), in the United States;
- Loan agreement between the Company and AOP Health International Management for US$10 million; and
- The Placing and Subscription, completed in January 2023, which raised gross proceeds of c.US$18.5 million (c.£15.1 million).

Refer to page 18 for further information on stakeholder engagement and the discharge of Directors' duties.

Approximately 36.55% of the Company's shares are held by two investors. The Chief Executive Officer and other members of the Board communicate from time to time with these shareholders and have a good understanding of their interests. The Chief Executive Officer and other members of the Senior Executive Team meet regularly with other shareholders, both institutional and private, to explain and discuss the Group's strategy and objectives and to understand the interests of smaller shareholders in the Company. The Board recognises its responsibility to act fairly between all shareholders of the Company.

The Group employed between 22 and 27 staff during 2022. The Chief Executive Officer and the other members of the Senior Executive Team interact daily with all employees. Management has implemented employee policies and procedures which are appropriate for the size of the Group.

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

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

Future development

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

Capital structure

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

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

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

Results and dividend

The consolidated statement of profit and loss and other comprehensive income is set out on page 52. The Group's loss after taxation for the year was £40,444,000.

The Directors do not recommend the payment of a dividend in respect of the year ended 31 December 2022.

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

Hans Peter Hasler

Greg Madison

Peter Llewellyn-Davies

Dr Christian Schweiger

Fabiana Lacerca-Allen

Anders Lundstrom

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

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

Branches outside the U.K.
As at December 31, 2022, the Group consists of certain subsidiaries which are incorporated outside the United Kingdom. Further information can be found in of the financial statements. There are no branches of the Company outside the United Kingdom.

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

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

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

Post-balance sheet events
Further information on post-balance sheet events is provided in note 27 within the consolidated financial statements contained within this report.

Corporate governance report
The Company's corporate governance report can be found on pages 31 to 33 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:

AOP Orphan International AG	26.99%
Inventages	9.56%
Hargreaves Landsdown	5.8%

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.

Annual General Meeting
The AGM of the Company will be held at 2pm (BST) on 28 June 2023.

By order of the Board

Greg Madison
Chief Executive Officer
5 May 2023

Statement of Directors' responsibilities

in respect of the Annual Report and the financial statements

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

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

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

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

- Select suitable accounting policies and then apply them consistently;
- Make judgements and estimates that are reasonable, relevant and reliable;
- State whether they have been prepared in accordance with UK-adopted international accounting standards (UK-adopted IFRS);
- Assess the Group and parent company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern; and
- Use the going concern basis of accounting unless they either intend to liquidate the Group or the parent company or to cease operations, or have no realistic alternative but to do so.

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

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

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

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

By order of the Board

Greg Madison
Chief Executive Officer
5 May 2023

Independent auditor's report
to the members of Shield Therapeutics Plc

Opinion
We have audited the financial statements of Shield Therapeutics Plc (the 'parent company') and its subsidiaries (the 'group') for the year ended 31 December 2022 which comprise Consolidated statement of profit and loss and other comprehensive income, Group balance sheet, Company balance sheet, Group statement of changes in equity, Company statement of changes in equity, Group statement of cash flows, Company statement of cash flows and notes to the financial statements, including a summary of significant accounting policies. The financial reporting framework that has been applied in their preparation is applicable law and international accounting standards in conformity with the requirements of the Companies Act 2006 and as regards the group financial statements, international financial reporting standards adopted in the United Kingdom.

In our opinion, the financial statements have been prepared in accordance with the requirements of the Companies Act 2006 and:

- give a true and fair view of the state of the group's and of the parent company's affairs as at 31 December 2022 and of the group's loss for the year then ended;
- the group financial statements have been properly prepared in accordance with international accounting standards in conformity with the requirements of the Companies Act 2006 and international financial reporting standards adopted in the United Kingdom; and
- the parent company financial statements have been properly prepared in accordance with international accounting standards in conformity with the requirements of the Companies Act 2006, as applied in accordance with the provisions 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 under those standards are further described in the Auditor's responsibilities for the audit of the financial statements section of our report. We are independent of the company in accordance with the ethical requirements that are relevant to our audit of the financial statements in the UK, including the FRC's Ethical Standard, as applied to listed entities and public interest entities and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Conclusions relating to principal risks and going concern
We have nothing to report in respect of the following information in the annual report, in relation to which the ISAs (UK) require us to report to you whether we have anything material to add or draw attention to:

- the disclosures in the annual report set out on page 23 that describe the principal risks and explain how they are being managed or mitigated;
- the directors' confirmation set out on page 26–27 in the annual report 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 or liquidity;
- the directors' statement set out on page 44 and 57 in the financial statements about whether the directors considered it appropriate to adopt the going concern basis of accounting in repairing the financial statements and the directors' identification of any material uncertainties to the Group and the parent company's ability to continue to do so over a period of at least twelve months from the date of approval of the financial statements;
- whether the directors' statement relating to going concern is materially inconsistent with our knowledge obtained in the audit; or
- the directors' explanation set out on page 57 in the annual report as to how they have assessed the prospects of the group, over what period they have done so and why they consider 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.

Key audit matters
Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the financial statements of the current period and include the most significant assessed risks of material misstatement (whether or not due to fraud) we identified, 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.

We summarise below the key audit matters in forming our audit opinion above, together with an overview of the principal audit procedures performed to address each matter and, where relevant, key observations arising from those procedures. These matters, together with our findings, were communicated to those charged with governance through our Audit Completion Report.

Recoverability of intangible assets

The Group's cash generating unit (CGU) primarily includes intangible assets of £11.7 million (2021: £26.9 million) relating to the Group's drugs (Accrufer®/Feraccru® and PT20). These intangible assets require impairment assessments in line with the requirements of IAS 36. The recoverability of the Parent Company's investment in subsidiaries is also covered by these asset impairment assessments as explained under 'Recoverability of investments in subsidiaries and intercompany receivables' below.

Determining the recoverable amount of the Group's CGUs under IAS 36 involves making judgement and estimates about future cash flows, and use of assumptions such as discount rate and growth rate. The Group's projected cash flows include future royalties, forecast sales and other income from current or prospective licensees and outflows of the estimated costs to progress the commercialisation of these assets.

Management performed an impairment assessment at year end which resulted in an impairment loss of £14.7m relating to the Phosphate Therapeutic intangible assets. Management also performed a value in use (VIU) calculation for the Group's remaining CGU primarily relating to Accrufer®/Feraccru® which revealed that no further was impairment required.

Refer to the accounting policies included within note 2 to the financial statements and the disclosures included within note 14.

Our audit response included:

- Reviewing the appropriateness of management's impairment assessment in line with IAS 36 requirements.
- Challenging the appropriateness of management's forecast and related assumptions based on our knowledge of the industry and by considering contradictory evidence.
- Checking the mathematical accuracy of management's value in use calculation.
- Involving our internal expert in reviewing and challenging the discount rate applied by management.
- Performing sensitivity on management's cash flow forecast.
- Reviewing the appropriateness of the financial statement disclosures.

Our observations

Based on the results of our audit procedures, we are satisfied with the valuation of the Group's intangible assets and related financial statements disclosures. Furthermore, the discount rate applied of 15% is within our acceptable range for similar businesses in the industry.

Recoverability of investments in subsidiaries and intercompany receivables (relevant to parent company only)

The parent company has receivables from subsidiaries and investments in subsidiaries amounting to £77.3 million (2021: £60.1 million) and £79.0 million (2021: £105.3 million) respectively at year end. These subsidiaries are currently in a loss-making position and during the year, an impairment loss of £26.8 million was recognised in respect of the investment held in Phosphate Therapeutics Limited.

Determining the recoverable amount of these balances depends on value in use calculations as explained under 'Recoverability of intangible assets' above and involves inherent uncertainty in forecasting and discounting future cash flows.

Refer to the accounting policies included within note 2 to the financial statements and the disclosures included within notes 14 and 16.

Our audit response included:

- Comparing the carrying value of investments with the relevant subsidiaries' net assets to identify whether their net assets, approximating their minimum recoverable amount, were in excess of their carrying amounts and covered the debt owed.
- Challenging management's discounted cash flows as explained under 'Recoverability of intangible assets' above.
- Assessing compliance with the requirements of IFRS 9 in relation to expected credit losses on intercompany receivables.
- Evaluating the non-current classification of intercompany receivables in the financial statements.

Our observations

Based on our audit procedures, we are satisfied on the recoverability of the parent company's investments and receivables from subsidiaries.

Valuation of share based payments

The Group operates share-based option schemes which are highly material to the Group's financial statements. Share based payment charge for the year amounted to £0.7 million (2021: £1.0 million).

Determining the fair value of shared-based options under IFRS 2 share-based payments involves the use of complex valuation models, techniques and use of judgements that may result in material misstatements in the financial statements. The accounting standard also requires extensive financial statements disclosures of the Group's share-based payment options.

Refer to the accounting policies included within note 2 to the financial statements and the disclosures included within note 23.

Our audit response included:

- Reviewing the share option scheme papers and option grant contracts to understand and challenge the classification of the Group's share option scheme as equity settled.
- With the assistance of our internal expert, challenging management's valuation of unvested share options including the model, inputs and assumptions in line with the accounting standard.
- Evaluating the financial statement disclosures on share-based payments.

Our observations

The Group's share-based payment options have been valued and disclosed in accordance with the relevant accounting standards.

Our application of materiality

The scope of our audit was influenced by our application of materiality. We set certain quantitative thresholds for materiality. These, together with qualitative considerations, helped us to determine the scope of our audit and the nature, timing and extent of our audit procedures on the individual financial statement line items and disclosures and in evaluating the effect of misstatements, both individually and on the financial statements as a whole. Based on our professional judgement, we determined materiality for the financial statements as follows:

	Group materiality	Parent company materiality
Overall materiality	£221,000	£38,000
How we determined it	We determined overall materiality for the group by applying a benchmark corresponding to 1% of group's total assets.	We determined overall materiality for the group using a benchmark of 1% of total assets, capped at 60% of group materiality.
Rationale for benchmark applied	We have considered total assets to be the critical component for determining materiality given the group's focus on continued growth through its intangible asset portfolio, therefore this is considered most relevant measure of the underlying positions of both the group and parent company.	
Performance materiality	Performance materiality is set to reduce to an appropriately low level the probability that the aggregate of uncorrected and undetected misstatements in the financial statements exceeds materiality for the financial statements as a whole. Based on our risk and internal control assessments including considerations applicable to first-year audit, we have set: ▪ the group's performance materiality at £110,000, representing approximately 50% of our overall materiality. ▪ the parent company's performance materiality at £19,000, representing 50% of the parent company's overall materiality.	
Reporting threshold	We agreed with the Audit Committee that we would report to them misstatements identified during our audit above £7,000 as well as misstatements below that amount that, in our view, warranted reporting for qualitative reasons. In relation to the parent company, the reporting threshold applied was £1,000 as well as misstatements below that amount that, in our view, warranted reporting for qualitative reasons.	

An overview of the scope of our audit, including extent to which the audit was considered capable of detecting irregularities, including fraud

As part of designing our audit, we determined materiality and assessed the risk of material misstatement in the financial statements, whether due to fraud or error, and then designed and performed audit procedures responsive to those risks. In particular, we looked at where the directors made subjective judgements such as making assumptions on significant accounting estimates. We tailored the scope of our audit to ensure that we performed sufficient work to be able to give an opinion on the financial statements as a whole. We used the outputs of a risk assessment, our understanding of the group and parent company, its environment, controls and critical business processes, to consider qualitative factors in order to ensure that we obtained sufficient coverage across all financial statement line items.

Our audit procedures were designed to respond to those identified risks, including non-compliance with laws and regulations (irregularities) and fraud that are material to the financial statements. In identifying and assessing risks of material misstatement in respect to irregularities including non-compliance with laws and regulations, our procedures included but were not limited to:

- at planning stage, we gained an understanding of the legal and regulatory framework applicable to the group and parent company, the industry in which it operates and considered the risk of acts by the Group and Parent Company which were contrary to the applicable laws and regulations;
- we discussed with the directors the policies and procedures in place regarding compliance with laws and regulations;
- we discussed amongst the engagement team the identified laws and regulations, and remained alert to any indications of non-compliance; and
- during the audit, we focused on areas of laws and regulations that could reasonably be expected to have a material effect on the financial statements from our general commercial and sector experience and through discussions with the directors (as required by auditing standards), from inspection of the parent company's and group's regulatory and legal correspondence and review of minutes of directors' meetings in the year.

Our procedures in relation to fraud included but were not limited to:

- inquiries of management and those charged with governance whether they have knowledge of any actual, suspected or alleged fraud;
- gaining an understanding of the internal controls established to mitigate risk related to fraud;
- discussion amongst the engagement team regarding risk of fraud such as opportunities for fraudulent manipulation of financial statements, and determined that the principal risks were related to posting manual journal entries to manipulate financial performance, management bias through judgements and assumptions in significant accounting estimates and significant one-off or unusual transactions; and
- addressing the risk of fraud through management override of controls by performing journal entry testing.

The primary responsibility for the prevention and detection of irregularities including fraud rests with both those charged with governance and management. As with any audit, there remained a risk of non-detection of irregularities, as these may involve collusion, forgery, intentional omissions, misrepresentations or the override of internal controls.

As a result of our procedures, we did not identify any "Key audit matters" relating to irregularities. The risks of material misstatement that had the greatest effect on our audit, including fraud, are discussed under "Key audit matters" within this report.

Other information

The directors are responsible for the other information. The other information comprises the information included in the annual report, other than the financial statements and our auditor's report thereon. Our opinion on the financial statements does not cover the other information and, except to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements, or our knowledge obtained in the audit or otherwise appears to be materially misstated. If we identify such material inconsistencies or apparent material misstatements, we are required to determine whether there is a material misstatement in the financial statements or a material misstatement of the other information. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact.

We have nothing to report in this regard.

Opinions on other matters prescribed by the Companies Act 2006

In our opinion, the part of the directors' remuneration report to be audited has been properly prepared in accordance with the Companies Act 2006.

In our opinion, based on the work undertaken during the audit the information given in the Strategic Report and the Directors' Report for the financial year for which the financial statements are prepared is consistent with the financial statements and those reports have been prepared in accordance with applicable legal requirements.

Matters on which we are required to report by exception

In light of the knowledge and understanding of the group and the parent company and its environment obtained in the course of the audit, we have not identified material misstatements in the Strategic Report or the Directors' Report.

We have nothing to report in respect of the following matters in relation to which the Companies Act 2006 requires us 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 and the part of the directors' remuneration report to be audited 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.

Responsibilities of Directors

As explained more fully in the directors' responsibilities statement set out on page 44, the directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view, and for such internal control as the directors determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the directors are responsible for assessing the group's and the 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 the directors 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 for the audit of the financial statements

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 an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a 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 the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

A further description of our responsibilities for the audit of the financial statements is located on the Financial Reporting Council's website at www.frc.org.uk/auditorsresponsibilities. This description forms part of our auditor's report.

Other matters which we are required to address

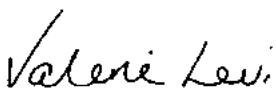
Following the recommendation of the Audit Committee, we were appointed by the shareholders of the group on 24 January 2023 to audit the financial statements for the year ended 31 December 2022 and subsequent financial periods. The period of total uninterrupted engagement is 1 year, covering the year ending 31 December 2022.

The non-audit services prohibited by the FRC's Ethical Standard were not provided to the group or the parent company and we remain independent of the group and the parent company in conducting our audit.

Our audit opinion is consistent with the additional report to the Audit Committee.

Use of the audit report

This report is made solely to the parent 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 parent 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 parent company and the parent company's members as a body for our audit work, for this report, or for the opinions we have formed.



Valerie Levi (Senior Statutory Auditor) for and on behalf of Mazars LLP
Statutory Auditor
One St Peter's Square
Manchester
M2 3DE

5 May 2023

Consolidated statement of profit and loss and other comprehensive income

for the year ended 31 December 2022

	Notes	2022 £000	2021 (Restated)[1] £000
Revenue	5	**4,467**	1,519
Cost of sales		**(2,470)**	(980)
Gross profit		**1,997**	539
Other operating income		**700**	111
Operating costs – selling, general and administrative expenses	7	**(27,331)**	(20,150)
Operating loss before impairment and research and development expenditure		**(24,634)**	(19,500)
Impairment of intangible assets	13	**(14,708)**	—
Research and development expenditure	6	**(1,072)**	(794)
Operating loss		**(40,414)**	(20,294)
Financial income	9	**721**	395
Financial expense	9	**(389)**	(8)
Loss before tax		**(40,082)**	(19,907)
Taxation	11	**(362)**	229
Loss for the year		**(40,444)**	(19,678)
Other comprehensive income			
Items that are or may be reclassified subsequently to profit or loss:			
Foreign currency translation differences – foreign operations		**2,186**	1,396
Total comprehensive expenditure for the year		**(38,258)**	(18,282)
Loss per share			
Basic and diluted loss per share (in pence)	10	**(17)**	(10)

1 More information is detailed in Note 28 to the financial statements.

The notes on pages 57 to 77 are an integral part of these consolidated financial statements.

Group balance sheet

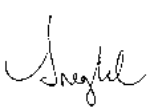
at 31 December 2022

	Notes	2022 £000	2021 (Restated)[1] £000
Non-current assets			
Intangible assets	13	**11,783**	26,851
Property, plant and equipment	12	**197**	304
		11,980	27,155
Current assets			
Inventories	15	**1,457**	1,635
Trade and other receivables	16	**5,380**	2,929
Current tax asset	11	**436**	576
Cash and cash equivalents	17	**2,821**	12,117
		10,094	17,257
Total assets		**22,074**	44,412
Non-current liabilities			
Convertible shareholder loan	20	**(5,542)**	—
Fair value of loan conversion feature	20	**(466)**	—
		(6,008)	—
Current liabilities			
Trade and other payables	18	**(9,489)**	(3,455)
Other liabilities	19	**(1,061)**	(110)
Lease liabilities	24	**(89)**	(156)
		(10,639)	(3,721)
Total liabilities		**(16,647)**	(3,721)
Net assets		**5,427**	40,691
Equity			
Share capital	21	**(3,891)**	(3,238)
Share premium	22	**(116,263)**	(114,583)
Merger reserve	22	**(28,358)**	(28,358)
Currency translation reserve	22	**(3,635)**	(1,449)
Deposit for shares	22	**82**	—
Accumulated deficit	22	**146,638**	106,937
Total equity		**(5,427)**	(40,691)

1 More information is detailed in Note 28 to the financial statements.

The notes on pages 57 to 77 are an integral part of these consolidated financial statements.

These financial statements were approved by the Board of Directors on 5 May 2023 and were signed on its behalf by:



Greg Madison
Director
Company registered number: 09761509

Company balance sheet

at 31 December 2022

	Notes	2022 £000	2021 (Restated)[1] £000
Non-current assets			
Investments in subsidiaries	14	**78,984**	105,285
Trade and other receivables	16	**77,352**	60,088
		156,336	165,373
Current assets			
Trade and other receivables	16	**296**	69
Cash and cash equivalents	17	**309**	10,559
		605	10,628
Total assets		**156,941**	176,001
Non-current liabilities			
Convertible shareholder loan	20	**(5,542)**	—
Fair value of loan conversion feature	20	**(466)**	—
		(6,008)	—
Current liabilities			
Trade and other payables	18	**(1,465)**	(649)
Other liabilities	19	**(368)**	(3)
		(1,833)	(652)
Total liabilities		**(7,841)**	(652)
Net assets		**149,100**	175,349
Equity			
Share capital	21	**(3,891)**	(3,238)
Share premium	22	**(116,263)**	(114,583)
Merger reserve	22	**(117,323)**	(117,323)
Deposit for shares	22	**82**	—
Accumulated deficit	22	**88,295**	59,795
Total equity		**(149,100)**	(175,349)

1 More information is detailed in Note 28 to the financial statements.

The notes on pages 57 to 77 are an integral part of these financial statements.

The parent company's loss for the year was £29,243k (FY2021: £1,060k). These financial statements were approved by the Board of Directors on 5 May 2023 and were signed on its behalf by:

Greg Madison
Director
Company registered number: 09761509

Group statement of changes in equity

for the year ended 31 December 2022

	Issued capital £000	Deposit for shares £000	Share premium £000	Merger reserve £000	Currency translation reserve £000	Accumulated deficit £000	Total £000
Balance at 1 January 2021	1,764	—	88,352	28,358	53	(88,251)	30,276
Loss for the year (Restated)[1]	—	—	—	—	—	(19,678)	(19,678)
Other comprehensive income:							
Foreign currency translation differences	—	—	—	—	1,396	—	1,396
Total comprehensive expense for the year	—	—	—	—	1,396	(19,678)	(18,282)
Transactions with owners, recorded directly in equity							
Equity placing – new shares issued	1,459	—	26,220	—	—	—	27,679
Equity-settled share-based payment transactions	15	—	11	—	—	992	1,018
Balance at 31 December 2021	3,238	—	114,583	28,358	1,449	(106,937)	40,691
Loss for the year	—	—	—	—	—	(40,444)	(40,444)
Other comprehensive income:							
Foreign currency translation differences	—	—	—	—	2,186	—	2,186
Total comprehensive expense for the year	—	—	—	—	2,186	(40,444)	(38,258)
Transactions with owners, recorded directly in equity							
Share options exercised	35	—	52	—	—	—	87
Loan conversion	618	—	1,628	—	—	—	2,246
Deposit for shares	—	(82)	—	—	—	—	(82)
Equity-settled share-based payment transactions	—	—	—	—	—	743	743
Balance at 31 December 2022	**3,891**	**(82)**	**116,263**	**28,358**	**3,635**	**(146,638)**	**5,427**

1 More information is detailed in Note 28 to the financial statements.

The notes on pages 57 to 77 are an integral part of these consolidated financial statements.

Company statement of changes in equity

for the year ended 31 December 2022

	Issued capital £000	Deposit for shares £000	Share premium £000	Merger reserve £000	Retained earnings £000	Total £000
Balance at 1 January 2021	1,764	—	88,352	117,323	(59,732)	147,707
Loss for the year (Restated)[1]	—	—	—	—	(1,060)	(1,060)
Total comprehensive expense for the year	—	—	—	—	(1,060)	(1,060)
Transactions with owners, recorded directly in equity						
Share options exercised	15	—	11	—	—	26
Equity placing – new share issued	1,459	—	26,220	—	—	27,679
Equity-settled share-based payment transactions	—	—	—	—	997	997
Balance at 31 December 2021	3,238	—	114,583	117,323	(59,795)	175,349
Loss for the year	—	—	—	—	(29,243)	(29,243)
Total comprehensive expense for the year	—	—	—	—	(29,243)	(29,243)
Transactions with owners, recorded directly in equity						
Share options exercised	35	—	52	—	—	87
Loan conversion	618	—	1,628	—	—	2,246
Deposit for shares	—	(82)	—	—	—	(82)
Equity-settled share-based payment transactions	—	—	—	—	743	743
Balance at 31 December 2022	**3,891**	**(82)**	**116,263**	**117,323**	**(88,295)**	**149,100**

1 More information is detailed in Note 28 to the financial statements.

The notes on pages 57 to 77 are an integral part of these financial statements.

Group statement of cash flows

for the year ended 31 December 2022

	Notes	2022 £000	2021 (Restated)[1] £000
Cash flows from operating activities			
Loss for the year		**(40,444)**	(19,678)
Adjustments for:			
Depreciation and amortisation		**2,362**	2,207
Equity-settled share-based payment expenses		**743**	992
Financial income		**(721)**	(395)
Financial expense	9	**389**	42
Impairment of intangible assets	13	**14,708**	—
Income tax		**362**	(229)
		(22,601)	(17,061)
Decrease/(increase) in inventories		**178**	(256)
Increase in trade and other receivables		**(2,311)**	(2,879)
Increase in trade and other payables		**6,030**	1,985
Increase/(decrease) in other liabilities		**1,047**	(643)
Income tax (paid)/received		**(354)**	592
Fair value of conversion option		**699**	—
Net cash flows from operating activities		**(17,312)**	(18,262)
Cash flows from investing activities			
Financial income	9	**30**	13
Additions to intangible assets	13	**—**	(9)
Additions to tangible assets	12	**(53)**	(372)
Capitalised development expenditure	13	**(1,842)**	(1,683)
Net cash flows from investing activities		**(1,865)**	(2,051)
Cash flows from financing activities			
Interest paid		**(334)**	(42)
Leases – interest payment	24	**(4)**	(3)
Change in lease assets and liabilities (new leased assets)		**(63)**	128
Proceeds from equity raise		**—**	27,679
Proceeds from convertible shareholder loan	20	**7,529**	—
Deposit for shares		**(82)**	—
Proceeds of share options exercised		**87**	26
Total cash outflow for leases	24	**(126)**	(76)
Net cash flows from financing activities		**7,007**	27,712
Net (decrease)/increase in cash		**(12,170)**	7,399
Effect of foreign exchange differences		**2,874**	1,778
Cash and cash equivalents at 1 January		**12,117**	2,940
Cash and cash equivalents at 31 December		**2,821**	12,117

1 More information is detailed in Note 28 to the financial statements.

The notes on pages 57 to 77 are an integral part of these consolidated financial statements.

Company statement of cash flows

for the year ended 31 December 2022

	Notes	2022 £000	2021 (Restated)[1] £000
Cash flows from operating activities			
Loss for the year		**(29,243)**	(1,060)
Adjustments for:			
Equity-settled share-based payment expenses		**280**	442
Impairment of investments in subsidiaries	14	**26,764**	—
Financial income		**(1,700)**	(895)
Financial expense		**56**	—
		(3,843)	(1,513)
Increase in trade and other receivables		**(321)**	(30)
Increase in trade and other payables		**1,308**	377
Net cash flows from operating activities		**(2,856)**	(1,166)
Cash flows from investing activities			
Financial income received		**876**	497
Repayment of loans to Group undertakings		**—**	1,486
Loans made to Group undertakings		**(17,170)**	(20,102)
Net cash flows from investing activities		**(16,294)**	(18,119)
Cash flows from financing activities			
Proceeds of share option exercise		**87**	26
Proceeds from shareholder loan	20	**8,228**	—
Deposit for shares		**(82)**	—
Proceeds from equity raise		**—**	27,679
Net cash flows from financing activities		**8,233**	27,705
Net (decrease)/increase in cash		**(10,917)**	8,420
Effect of exchange rate fluctuations on cash held		**667**	398
Cash and cash equivalents at 1 January		**10,559**	1,741
Cash and cash equivalents at 31 December		**309**	10,559

1 More information is detailed in Note 28 to the financial statements.

The notes on pages 57 to 77 are an integral part of these financial statements.

Notes (forming part of the financial statements)
for the year ended 31 December 2022

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.

These consolidated financial statements comprise the Company and its subsidiaries (together referred to as the 'Group'). The Group is engaged in the late-stage development and commercialisation of clinical stage pharmaceuticals to treat unmet medical needs.

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

2. Accounting policies
The consolidated and parent company financial statements have been prepared and approved by the Directors in accordance with UK-adopted international accounting standards (UK-adopted IFRS).

The accounting policies set out below have been applied consistently to all periods presented in these financial statements. The financial statements are prepared on the historic cost basis, except for the loan conversion feature which is held at 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 £29.2 million. The total comprehensive expenditure for the year comprises the net loss and is wholly attributable to the equity holders of Shield Therapeutics plc; therefore, no statement of comprehensive income has been disclosed.

Basis of preparation
Going concern
At 31 December 2022, the Group held £2.8 million in cash. On 5 January 2023, the Company's shareholders approved an equity fundraise which raised £16.4 million net of expenses. Additionally, on 12 January 2023, the Company drew £8.2 million (or US$10 million) on the convertible shareholder loan with AOP Health International Management AG (AOP) in accordance with an amendment of the original loan agreement, dated 1 August 2022. That amendment was executed on 12 December 2022. The Group's unaudited cash balance at 31 March 2023 was £19.2 million.

The Group is planning to use these funds to drive continuing growth in sales volumes of Accrufer® in the US. The Directors have considered the funding requirements of the Group through the preparation of detailed cash flow forecasts for the period to December 2024, including the prospective Accrufer® sales revenues and the related commercial operating costs. These forecasts show that the Group's monthly cash flows start to turn positive by the end of 2024 and that the recent fundraise should provide sufficient cash to allow the business to continue in operations for at least twelve months from the balance sheet date. The Directors have considered scenarios in which sales revenues fall below base case forecasts. In these circumstances mitigating actions such as reduction of discretionary selling and marketing expenditure could be taken to preserve cash. The Directors also believe that other forms of finance, such as debt finance or royalty finance are likely to be available to the Group.

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

Basis of consolidation
The consolidated financial statements comprise the financial statements of the Group and its subsidiaries as at 31 December 2022.

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

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

2. Accounting policies continued

Foreign currency

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

Revenue

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

The co-promote arrangement with Viatris has been assessed as a collaborative sales agreement whereby both parties are actively involved in the commercial success and both parties are exposed to significant risks and rewards dependent on the commercial success of the activity. Since the related activities are performed by the two parties and not by a separate legal entity, the revenues and costs incurred in connection with this arrangement will be presented in accordance with the principal/agent guidance in IFRS 15, whereby the Group is the principal for the related sales transactions and therefore presents 100% of the net product revenue in the consolidated statement of profit and loss and other comprehensive income. Viatris' net revenue share is recorded within cost of sales.

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

- Execution of the licence – revenue from both contracts was recognised at the time when the partner can use and obtain the benefits associated with the respective license;
- Event-based milestones such as completion of the paediatric clinical study, approval of the product in China and the achievement of sales thresholds – these comprise variable consideration and, as such, revenue is only recognised when it is highly probable that such revenue will not be reversed in future. No revenue has been recognised in respect of these milestones in either 2022 or 2021; and
- Sales-based royalties – these are attributable to the licence and revenue is recognised when sales occur.

Revenue also arises from sales within the US. We sold Accrufer® through exclusive distributions agreements with third-party logistics companies, or 3PLs, that took title to Accrufer®. They then distributed Accrufer® to a specialty pharmacy and a specialty distributor, which we collectively refer to as wholesalers, who then distributed Accrufer® to HCPs and patients.

We recognised Accrufer® commercial revenue in the period when our customer (3PLs) obtained control of our products, which occurred at a point in time upon transfer of title to the customer.

We recorded Accrufer® commercial revenue at our net sales price. We included in our transaction price estimated reserves for discounts, returns, chargebacks, rebates and other allowances that we offered within contracts between us and our customers, wholesales, distributors, HCPs and other indirect customers.

Cost of sales

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

The cost of manufacturing product is the cost incurred with contract manufacturing organisations who manufacture the product on behalf of the Group. Under the APA, Vitra has the right to receive a 5% royalty on net sales of products falling within the scope of the acquired intellectual property.

Research and development

Research expenditure is charged to the consolidated statement of profit and loss and other comprehensive income in the period in which it is incurred.

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

2. Accounting policies continued

Employee benefit costs

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

Share-based payments

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

Finance income and costs

Finance income and costs comprise interest income and interest payable during the year and foreign exchange gains and losses arising on cash balances held in currencies other than GBP.

Taxation

Income tax expense comprises current and deferred tax. Income tax expense is recognised in the consolidated statement of profit or loss and comprehensive income except to the extent that it relates to items recognised directly in equity or in other comprehensive income. Current income tax assets (including research and development income tax credit) and liabilities for the current and prior periods are measured at the amount expected to be recovered from, or paid to, the tax authorities. The tax rates and tax laws used to compute the amount are those that are enacted or substantively enacted by the reporting date. Deferred income tax is recognised on all temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the financial statements with the following exceptions: where the temporary difference arises from the initial recognition of goodwill or of an asset or liability in a transaction that is not a business combination that at the time of the transaction affects neither accounting nor taxable profit or loss; and in respect of taxable temporary differences associated with investments in subsidiaries where the timing of the reversal of the temporary differences can be controlled and it is probable that the temporary differences will not reverse in the foreseeable future.

Deferred income tax assets and liabilities are measured on an undiscounted basis using the tax rates and tax laws that have been enacted or substantively enacted by the balance sheet date and which are expected to apply when the related deferred tax asset is realised or the deferred tax liability is settled. Deferred income tax assets are recognised to the extent that it is probable that future taxable profits will be available against which differences can be utilised. An asset is not recognised to the extent that the transfer of economic benefits in the future is uncertain. Deferred income tax assets and liabilities are offset only if a legally enforceable right exists to set off current tax assets against current tax liabilities, the deferred income taxes relate to the same taxation authority and that authority permits the group to make a single payment.

Intangible assets

Intellectual property and in-process research and development acquired through business combinations are recognised as intangible assets at fair value. Other acquired intangible assets are initially recognised at cost. Expenditure incurred on development projects is recognised as an intangible asset when it is probable that the project will generate future economic benefits, considering factors including its commercial and technological feasibility, status of regulatory approval, and the ability to measure costs reliably. Development expenditure which has been capitalised and has a finite useful life is amortised from the commencement of the commercial production of the product on a straight-line basis over the period of its expected benefit.

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

Amortisation is charged as follows:

Patents, trademarks and development costs	– over the term of the patents (currently until 2029–2035)
Intellectual property purchase costs	– over the term of the patents

Within the statement of comprehensive income amortisation is included within the operating costs.

2. Accounting policies continued

Impairment of non-financial assets excluding inventories and deferred tax assets

The carrying amounts of the Group's non-financial assets, other than inventories and deferred tax assets, are reviewed at each reporting date to determine whether there is any indication of impairment. If any such indication exists, then the asset's recoverable amount is estimated. For goodwill, and intangible assets that have indefinite useful lives or that are not yet available for use, the recoverable amount is estimated each year at the same time.

The recoverable amount of an asset or cash-generating unit is the greater of its value in use and its fair value less costs to sell. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. For the purpose of impairment testing, assets that cannot be tested individually are grouped together into the smallest group of assets that generates cash inflows from continuing use that are largely independent of the cash inflows of other assets or groups of assets (the "cash-generating unit"). The goodwill acquired in a business combination, for the purpose of impairment testing, is allocated to cash-generating units, or ("CGU"). Subject to an operating segment ceiling test, for the purposes of goodwill impairment testing, CGUs to which goodwill has been allocated are aggregated so that the level at which impairment is tested reflects the lowest level at which goodwill is monitored for internal reporting purposes. Goodwill acquired in a business combination is allocated to groups of CGUs that are expected to benefit from the synergies of the combination.

An impairment loss is recognised if the carrying amount of an asset or its CGU exceeds its estimated recoverable amount. Impairment losses are recognised in profit or loss. Impairment losses recognised in respect of CGUs are allocated first to reduce the carrying amount of any goodwill allocated to the units, and then to reduce the carrying amounts of the other assets in the unit (group of units) on a pro rata basis.

An impairment loss in respect of goodwill is not reversed. In respect of other assets, impairment losses recognised in prior periods are assessed at each reporting date for any indications that the loss has decreased or no longer exists. An impairment loss is reversed if there has been a change in the estimates used to determine the recoverable amount. An impairment loss is reversed only to the extent that the asset's carrying amount does not exceed the carrying amount that would have been determined, net of depreciation or amortisation, if no impairment loss had been recognised.

Property, plant and equipment

Purchased property, plant and equipment is stated at historical cost less depreciation. The cost of property, plant and equipment includes the purchase price and any costs directly attributable to bringing it into working order.

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

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

Depreciation on leased property is charged over the lower of the lease term or the useful life of the asset.

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 to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount.

Leases

At inception of a contract, the Group assesses whether a contract is, or contains, a lease. A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

The Group has not entered into any contracts where it acts as a lessor.

When acting as a lessee, at commencement or on modification of a contract that contains a lease component, the Group allocates the consideration in the contract to each lease component on the basis of its relative stand-alone prices. However, for the leases of property the Group elected not to separate non-lease components and account for these lease and non-lease components as a single lease component.

The Group recognises a right-of-use asset and a lease liability at the lease commencement date. The right-of-use asset is initially measured at cost, which comprises the initial amount of the lease liability adjusted for any lease payments made at or before the commencement date, plus any initial direct costs incurred and an estimate of costs to dismantle and remove the underlying asset or to restore the underlying asset or the site on which it is located, less any lease incentives received.

2. Accounting policies continued

Leases continued

The right-of-use asset is subsequently depreciated using the straight-line method from the commencement date to the end of the lease term, unless the lease transfers ownership of the underlying asset to the Group by the end of the lease term or the cost of the right-of-use asset reflects that the Group will exercise a purchase option. In that case the right-of-use asset will be depreciated over the useful life of the underlying asset, which is determined on the same basis as those of property and equipment. In addition, the right-of-use asset is periodically reduced by the impairment losses, if any, and adjusted for certain remeasurements of the lease liability.

The lease liability is initially measured at the present value of the lease payments that are not paid at the commencement date, discounted using the interest rate implicit in the lease or, if that rate cannot be readily determined, the Group's incremental borrowing rate. Generally, the Group uses its incremental borrowing rate as the discount rate.

The Group determines its incremental borrowing rate by obtaining interest rates from various external financing sources and makes certain adjustments to reflect the terms of the lease type of the asset leased.

Lease payments included in the measurement of the lease liability comprise the following:

- fixed payments, including in-substance fixed payments;
- variable lease payments that depend on an index or a rate, initially measured using the index or rate as at the commencement date;
- amounts expected to be payable under a residual value guarantee; and
- the exercise price under a purchase option that the Group is reasonably certain to exercise, lease payments in an optional renewal period if the Group is reasonably certain to exercise an extension option, and penalties for early termination of a lease unless the Group is reasonably certain not to terminate early.

The lease liability is measured at amortised cost using the effective interest method. It is remeasured when there is a change in future lease payments arising from a change in an index or rate, if there is a change in the Group's estimate of the amount expected to be payable under a residual value guarantee, if the Group changes its assessment of whether it will exercise a purchase, extension or termination option or if there is a revised in-substance fixed lease payment.

When the lease liability is remeasured in this way, a corresponding adjustment is made to the carrying amount of the right-of-use asset, or is recorded in profit or loss if the carrying amount of the right-of-use asset has been reduced to zero.

From 1 January 2021, where the basis for determining future lease payments changed as required by interest rate benchmark reform, the Group remeasures the lease liability by discounting the revised lease payments using the revised discount rate that reflects the change to an alternative benchmark interest rate.

The Group presents right-of-use assets that do not meet the definition of investment property in "property, plant and equipment" and lease liabilities in "loans and borrowings" in the statement of financial position.

The Group has elected not to recognise right-of-use assets and lease liabilities for leases of low-value assets and short-term leases, including IT equipment. The Group recognises the lease payments associated with these leases as an expense on a straight-line basis over the lease term.

Investments in subsidiaries

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

Inventories

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

2. Accounting policies continued

Financial assets and liabilities

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

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

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

Financial liabilities are classified as measured at amortised cost or fair value through profit and loss (FVTPL). A financial liability is classified as 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.

Derivatives are recognised initially at fair value at the date a derivative contract is entered into and are subsequently remeasured to their fair value at each reporting date. The resulting gain or loss is recognised in profit or loss immediately unless the derivative is designated and effective as a hedging instrument, in which event the timing of the recognition is profit or loss depends on the nature of the hedge relationship.

3. Estimates and judgments

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

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

Judgment in determining the recognition of upfront payment received from co-promote arrangement

The Group entered into a multi-year arrangement with Viatris to co-commercialise its lead product, Accrufer® (ferric maltol), in the United States. Upon execution of this agreement, the Group received a one-time, non-refundable, upfront payment in the amount of £4.2 million (or US$5.0 million). This upfront payments serves as compensation for expenditure, which the Group incurs to expand and prepare its operating functions and processes for the combined commercial activities. An amount of £0.7 million (or US$0.8 million), equal to such costs spent during 2022, has been recorded within other income of the consolidated statement of profit and loss and other comprehensive income for the year ended 31 December 2022 and not as revenue because judgement has been applied in determining that this income is outside the scope of IFRS 15. The balance of £3.5 million (or US$4.2 million) is expected to be recognised in the year ended 31 December 2023.

Judgment in determining the carrying amount of share-based payments

Fair values used in calculating the amount to be expensed as a share-based payment is subject to a level of uncertainty. The Group is required to calculate the fair value of the cash-settled instruments granted to employees in terms of the share option schemes, and the share-based payment charges relating to empowerment transactions. These fair values are calculated by applying a valuation model, which is in itself judgmental, and takes into account certain inherently uncertain assumptions. The basic assumptions that are used in the calculations are explained further in note 23.

Development expenditure

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

Development expenditure in 2022, such as the development of a formulation for the paediatric clinical study, have not been capitalised as there is considerable technical uncertainty as to whether the formulation and the paediatric study will lead to approval of the product for use in children.

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

4. New standards and interpretations

The following new and amended accounting standards are relevant to the Group and are in issue but were not effective at the balance sheet date:

IAS 1 (Amended) – Classification of Liabilities as Current or Non-current

IAS 1 (Amended – Disclosure of Accounting Policies

IAS 8 (Amended) – Definition of Accounting Estimates

IAS 12 (Amended) – Deferred Tax Related to Assets and Liabilities Arising from a Single Transaction

IFRS 17 – Insurance Contracts

The Directors do not expect that the adoption of these new and amended standards (which the Group does not expect to early adopt) will have a material impact on the financial performance or position of the Group in future periods.

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; and
- PT20 – development of the Group's secondary asset. All assets related to PT20 were written off as an impairment expense during the year ended 31 December 2022.

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

	Feraccru® 2022 £000	**PT20 2022 £000**	**Central and unallocated 2022 £000**	**Total 2022 £000**	Feraccru® 2021 (Restated) £000	PT20 2021 £000	Central and unallocated 2021 £000	Total 2021 (Restated) £000
Revenue	**4,467**	**—**	**—**	**4,467**	1,519	—	—	1,519
Operating loss	**(22,525)**	**(15,423)**	**(2,467)**	**(40,414)**	(18,549)	(107)	(1,638)	(20,294)
Financial income				**721**				395
Financial expense				**(389)**				(8)
Tax				**(362)**				229
Loss for the year				**(40,444)**				(19,678)

The revenue analysis in the table below is based on the country of registration of the fee-paying party. £2.9 million (2021: £0.1 million) of revenue is derived from net product revenue from Accrufer® sales in the US and £1.4 million (2021: £0.9 million) from royalties. The remainder represents upfront and milestone payments from commercial partners, which amounted to £0.2 million (2021: £0.5 million).

	Year ended 31 December 2022 £000	Year ended 31 December 2021 £000
The Netherlands	**1,438**	908
Canada	**150**	—
South Korea	**5**	550
USA	**2,874**	61
	4,467	1,519

Notes (forming part of the financial statements) continued

for the year ended 31 December 2022

5. Segmental reporting continued

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

	Year ended 31 December 2022 £000	Year ended 31 December 2021 £000
Customer A	**1,438**	908
Customer B	**—**	550
Customer C	**150**	—
Other customers	**2,879**	61
	4,467	1,519

As at 31 December 2022	Feraccru® £000	PT20 £000	Central and unallocated £000	Total £000
Segment assets	**16,685**	**—**	**5,389**	**22,074**
Segment liabilities	**(18,470)**	**(19)**	**1,842**	**(16,647)**
Total net assets	**(1,785)**	**(19)**	**7,231**	**5,427**
Depreciation, amortisation and impairment	**908**	**16,162**	**—**	**17,070**
Capital expenditure	**58**	**—**	**—**	**58**
Capitalised development costs	**1,842**	**—**	**—**	**1,842**

As at 31 December 2021	Feraccru® (Restated) £000	PT20 (Restated) £000	Central and unallocated (Restated) £000	Total (Restated) £000
Segment assets	14,068	15,820	14,524	44,412
Segment liabilities	(12,153)	(15)	8,447	(3,721)
Total net assets	1,915	15,805	22,971	40,691
Depreciation, amortisation and impairment	753	1,454	—	2,207
Capital expenditure	372	—	—	372
Capitalised development costs	1,683	—	—	1,683

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

6. Expenses and auditor's remuneration

	Year ended 31 December 2022 £000	Year ended 31 December 2021 (Restated) £000
Loss for the year has been arrived at after charging:		
Research and development expenditure	**1,072**	794
Fees payable to Company's auditor and its associates for the audit of parent company and consolidated financial statements	**84**	61
Fees payable to Company's auditor and its associates for other services:		
The audit of Company's subsidiaries	**21**	47
Tax compliance services	**—**	4

7. Operating costs – selling, general and administrative expenses

Operating costs comprise:

	Year ended 31 December 2022 £000	Year ended 31 December 2021 (Restated) £000
Selling costs	**16,008**	10,369
General administrative expenses	**8,962**	7,574
Depreciation and amortisation	**2,362**	2,207
	27,332	20,150

8. Staff numbers and costs

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

	Number of employees	
	2022 Number	2021 Number
R&D	**5**	5
Medical	**3**	2
Commercial	**12**	8
Management and administration	**8**	8
	28	23

The number of staff employed by the Group at 31 December 2022 was 27 (31 December 2021: 22).

The aggregate payroll costs of these persons were as follows:

	2022 £000	2021 £000
Wages and salaries	**6,002**	4,118
Share-based payments (see Note 23)	**743**	992
Other employee benefits	**617**	18
Pensions	**110**	76
	7,472	5,204

Key management compensation information is as follows:

	2022 £000	2021 £000
Wages and salaries	**2,461**	1,765
Share-based payments	**672**	564
Other employee benefits	**151**	7
Pensions	**84**	51
	3,368	2,387

Details of Directors' remuneration information is shown on page 39 within the Directors' remuneration report. The details for the highest paid Director are included in the single figure tables of the Directors' remuneration report on page 39.

Notes (forming part of the financial statements) continued

for the year ended 31 December 2022

9. Financial income and expenses

	Year ended 31 December 2022 £000	Year ended 31 December 2021 £000
Financial income		
Net foreign exchange gains	**691**	382
Total interest income on financial assets measured at amortised cost	**30**	13
	721	395

	Year ended 31 December 2022 £000	Year ended 31 December 2021 £000
Financial expense		
Loan interest	**(327)**	—
Effect of revaluation of financial liabilities measured at fair value	**(55)**	—
Bank charges	**(7)**	(8)
	(389)	(8)

10. Loss per share

	2022			2021		
	Loss £000	**Weighted shares 000**	**Loss per share pence**	Loss (Restated) £000	Weighted shares 000	Loss per share (Restated) pence
Basic and diluted	**(40,444)**	**233,191**	**(17)**	(19,678)	204,409	(10)

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 24,573,739 of share options were in issue under the Company's share option plans (see Note 23), which potentially provide 24,573,739 additional Ordinary Shares (approximately 9.5% of the current share capital).

11. Taxation

Recognised in the income statement:

	Year ended 31 December 2022 £000	Year ended 31 December 2021 £000
Current income tax – UK	**(248)**	(188)
Current income tax – UK adjustments in respect of prior years	**(93)**	55
Current income tax – overseas	**349**	(96)
Current income tax – overseas adjustments in respect of prior years	**354**	—
Total tax credit/(charge)	**362**	(229)

11. Taxation continued

Reconciliation of total tax credit:

	Year ended 31 December 2022 £000	Year ended 31 December 2021 (Restated) £000
Loss for the year	**(40,444)**	(19,678)
Taxation	**(362)**	(229)
Loss before tax	**(40,082)**	(19,907)
Standard rate of corporation tax in the UK	**19%**	19%
Tax using the UK corporation tax rate	**(7,616)**	(3,739)
Expenses not deductible for tax purposes	**2,628**	(147)
R&D tax credits – current year	**77**	25
Adjustments in respect of prior years	**261**	77
Foreign taxation suffered	**—**	55
Differences in foreign tax rate	**48**	7
Unrelieved tax losses carried forward and other temporary differences not recognised for deferred tax	**4,964**	3,493
Total tax credit/(charge)	**362**	(229)

Factors affecting the future tax charge

The UK corporation tax rate remains unchanged at 19%. The unrecognised UK deferred tax asset as at 31 December 2021 has been calculated based on this rate. From 1 April 2023 the UK main corporation tax rate is 25%. This will increase the Company's future tax charge accordingly. The unrecognised deferred tax asset as at 31 December 2022 has been calculated based on these rates, reflecting the expected timing of reversal of the related timing differences (2021: 19%).

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.

	2022 £000	2021 £000
Unutilised Swiss tax losses to carry forward	**473**	—
Potential deferred tax asset thereon	**56**	—
Unutilised UK tax losses to carry forward	**77,298**	52,991
Potential deferred tax asset thereon	**19,325**	13,247
Total potential deferred tax asset	**19,381**	13,247

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

The current asset of £0.4 million at 31 December 2022 (2021: £0.6 million) relates to the anticipated R&D tax credit claim made in respect of 2021 and 2022.

Notes (forming part of the financial statements) continued

for the year ended 31 December 2022

12. Property, plant and equipment

Group	Computer equipment £000	Fixtures, fittings and equipment £000	Right-of-use asset £000	Total £000
Cost				
Balance 1 January 2021	9	21	54	84
Additions	73	95	204	372
Balance at 31 December 2021	82	116	258	456
Additions	—	2	56	58
Disposals	—	—	(62)	(62)
Balance at 31 December 2022	**82**	**118**	**252**	**452**
Accumulated depreciation				
Balance at 1 January 2021	9	17	26	52
Charge for the period	7	15	78	100
Balance at 31 December 2021	16	32	104	152
Charge for the period	16	24	120	160
Disposals	—	—	(57)	(57)
Balance at 31 December 2022	**32**	**56**	**167**	**255**
Net book value				
December 2022	**50**	**62**	**85**	**197**
31 December 2021	66	84	154	304

Included within property, plant and equipment are £85,000 (2021: £154,000) net book value of assets recognised as leases under IFRS 16. Further details of these leases are disclosed in Note 24.

13. Intangible assets

Group	Feraccru® patents and trademarks £000	Feraccru® development costs £000	Phosphate Therapeutics licences £000	Total £000
Cost				
Balance at 1 January 2021	2,055	9,943	27,070	39,068
Additions – externally purchased	9	1,683	—	1,692
Balance at 31 December 2021	2,064	11,626	27,070	40,760
Additions – externally purchased	—	1,842	—	1,842
Impairment of intangible asset	(171)	—	(27,070)	(27,241)
Balance at 31 December 2022	**1,893**	**13,468**	**—**	**15,361**
Accumulated amortisation				
Balance at 1 January 2021	668	1,509	9,625	11,802
Charge for the period	65	588	1,454	2,107
Balance at 31 December 2021	733	2,097	11,079	13,909
Charge for the period	136	612	1,454	2,202
Impairment of intangible asset	—	—	(12,533)	(12,533)
Balance at 31 December 2022	**869**	**2,709**	**—**	**3,578**
Net book value				
31 December 2022	**1,024**	**10,759**	**—**	**11,783**
31 December 2021	1,331	9,529	15,991	26,851

During the year we did a review of the carrying value of patents and trademarks resulting in a cost write off of £182,000 and an amortisation write off of £11,000.

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

	2022 £000	2021 £000
Feraccru®	**11,783**	10,860
Phosphate Therapeutics Limited	**—**	15,991
	11,783	26,851

Following the completion of the collaborative sales agreement for Accrufer® in the United States with Viatris Inc., and the equity fundraise in January 2023, the Group carried out a review of the recoverable amount of its intangible assets. As a result of this review, the Directors decided to concentrate the Group's available resources on the continuing commercial development of Accrufer®/Feraccru® and the ongoing paediatric study. Based on that, along with the limited remaining patent life of PT20, the Directors decided to write off all assets related to the Phosphate Therapeutics Limited business effective 31 December 2022. The related impairment loss of £14.7 million has been recognised in the current year profit and loss.

Notes (forming part of the financial statements) continued

for the year ended 31 December 2022

13. Intangible assets continued

Feraccru®

The value in use has been calculated based on royalty income forecast to arise from the commercialisation licence agreements with Norgine BV covering Europe, Australia and New Zealand and with Beijing Aosaikang Pharmaceutical Co. Ltd covering China, Taiwan, Hong Kong and Macau, through 2030, plus profits arising from Shield's own sales in the US market. The forecast for the sales and costs in the US are based primarily on management's detailed planning and the assumption that US prescriptions of Accrufer® grow to around 8.5% of prescriptions for oral iron therapy by 2034. These forecasts are supported by third-party sales forecasts. Sales forecasts in each territory have been derived from discussions with partners and potential partners, and from other third-party market projections. A discount rate of 15% has been applied to the Group cash flows arising from these assumptions. That discount rate has not changed since the previous year. Sensitivity analysis shows that sales in the US would need to be reduced by around 75% from management's base case assumptions, with no reduction in costs, before an impairment of the carrying value of the intangible asset would be required. The Group therefore does not expect a reasonable range of sensitivities in the assumptions used to give rise to material differences within the recoverability of Feraccru®, however in the event of multiple changes in assumptions relating to the ability to successfully commercialise the products this could lead to an impairment.

14. Investments

Company	2022 £000	2021 £000
Cost		
1 January	**165,685**	165,131
Additions	**463**	554
31 December	**166,148**	165,685
Accumulated impairment		
Balance as at 1 January 2022	**(60,400)**	(60,400)
Impairment	**(26,764)**	—
Balance as at 31 December 2022	**(87,164)**	(60,400)
Net book value		
31 December	**78,984**	105,285
1 January	**105,285**	104,731

Other additions of £0.5 million (2021: £0.6 million) relate to investments during the year arising due to share-based payments costs in respect of Group share-based payments arrangements.

The Group's equity interests were as follows:

At 31 December 2022 and 31 December 2021

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

* Investment held indirectly.

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

	2022 £000	2021 £000
Shield TX (Switzerland) AG	**78,449**	78,373
Shield Therapeutics Inc	**535**	148
Phosphate Therapeutics Limited	**—**	26,764
	78,984	105,285

14. Investments continued

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

Shield TX (Switzerland) AG

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

Phosphate Therapeutics Limited

Based on a review of the optimal allocation of the Group's resources and based on the limited remaining patent life of PT20, the main asset of the subsidiary, the Directors decided to write off this asset along with the Company's investment in Phosphate Therapeutics Limited effective 31 December 2022. The related impairment loss of £26.8 million has been recognized in the Company's current year profit and loss.

15. Inventories

Group	**2022 £000**	2021 £000
Raw materials	**—**	1,344
Finished goods	**1,457**	291
	1,457	1,635

Inventories have been reduced by £778,000 (2021: nil) as a result of the write-down to net realisable value. This write-down was recognised as an expense during 2022.

The cost of inventories recognised as an expense and included in cost of sales was £1,027,000 (2021: £492,000). Cost of sales includes royalties payable to Vitra Pharmaceuticals Limited.

16. Trade and other receivables

	Group		Company	
	2022 £000	2021 (Restated) £000	**2022 £000**	2021 £000
Trade receivables	**2,809**	816	**—**	—
Other receivables	**499**	381	**296**	69
Prepayments	**2,072**	1,732	**—**	—
Amounts due from Group undertakings	**—**	—	**77,352**	60,088
	5,380	2,929	**77,648**	60,157

Trade receivables are exclusively from large, well-recognised businesses. Management continuously manages and monitors the relationship with these customers and based on that, as well as the lack of past credit losses, that a credit loss allowance is not required at this time.

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

	Group		Company	
	2022 £000	2021 (Restated) £000	**2022 £000**	2021 £000
Non-current	**—**	—	**77,352**	60,088
Current	**5,380**	2,929	**296**	69
	5,380	2,929	**77,648**	60,157

At the year end no trade receivables were past due or impaired (2021: £Nil).

Notes (forming part of the financial statements) continued

for the year ended 31 December 2022

17. Cash and cash equivalents

	Group		Company	
	2022 £000	2021 £000	**2022 £000**	2021 £000
Cash at bank and in hand	**2,821**	12,117	**309**	10,559

18. Trade and other payables

	Group		Company	
	2022 £000	2021 (Restated) £000	**2022 £000**	2021 (Restated) £000
Trade payables	**1,439**	1,311	**281**	372
Accruals	**8,050**	2,144	**1,184**	277
	9,489	3,455	**1,465**	649

19. Other liabilities

	Group		Company	
	2022 £000	2021 £000	**2022 £000**	2021 £000
Taxation and social security	**224**	49	**4**	3
Other payables	**837**	61	**364**	—
	1,061	110	**368**	3

20. Financial instruments and financial risk management

On 30 June 2022, the Group announced it agreed with AOP Health International Management ("AOP"), an existing shareholder of the Company, on a convertible shareholder loan in the amount of £8.2 million (or US$10 million). The related loan agreement was signed following approval by the Company's shareholders during a general meeting held on 27 July 2022.

The entire loan balance of US$10 million was drawn down on 1 August 2022 and is secured over Shield's US intellectual property rights associated with Accrufer®. The interest rate is 9.1% above the Secured Overnight Financing Rate ("SOFR") and the loan is repayable in full in cash no later than 31 December 2023.

AOP has the right, but not the obligation, to convert any outstanding loan balances into ordinary shares at any time at a 10% discount to the average closing share price over the preceding then business days or, in the event of a new equity raise, on the same terms as all other investors subscribe, in each case up to a maximum of 100,000,000 ordinary shares of the Company. The parties agreed that the Company is not required to allot shares to AOP to the extent that following such allotment, AOP (together with any person or persons with whom AOP is acting in concert) would control thirty per cent or more of the voting rights in Shield.

The shareholder loan agreement contains customary representations, undertakings and events of default. The Company paid an arrangement fee of US$200k to AOP on drawdown of the loan.

Immediately following the finalization of the loan agreement, AOP requested the conversion of a portion of the shareholder loan into 41,195,246 ordinary shares of £0.015 each in the Company. The conversion price was 5.5215p per ordinary share, calculated to be 10 per cent below the average mid-market closing price of the shares during the ten business days preceding the conversion date, and the loan balance converted therefore had a value of £2,274k (approximately US$2,765k). Under the terms of the conversion, AOP was allotted and issued 41,195,246 new ordinary shares.

20. Financial instruments and financial risk management continued

In accordance with the underlying accounting guidance, the Company recorded a separate derivate financial instrument to account for the conversion feature of the shareholder loan. This derivative will be adjusted to fair value at each balance sheet date with any resulting increases as financial income or expense. The loan balance and the derivative carry the following balances:

	Shareholder Loan £000	Fair Value of Conversion Feature £000
Balance on 1 January 2022	**—**	**—**
Draw down of loan amount	**7,529**	**699**
Partial conversion	**(1,987)**	**(288)**
Fair value adjustment of conversion feature	**—**	**55**
Balance on 31 December 2022	**5,542**	**466**

The Group and Company's other financial instruments comprise cash and cash equivalents, trade and other receivables, trade and other payables, Shareholder loan, Fair value of the conversion feature on the shareholder loan and leases.

The Group had the following financial instruments at 31 December:

	2022 £000	2021 (Restated) £000
Cash and cash equivalents (Note 17)	**2,821**	12,117
Trade and other receivables	**5,380**	2,929
Trade and other payables	**9,489**	3,455
Shareholder loan	**5,542**	—
Fair value of conversion feature on the shareholder loan	**466**	—
Lease liabilities	**89**	156

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

	2022 £000	2021 £000
Sterling	**321**	1,997
US Dollar	**2,179**	9,781
Swiss Franc	**57**	49
Euro	**264**	290
	2,821	12,117

The Group's long-term liabilities are shown below:

	2022 £000	2021 £000
Due for repayment within 1-2 years	**—**	—
Due for repayment within 3-5 years	**6,008**	—
	6,008	—

Financial risk factors

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

Notes (forming part of the financial statements) continued

for the year ended 31 December 2022

20. Financial instruments and financial risk management continued

Financial risk factors continued

(a) Foreign exchange risk

In 2022 the Group's recurring revenues from royalties were mostly denominated in Euros. The majority of operating costs are denominated in US Dollars now although certain of its expenditures were payable in Euros and Sterling. A 5% difference in the exchange rates would have had the impacts set out in the table below:

		Effect on loss before tax	
	Change in GBP vs EUR rate	**Year ended 31 December 2022 £000**	Year ended 31 December 2021 £000
EUR	+5.00%	**(14)**	(14)
	-5.00%	**14**	14
USD	+5.00%	**(103)**	(466)
	-5.00%	**103**	466

(b) Interest rate risk

The Group's policy is to maximise interest receivable on deposits, subject to maintaining access to sufficient liquid funds to meet day-to-day operational requirements and preserving the security of invested funds. With the current level of bank interest rates, interest receivable on bank deposits in 2022 was £29,000 (2021: £13,000). If interest rates had been 1% higher in 2022 the impact on cash interest received would have been £28,000 (2021: £134,000).

Interest payable arises principally on the Group's leases. If interest rates had been 1% higher in 2022 the impact on cash interest paid would have been £1,000 (2021: £1,000).

(c) Credit risk

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

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

21. Share capital

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.

	2022 Number		2021 Number	
	000	**£000**	000	£000
At 1 January	**215,885**	**3,238**	117,620	1,764
Exercise of share options	**2,348**	**35**	985	15
Conversion of loan	**41,155**	**618**		
Issuance of shares pursuant to placing	**—**	**—**	97,280	1,459
Total shares authorised and in issue as at 31 December – fully paid	**259,388**	**3,891**	215,885	3,238

2,307,438 share options were exercised during the year (2021: 985,104).

22. Reserves

The Group's balance sheet contains the following reserves:

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

23. Share-based payments

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

The schemes which the Group operates are:

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

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

The number of options outstanding at the start and end of both 2021 and 2022, the movements through both years, and the expense charged to the Group financial statements were as follows:

2022

Scheme	Settlement	1 January 2022	Forfeited/ lapsed	Exercised	Granted	**31 December 2022**	Exercisable	Expense £000
LTIP	Equity	24,274	—	—	—	**24,274**	24,274	—
CSOP	Equity	315,625	—	—	—	**315,625**	315,625	—
RSP	Equity	12,136	—	—	—	**12,136**	12,136	—
RPSP	Equity	7,110,081	(1,035,498)	(2,307,438)	20,494,710	**24,261,855**	1,864,129	743
Total		7,462,116	(1,035,498)	(2,307,438)	20,494,710	**24,613,890**	2,216,164	743

2021

Scheme	Settlement	1 January 2021	Forfeited/ lapsed	Exercised	Granted	31 December 2021	Exercisable	Expense £000
LTIP	Equity	143,033	—	(118,759)	—	24,274	24,274	—
CSOP	Equity	381,732	(19,048)	(47,059)	—	315,625	315,625	3
RSP	Equity	12,136	—	—	—	12,136	12,136	—
RPSP	Equity	3,413,456	(1,430,489)	(819,286)	5,946,400	7,110,081	999,603	989
Total		3,950,357	(1,449,537)	(985,104)	5,946,400	7,462,116	1,351,638	992

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

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

The CSOP scheme was used to issue both HMRC-approved and unapproved options to employees of the Group. Options were granted in July 2017, May 2018 and October 2018.

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

23. Share-based payments continued

In March 2021, 307,438 share options were granted under the RPSP to the Chief Commercial Officer as an onboarding incentive package which will vest during 2022. In June 2021, 1,000,000 share options were granted under the RPSP to the Chief Executive Officer as an onboarding incentive package which will vest during 2022. Also in June 2021, 486,344 share options were granted under the RPSP with no performance conditions and automatic vesting in June 2024. All of the above options were valued at £0.58 each using a Black Scholes valuation model. In June 2021, 2,856,243 options were granted under the RPSP to senior executives with a number of performance measures to be assessed after the end of 2021. To the extent that the performance measures are met, options will vest one year after the Board's assessment of the performance conditions. The fair value of these options has been measured at £0.21 using a Monte Carlo valuation model. In December 2021, 1,000,000 options were granted under the RPSP to the Chief Medical Officer as an onboarding incentive package which will vest during 2022, these have been measured using a Black Scholes model at £0.40 each. Lastly, in December 2021, 296,375 options were granted under the RPSP to senior executives as an onboarding incentives package which will vest during 2022, these have been measured using a Black Scholes model at £0.29 each. The BSPs were cash-settled share options. All of the remaining share options schemes are equity settled.

Between January 2022 and September 2022 521,000 share options were granted under the RPSP as an onboarding incentive package which will vest during 2023.

In August 2022 19,973,710 share options were granted under the RPSP with vesting periods of 1 to 3 years. 50% of the options will vest within 1 year, 25% within 2 years and 25% within 3 years.

All of the shares option schemes are equity settled.

Current year measurement inputs and assumptions used in the Black Scholes valuations were as follows:

	September 2022 Black Scholes	August 2022 Black Scholes	May 2022 Black Scholes	April 2022 Black Scholes	February 2022 Black Scholes	January 2022 Black Scholes
Weighted average share price	**£0.02**	**£0.01**	**£0.03**	**£0.05**	**£0.06**	**£0.07**
Exercise price	**£0.07**	**£0.07**	**£0.19**	**£0.20**	**£0.36**	**£0.41**
Expected volatility	**40%**	**40%**	**40%**	**40%**	**40%**	**40%**
Expected option life	**1 year**	**3 years**	**1 year**	**1 year**	**3 years**	**1 year**
Expected dividends	**Nil**	**Nil**	**Nil**	**Nil**	**Nil**	**Nil**
Risk-free interest rate (based on UK Government bonds)	**3.29%**	**1.87%**	**1.66%**	**1.36%**	**1.06%**	**0.91%**
Fair value at measurement date	**£0.07**	**£0.07**	**£0.19**	**£0.20**	**£0.36**	**£0.41**

24. Leases

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

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

Analysis of property, plant and equipment between owned and leased assets	2022	2021
Net book value property, plant and equipment owned	**113**	148
Net book value right-of-use assets	**84**	156
Total	**197**	304

Lease liabilities	2022	2021
Less than one year	**89**	156
Total	**89**	156

Amounts recognised in profit or loss	2022	2021
Interest on lease liabilities	**4**	3
Expenses relating to short-term leases	**122**	73
Total	**126**	76

24. Leases continued

During 2022 the Group entered into a new operating lease arrangement for the Gateshead office, for an office in Texas US and Boston US. These leases have been capitalised in accordance with IFRS 16.

25. Capital management policy

The primary objective of the Group's capital management is to ensure that it has the capital required to operate and grow the business at a reasonable cost of capital without incurring undue financial risks. The Board periodically reviews its capital structure to ensure it meets changing business needs. The Group defines its capital as its share capital, share premium account, retained earnings, plus the convertible shareholder loan. There have been changes to the capital requirements each year as the Group has required regular suitable levels of capital injections to fund development.

The Group also manages capital by monitoring its net debt position, calculated as total liabilities (as shown in the statement of financial position) less cash and cash equivalents. The net debt position at 31 December 2022 and 2021 was as follows:

	2022 £000	2021 £000
Total liabilities	**16,647**	3,721
Cash and cash equivalents	**(2,821)**	(12,117)
Net debt	**13,826**	(8,396)

26. Related party transactions

During the year the Company had intercompany loan balances with some of its subsidiaries as follows; Shield TX (UK) Limited £70,775,291 due to the Company (2021: £54,122,044 due to the Company), Shield TX (Switzerland) AG £2,796,300 due to the Company (2021: £2,753,482 due to the Company), Shield Therapeutics Inc. £807,965 due to the Company (2021: £28,275 due from the Company) and Phosphate Therapeutics Limited £411,622 due to the Company (2021: £382,734 due to the Company). All intercompany loans have an interest rate of 1% per annum.

27. Subsequent events

On 5 January 2023, the Company's shareholders approved an equity fundraise which raised £16.4 million net of related expenses.

As announced on 9 January 2023, AOP Health International Management AG (AOP) requested the conversion of a portion of the convertible shareholder loan facility between the Company and AOP into 31,438,189 Ordinary Shares of £0.015 each at £0.06 per share, equal to the price at which new Ordinary Shares were issued pursuant to the preceded equity fundraise. The loan balance converted at that time had a value of US$2,241,291 at an exchange rate of US$1.1882: £1.00.

As announced on 4 May 2023, AOP requested the conversion of a portion of the convertible shareholder loan facility between the Company and AOP into 127,366,565 Ordinary Shares of £0.015 each at £0.06 per share, calculated to be 10 percent below the average mid-market closing price of the shares during the ten business days preceding the conversion date, and the loan amount converted therefore had a value of £7,589k (approximately US$9,542k). As a result of this conversion AOP's shares in the Company exceeded 30 percent which led to AOP making a mandatory offer for the remaining Ordinary Shares in the Company.

28. Prior year restatement

The following table summarises the impact of restatements arising from the correction of prior year errors on the Group's equity:

	Accumulated deficit £000
At 1 January 2021 as reported	106,595
Amendment to operating costs – selling, general and administrative expenses	127
Amendment to research and development expenditure	215
Restated at 1 January 2021	**106,937**

During the preparation of the current year financial statements, management identified several supplier invoices, which applied to 2021, but which were erroneously recorded in 2022. As a result, the Company restated the consolidated financial statements for the year ended 31 December 2021 by increasing operating costs by £127,000 and research and development expenditure by £215,000, respectively, increasing the loss for the year 2021 from £19,336,000 to £19,678,000. Consequentially accrued expenditure increased by £342,000 in 2021.

This restatement increased the loss per share for the prior year 2021, from 9p to 10p.

Glossary

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

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