

Realising our global ambitions



Shield Therapeutics plc
Annual report and accounts 2021



About us

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

Revenue

£1.5m

(2020: £10.4m)

Loss for the year

£19.3m

(2020: £2.6m)

Net cash at year end

£12.1m

(2020: £2.9m)

Operational highlights

- Demand for Accrufer® in US grew by 170% in Q4 2021 as compared to previous quarter
- Current year-on-year sales of Feraccru® packs in Europe increased by ~60%
- Accrufer®/Feraccru® licensed to Korea Pharma in the Republic of Korea
- Phase I PK/PD study completed and Phase III IBD study initiated for Chinese regulatory approval
- Phase III (twelve-week) paediatric study initiated in the US and UK

Financial highlights

- Revenues of £1.5 million (2020: £10.4 million)
- Loss for the year of £19.2 million (2020: £2.6 million)
- Net cash of £12.1 million (2020: £2.9 million)

Post-period highlights

- Accrufer® licensed to KYE Pharmaceuticals in Canada
- New Drug Submission (NDS) submitted to Health Canada for Accrufer® marketing approval as a prescription medicine
- Continued progress on payer coverage by securing contracts with several large pharmacy benefit managers (PBMs) and downstream clients, now covering ~90 million patients

→ 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

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Reasons to invest in Shield

Significant unmet need

- Iron deficiency with or without anaemia affects ~20 million patients in the US, with over 13 million prescriptions generated annually for oral iron
- Current treatments limited by tolerability issues, specifically gastrointestinal (GI) related adverse events causing significant discontinuation among patients

Market adoption and payer coverage expanding

- 170% growth in prescription demand in 2nd quarter of launch
- 60 million lives currently covered by payers and growing
- Positive clinical experience among Health Care Providers (HCP's) with Accrufer®

Potential best in class product

- Approved product Accrufer®
- Indicated for the treatment of iron deficiency, with or without anaemia, in adults

Market cap

~\$128m

- Approximately £96 million (or \$128 million) at 31 December 2021
- Attractive entry point

Experienced new Executive Team

- Proven track record of building organisations and launching specialty pharmaceutical products
- Experience in driving market adoption and revenue growth in the US and throughout the rest of the world

Accrufer® market potential

\$2.2b

- Estimated US market opportunity of \$2.2 billion
- Patent coverage through 2035





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

Shield is a commercial stage 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.

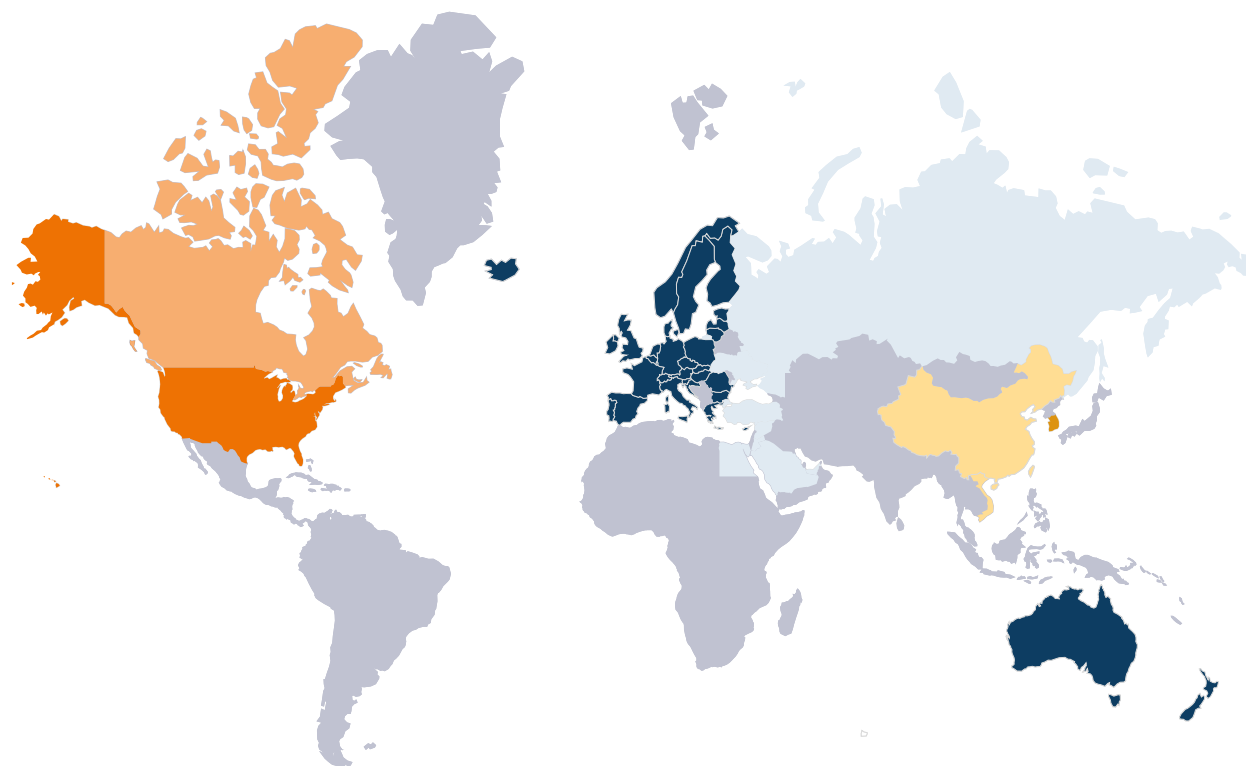
Shield's proprietary lead product, Accrufer®/Feraccru®, has been approved for use in the US, the EU, the UK, Australia and Switzerland. The product has patent coverage until 2035. The Company recently launched Accrufer® in the US. Feraccru® is being commercialised in the UK and EU by Norgine BV, which also has 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. in the Republic of Korea, with KYE Pharmaceuticals Inc. in Canada, and with AOP Orphan Pharmaceuticals AG in Egypt, Jordan, Russia, Saudi Arabia, Syria, Turkey, Ukraine and United Arab Emirates.





Our product pipeline

Product	Indication	Recent or upcoming milestones	Pre-clinical	Phase I	Phase II	Phase III	Filed	Marketed as
ACCRUFØR	Iron deficiency in adults (US)	Approved for marketing in US. Shield launched in July 2021.	[Progress bar: Pre-clinical to Phase III]					
FERACCRU	Iron deficiency in adults (Europe and Australia)	Approved for marketing in EU, UK, Norway, Iceland, Australia and Switzerland. Commercialisation led by Norgine BV.	[Progress bar: Pre-clinical to Phase III]					
	Iron deficiency anaemia in children	Paediatric study started in 2021.	[Progress bar: Pre-clinical to Phase II]					
PT20 Iron-based phosphate binder	Hyperphosphatemia	Phase II pivotal study completed. Requires one further Phase III pivotal study to allow an NDA to be filed.	[Progress bar: Pre-clinical to Phase II]					



Global coverage

- Accrufer® was launched by Shield in the US in July 2021.
- Feraccru® is being commercialised in the EU, the UK, Norway and Iceland, by Norgine BV, which also has the commercialisation rights in Australia, New Zealand and other non-EU European countries.
- Accrufer®/Feraccru® has been out-licensed for development and commercialisation in Egypt, Jordan, Russia, Saudi Arabia, Syria, Turkey, Ukraine and United Arab Emirates to AOP Orphan Pharmaceuticals AG.
- Accrufer®/Feraccru® has been out-licensed for development and commercialisation in China, Hong Kong, Macau and Taiwan to Beijing Aosaikang Pharmaceutical Co., Ltd.
- Accrufer® has been out-licensed for development and commercialisation in the Republic of Korea to Korea Pharma Co., Ltd.
- Accrufer® has been out-licensed for development and commercialisation in Canada to KYE Pharmaceuticals Inc.



Realising our global ambitions



Hans Peter Hasler
Chairman

“
Our focus is our people, patients, partnerships and medicines to create a working culture founded on our core values.”

Review of the year

Despite the continued challenges thrown at us by the COVID-19 pandemic, Shield has had a transformational 2021 which included the successful completion of a £27.6 million fundraise, the launch of Accrufer® in the US and a further licence agreement secured in the Republic of Korea.

The successful fundraise enabled Shield to establish a US entity and make the product available to physicians from July 2021. I would like to acknowledge the vast expertise and dedication shown by the team to enable Accrufer® to be launched in such a pivotal territory so that we can continue to realise our global ambitions and improve patients' lives all over the world.

The Group's financial results and going concern consideration are set out on pages 17 to 19.

Strong team with the ability to deliver

Our people are a major strength of the business and during 2021 we continued to attract and retain key talent, selecting and developing exceptional people who are motivated by our common purpose and goals.

At our Board level Shield welcomed to the Board of Directors, Fabiana Lacerca-Allen and Anders Lundstrom in 2021. Fabiana brings with her a wealth of expertise on corporate compliance and governance having implemented many compliance programmes at major pharmaceutical companies and is widely known as one of the pre-eminent specialists in the field of leadership and compliance.

Anders has over 25 years' experience in senior commercial roles within the pharmaceutical industry and is currently Executive Vice President and Chief Commercial Officer at Banner Life Sciences where he is executing a US launch of a novel fumarate, Bafiertam™, for the treatment of multiple sclerosis. His US commercial launch expertise has proved invaluable to the Company during 2021.



As well as the new additions to the Board of Directors, during 2021 Shield appointed three key hires who will be based in our Boston Office: Greg Madison joined the team in May as Chief Executive Officer. Greg's proven experience and skills will be key to support the ongoing launch in the USA and I am confident that under Greg's leadership the Company is equipped to materialise on the large US market opportunity for Accrufer®. Hans-Peter Rudolf joined the team in March as Group Chief Financial Officer and Dr. Jose Menoyo joined the team in September as Chief Medical Officer.

As reported at the 2021 AGM, Rolf Hoffmann stepped down from his position on the Board; I would like to thank Rolf for his contributions to Shield.

Strategy

The launch of Accrufer® in the US cemented the Group's strategy to make Accrufer® the brand leader in oral iron therapy in the US. In order to achieve this the Company continues to work hard to achieve patient coverage to as many patients as possible within the US. Currently the Company is pleased to report that 60 million commercial lives are covered and ensuring patient coverage is achieved from the other major pharmacy benefit managers (PBMs) continues to be a core focus.

In addition, the paediatric Phase III study was initiated by end of 2021 and our business development team continues to pursue out-license activities of Accrufer®/Feraccru® in other markets to further expand the product's reach.

Governance

The Board believes that good corporate governance improves long-term success. The Board applies the 2018 Quoted Companies Alliance Corporate Governance Code (the "QCA Code") as the basis of the Group's governance framework. The Company's statement of compliance continues to be made available on the Company's website. In addition to its UK corporate governance the Company has implemented a robust US compliance programme spearheaded by Fabiana. Our compliance programme incorporates the OIG's seven key principles on compliance and we have established a strong team made up of a representative from the Board, the Company and an external compliance specialist who manage all aspects of our legal, medical and regulatory compliance.

Culture

Our focus is our people, patients, partnerships and medicines to create a working culture founded on our core values. It's through this collaboration and alignment we're able to attract highly dedicated, ambitious people and demonstrate a genuine employee value proposition.

As our team has expanded across the US, the Company has been working to ensure there is a strong focus on culture within the business and we are working with the team to refresh the values and behaviours to ensure all geographies and the way they work are represented. This will be carried out by teams in both the US and UK working together and if the recent pandemic has taught us anything it is that we can break down those geographical communication barriers to enable cross-Group collaboration.

Hans Peter Hasler
Chairman

21 June 2022



Opportunity awaits



Greg Madison
Chief Executive Officer

“
With Accrufer® now available in the US, and Feraccru® available in Europe, I am excited about the long term prospects for our medicine and Shield.”

I joined the Shield organisation as CEO in early June of 2021, and what attracted me to Shield was both our medicine and the opportunity. Our medicine, Accrufer®/Feraccru®, or ferric maltol, is one that is very much needed by patients seeking treatment for iron deficiency, with or without anaemia. Highly effective, well tolerated, and broad label were all factors that stood out as potential differentiators from the 'other' oral irons in the marketplace. On the opportunity side, it is immense. Iron Deficiency is the most common and widespread nutritional disorder in the world, and iron deficiency anaemia (IDA) accounts for 50% of anaemia worldwide. In the US alone, there are an estimated 20 million people with anaemia. Despite there being a number of iron products available for patients, you can quickly determine that this is a very unsatisfied market and patient population. No matter where you go in the globe- Europe, China, Korea, Canada or the United States, one issue remains constant - the tolerability of currently available oral irons is a major concern. This is the proverbial Achilles heel of current treatments that creates an immense amount of dissatisfaction resulting in poor tolerability, high rates of gastrointestinal events and resulting discontinuation. Most importantly as a result, patients remain unable to treat their iron deficiency and reverse the effects of this disease. Our mission is to change this narrative, and this is why we are here 'to improve lives together'.

US Market

As noted above, we estimate that there are 20 million people in the US with anaemia. The US represents a very large and defined market, with approximately 13.4 million prescriptions of oral iron that are written by clinicians every year. When one thinks about planning the launch of a new medication in the US, companies routinely spend 12-18 months and significant capital as they prepare for the launch, in order to launch the medicine in the most effective way. During this time critical activities include creating awareness and buzz about your product/company, setting up the necessary infrastructure to support the launch, and starting engagements and education with US payers to accelerate timing for formulary coverage. Working with the resources it had available, including limited pre-launch spend, Shield mobilised its launch within three



months meaning that it was not able to implement pre-market development, the result being much of the work that's typically done pre-launch, now needed to be done during the launch.

With the core infrastructure in place at the time of launch (brand campaign, marketing materials, website), our main focus areas for the initial phase of launch were threefold: 1) create awareness among healthcare providers (HCP's), 2) generate clinical experience of Accrufer® and 3) initiate payer discussions to establish coverage. We have made excellent progress across each of these three priorities as described below:

Awareness – we saw a jump in awareness among HCP's from June to December 2021 according to market research. This increase in awareness was mainly the result of our thirty-person sales team getting in front of HCP's and discussing the clinical benefits of Accrufer®.

Clinical Experience – HCP's wrote a total of 2,500 prescriptions for Accrufer® during the first six months of launch, including 170% growth in Q4 vs. Q3 2021. This result is impressive considering almost no physicians knew about Accrufer® prior to July 2021. What we are also very happy to report is that the clinical experience for patients is very consistent with what we saw in our clinical trials- which is effectiveness at increasing iron stores, and well tolerated.

Payer discussions – Discussions with payers were initiated alongside our launch, and we successfully completed a number of medical presentations with payers about the clinical benefits of Accrufer®, a gating step towards contracting discussions. Late in Q4 2021, we signed several agreements with large payers, which provided formulary access of Accrufer® for almost 60 million patients. We expect access to continue to grow as we move throughout 2022.

All of these are critical foundational aspects of a successful launch of a brand in the US market and sets us up very well as we move into 2022. We also made several important personnel additions to the US team, bringing in highly experienced and motivated people in the areas of commercial operations, medical affairs, and sales leadership. Notably,

we moved away from a contract model for our field sales leadership team hiring our own VP, Sales and three Regional Sales Directors during the early part of 2022.

As we move into 2022, we are poised to take a major step forward as we continue to advance our launch of Accrufer®. We see a very significant opportunity to become the oral iron of choice in the US market. We continually hear from clinicians and patients how dissatisfied they are with over the counter (OTC) irons, and when they hear about Accrufer®, the interest level is high. Breaking the habits of these HCP's formed over a number of years takes a strong, consistent and dedicated effort amongst the entirety of the Shield commercial and medical affairs team, however we believe in our product and are driven to get it into the hands of patients as quickly as possible.

Europe/Australia

Upon my arrival as CEO, I wanted to better understand the existing commercial relationships in Europe with our product Feraccru®, and how we could develop a stronger partnership with our out-license partner, Norgine B.V. There were several reasons for this, notably so that we can identify opportunities to drive increased adoption of Feraccru® in key markets, but also to understand critical learnings and experiences that could shape our approach to the US launch.

Feraccru® pack sales coming out of Europe increased 60% on a full year over year basis in 2021, however this is not representative of the full opportunity. While the launch by Norgine B.V. was certainly impeded due to the timing of the coronavirus epidemic, working with our partner reviewing the German and UK markets, a key insight appeared – the market for Feraccru® primarily resides in Women's Health and General Practitioners (GP), not in GI which is where the bulk of the efforts until now have been focused. In fact, the market opportunity exactly mirrors the opportunity seen in the US from a physician specialty perspective. GPs and OB/GYN in Germany/UK routinely prescribe a lot of oral iron and express the same dissatisfaction (tolerability) and are actively seeking effective and well tolerated oral irons in lieu of sending patients to get an IV infusion.



Europe/Australia continued

Armed with this key insight, Norgine B.V. is re-aligning their strategic focus and efforts into the areas where the opportunity lies. In addition, due to the similarities between these markets and the US, there is a much stronger level of information sharing, collaboration and open communication that has progressed significantly between the two organisations in the past six months. I am pleased with the progress we have made, however recognise there remains much work to be done and remain focused on providing the right level of support, insight and resources to get our medicine to the patients.

Other Developments

We have made some very positive progress in other geographic areas that I'd like to take a moment and highlight, specifically China, Canada, and the Republic of Korea.

In China, there were two requirements for gaining potential approval for Accrufer® - completion of a successful pharmacokinetics (PK) study and Phase 3 study similar in design to those that led to approval by EMA and FDA in Europe and US respectively. We have completed the PK study and are currently enrolling patients into the Phase 3 study. As one of the largest countries in the world, we believe there is great opportunity for Accrufer®. We signed new out-licensing deals with KOREA PHARMA CO., LTD (Korea Pharma) for the Republic of Korea in 2021 and with KYE Pharmaceuticals Inc. (KYE) for Canada in early 2022. Both organisations showed a tremendous interest in the product and have wasted no time in getting things moving with an eye towards eventual approval in their respective markets. KYE has recently submitted their documentation for approval in the Canadian market, while Korea Pharma is actively engaged with the regulatory authorities negotiating the clinical/regulatory pathway for approval.

All of our respective out-licensing agreements entail a mix of attractive upfront payments, regulatory milestone payments, and royalties on net sales.

On the development side of things, we successfully enrolled our first patient into our paediatric study, which is for children and adolescents age 1 month to 17 years. This study encompasses sites both in the US and EU, and if successful, opens up an additional patient population that is in need of effective and well tolerated iron replacement therapies.

In conclusion, opportunity awaits. There has been a tremendous amount of progress by the 'new' Shield, particularly over the past six months that I have been a part of the organisation. Our people in the organisation are a source of pride, and we have put together an outstanding team of individuals that are focused on achieving our goals and our mission 'to improve lives together.'

Greg Madison
Chief Executive Officer
21 June 2022



Q&A

With Greg Madison
Chief Executive Officer



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

What are your first impressions of Shield/how have you found your time with Shield so far?

What stood out very quickly to me was the immense dedication, passion, and resilience of a core group of Shield employees located in our UK office. We have now added equally passionate and dedicated employees here in the US and it is an honour to work alongside them. They are fully committed to making Accrufer®/Feraccru® a success.

What experience are you bringing to Shield?

I've had the unique opportunity to not only lead both large and small organisations, but also work directly in the iron deficiency disease state in my recent past. I enjoy the commercial challenge of launching new brands, while also focusing on building and transforming the organisation as we look ahead. Lastly, I know the value of building great teams and how to recruit great talent and great people. That can have an immense effect on our growth both short and long-term.

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

We have an excellent foundational asset in ferric maltol. Our mission is to ensure that people with iron deficiency have the opportunity to experience the benefits that we believe Accrufer® can bring. We have made great strides in the second half of 2021, however there is so much more that we can and will do going forward to drive awareness among health care providers and patients. This is our immediate focus. Organisationally, we intend to build a powerhouse commercial and medical affairs structure that utilises cutting edge approaches to drive awareness and engagement of our products.

→ Read more on pages 15 and 16





The unmet need of iron deficiency

Up to one-third of the global population is affected by iron deficiency (ID) with or without anaemia (IDA) with a prevalence of ~20 million patients in the US. But with the poor tolerability and poor patient adherence rates mostly related to gastrointestinal adverse effects of the existing oral treatment options, many physicians agree there is a significant need in the market for an effective and well-tolerated oral iron replacement therapy.

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

Insufficient levels of iron, or decreased total iron in the body, is defined as iron deficiency. The aetiology of iron deficiency, with or without anaemia, can be multi-factorial and is caused by malnutrition, bleeding, or reduced ability to absorb iron. Iron deficiency is also associated with a range of diseases, notably: inflammatory bowel diseases (IBD), such as ulcerative colitis and Crohn's disease; chronic kidney disease (CKD); congestive heart failure (CHF); and cancer. Additionally, it is often seen in pregnant and pre-menopausal women with a prevalence of up to one in five women suffering from iron deficiency, with or without anaemia. Untreated, iron deficiency can lead to fatigue, neurobehavioural disorders and cognitive impairment. But because iron deficiency, with or without anaemia, is a common comorbidity of other medical conditions and not the main cause of disease, it is often overlooked and undertreated.

Iron deficiency treatment options

Once diagnosed, iron deficiency is typically treated with either generic and/or over-the-counter oral iron salt products or intravenous (IV) iron therapy. Oral iron salts (mainly ferrous-based) are usually prescribed as a first-line treatment for mild to moderate cases. IV therapy, which is less convenient and more costly to administer, is often used for treatment of more severe cases.

Oral iron salts account for well over 90% of patient prescriptions for iron deficiency, with or without anaemia, therapy in the US. Currently, there are over 13 million annual prescriptions of oral iron products written. These prescriptions are mostly generic products or they are over-the-counter ferrous-based iron salts, which have not changed for many years.

Tolerability presents a challenge

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



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® therefore 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 Term¹

	Ferric Maltol 30 mg BID (n = 175)	Placebo BID (n = 120)
Body System Adverse Reaction: GI		
Flatulence	4.6%	0.0%
Diarrhea	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%

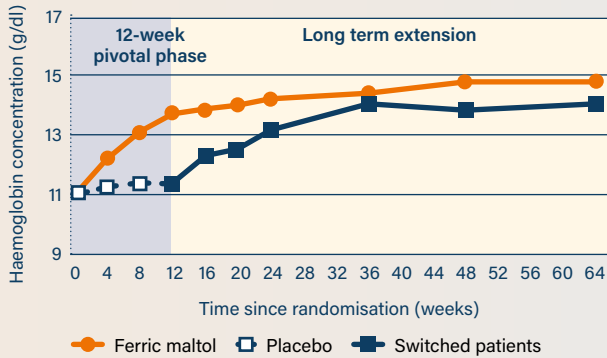
1. Accrufer® (ferric maltol) Prescribing Information. Austin, TX: Shield Therapeutics, 2021.



Clinical studies have demonstrated efficacy, tolerability and safety

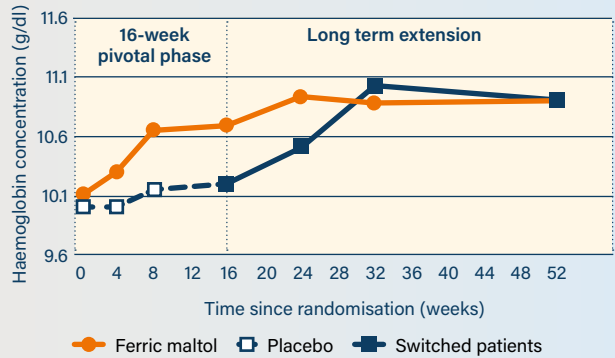
- The Phase III pivotal studies in patients suffering from inflammatory bowel disease (IBD) and chronic kidney disease (CKD) with iron deficiency anaemia were used for regulatory approval in the US, the EU, the UK, Australia and Switzerland. These studies demonstrated that Accrufer®/Feraccru®:
 - Improved 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 time³



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

Paediatric clinical study

- 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 vs 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.



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 rates. 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.





The US market opportunity

Based on latest research, there are ~20 million patients with iron deficiency and iron deficiency anaemia across multiple disease areas across the US. Of these two options, 90% of prescribed treatments are oral.



- 13.4 million oral iron prescriptions written annually in US
- ~11% of market volume driven by 4,000 physicians
- 80% prescriptions written by Primary Care Physicians (PCP), OB/GYN and NP/PAs

- Position as first line or first switch for patients with iron deficiency
- ~50% overall adherence with oral iron for IDA due to GI AEs
- Up to 60% of patients discontinue or switch therapies

- Move to first line treatment of choice, with market education and adoption
- Avoids the cycle of switches/ discontinuations
- Potential to also take share from IV Iron treatments

Accrufer®: A ~\$2.2 billion US market opportunity for iron deficiency

<p>Iron deficiency with or without anaemia ~20 million patients</p>	<p>Estimated potential US peak net sales \$500m</p>	<p>Patent Protection in US Until 2035</p>
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Lean and effective organisation

At Shield, it is our passion to improve the lives of people impacted by iron deficiency with or without anaemia. We strive to achieve this goal through the commercial development of Accrufer® (ferric maltol) in the US and a few selected, strategic partnerships for the development and commercialisation of Accrufer®/Feraccru® in other jurisdictions around the world. We operate on the basis of a small, dedicated, but experienced team of professionals.

Commercialisation

In the US, we launched Accrufer® in July 2021. We established a Shield US legal entity and built a US commercial team which led the launch and commercialisation using a mix of Shield employees and externally sourced service providers. By 31 December 2021, there were nearly 50 people working exclusively for Shield in the US, dedicated to the successful commercialisation of Accrufer®.

Strategic partnerships

We believe that partnerships are a strategic way to accelerate our goal of improving the lives of people impacted by iron deficiency with or without anaemia. We seek to enter partnerships to license the development and commercialisation of Accrufer®/Feraccru® to maximise the availability of our core medicine to people in many parts of the world.

Development and manufacturing

Product development and manufacturing in terms of strategy, planning and monitoring are led by our experienced UK team. They oversee these activities, most of which are outsourced to several contract research and manufacturing organisations (CROs, CMOs).

Team

Our culture emphasises passion, teamwork, collaboration and high-performance to improve the lives of people impacted by iron deficiency.

Our experienced Senior Executive Team includes:

- Greg Madison, Chief Executive Officer,
- Hans-Peter Rudolf, Chief Financial Officer,
- José Menoyo MD, Chief Medical Officer,
- Lucy Huntington-Bailey, General Counsel and Company Secretary,
- David Childs, VP Commercial Operations, and
- Dr Jackie Mitchell, VP Quality, Clinical and Regulatory Affairs.





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

2

Accelerate Global adoption of Accrufer®/Feraccru®

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

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

Key performance indicators

Financial KPIs

Revenue

£1.5m

2021: £1.5m
2020: £10.4m
2019: £0.7m

Loss for the year

£19.3m

2021: £19.3m
2020: £2.6m
2019: £8.8m

Net cash at year end

£12.1m

2021: £12.1m
2020: £2.9m
2019: £4.1m

Non-Financial KPIs

Headcount (at year end)

23

2021: 23
2020: 16
2019: 16

European sales volume growth

+60%

2021: +60%
2020: +70%
2019: +66%



Investing for the future



Hans-Peter Rudolf
Chief Financial Officer



Management estimates the US net product revenue potential by 2025 at around \$100 million."

Revenue

Revenue in 2021 was £1.5 million (2020: £10.4 million), comprising £0.9 million royalty income from Feraccru® sales in Europe by Norgine (2020: £0.7 million), £0.1 million net product revenue from Accrufer® sales in the US (2020: £Nil), and a £0.5 million upfront payment from Korea Pharma on the signing of the Korean licence agreement (2020: £9.7 million from ASK Pharm on the signing of the Chinese licence agreement).

The 25% year-over-year increase in royalty income from Feraccru® sales in Europe was achieved based on a 60% increase in packs sold over the same period, lessened by a lower average sales price due to the recent launches in Scandinavia, Luxembourg and Belgium.

The approximately 2,500 prescriptions of Accrufer® sold since the launch of the product in the US in July 2021 yielded net revenue of £0.1 million. A majority of the 2021 prescription sales were subsidised through patient assistance programs, due to payer coverage through agreements with various pharmacy benefit managers only becoming effective in December 2021.

Cost of sales

Cost of sales of £1.0 million (2020: £1.4 million) includes the cost of finished packs supplied to Norgine for sale in Europe and the 5% royalty payable to Vitra Pharmaceuticals Limited ("Vitra") on European net sales, and the payment to Vitra of 10% of the licence upfront received from Korea Pharma.

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

H1 2020 cost of sales also includes the cost of finished goods supplied to Norgine along with the 5% royalty payable to Vitra on Norgine's net sales.



Selling, general and administrative expenses

Selling, general and administrative expenses were £20.0 million in 2021 (2020: £8.6 million). This increase was due to the set up of the commercial functions related to the product launch of Accrufer® in the US, either in the form of an increase in selling costs or general administrative expenses. As a result, the average number of persons employed by the Group increased from 16 employees in 2020 to 23 employees in 2021.

Research and development

The total cost of research and development was £1.4 million (2020: £2.6 million), including capitalised development expenditure of £0.9 million (2020: £Nil) in connection with the ongoing paediatric study.

Financial income

Financial income of £0.4 million was reported in 2021 (2020: £0.3 million). This income was largely generated in connection with currency gains on the cash held in US Dollars.

Tax

The tax credit of £0.2 million compares with a tax charge of £0.7 million in 2020. The 2021 tax credit was created from an accrual for the expected R&D tax credit, whereas the 2020 charge comprises the Chinese withholding tax of £1.0 million arising on the upfront payment from ASK Pharm offset by the anticipated R&D tax credit for 2020.

Balance sheet

Intangible assets at 31 December 2021 were £26.9 million (2020: £27.3 million). The components of this are £16.0 million (31 December 2020: £17.4 million) relating to the acquisition costs of PT20, the phosphate binder product in our development portfolio; £9.5 million (31 December 2020: £8.4 million) relating to capitalised Feraccru® development expenditure, in particular the AEGIS-H2H study and the paediatric pharmacokinetic study; and £1.3 million (31 December 2020: £1.4 million) expenditure on strengthening the Group's intellectual property.

Inventory at 31 December 2021 amounted to £1.6 million (31 December 2020: £1.4 million). The increase is due to the conversion of bulk ferric maltol held at 31 December 2020 into finished product which is now located in the US.

Trade and other receivables of £2.9 million at 31 December 2021 are higher than in 2020 (£0.6 million) due to the increase in trading volume subsequent to the US product launch.

The current tax asset of £0.6 million (31 December 2020: £0.3 million) represents the R&D tax credit expected to be received in respect of 2020 and 2021.

Cash at 31 December 2021 was £12.1 million (31 December 2020: £2.9 million).

Trade and other payables were £3.1 million at 31 December 2021 compared with £1.5 million at 31 December 2020. Other payables at the end of 2021 were £0.1 million (31 December 2020: £0.8 million), the reduction being due to the payment of Swiss corporation tax during 2021 in relation to the 2020 tax liability.

Cash flow

The cash inflow during 2021 was £8.8 million, including £27.6 million net proceeds from the equity raise in March 2021. The loss for the year of £19.3 million, adjusted for non-cash items of £4.0 million (depreciation and amortisation £2.2 million, share-based payments £1.0 million, net financial gains £1.4 million, and income tax credit £0.2 million) and working capital outflows of £1.4 million, resulted in a net cash outflow from operating activities of £16.7 million.

Net cash outflows from investing activities of £2.0 million are the result of capitalised development expenditure of £1.7 million and the acquisition of tangible assets of £0.4 million.

Net cash inflows from financing activities of £27.6 million are attributable to the net proceeds from the equity raise in March 2021.

Currency gains of £0.4 million on US Dollar denominated cash balances reduced the total cash outflow to £9.2 million.



Going concern

At 31 December 2021 the Group held £12.1m in cash. Since year-end, Shield secured an exclusive license agreement with KYE Pharmaceuticals Inc. for the development and commercialisation of Accrufer® in Canada, resulting in £0.15m being received as an upfront payment. In addition, the Group is starting to receive cash deposits related to Accrufer® product sales. The Group's unaudited cash balance at 30 April 2022 was £5.7 million.

The Directors have considered the funding requirements of the Group through the preparation of detailed cash flow forecasts for the period to December 2023. Under current business plans, the current cash resources will extend into the third quarter of 2022. As a result, additional revenue generating transactions or financing would therefore be needed by that time to allow the business plans to continue.

The Group is currently considering various forms of finance, such as debt finance and royalty finance underpinned by the expected net product revenues generated in the US over the next few years. However, there can be no guarantee that any of these opportunities will be successfully concluded. Based on the status of the various finance considerations, the Directors believe that it remains appropriate to prepare the financial statements on a going concern basis. However, the above matters indicate the existence of a material uncertainty related to events or conditions which may cast significant doubt on the Group's and the Company's ability to continue as a going concern and, therefore, that the Group and the Company may be unable to realise their assets and discharge their liabilities in the normal course of business.

The financial statements do not include any adjustments that would result from the basis of preparation being inappropriate.

Financial outlook

The Group plans to accelerate the US revenue growth by expanding its field sales force, increasing product awareness by amplifying digital strategies and direct-to-consumer programs, as well as enhancing data systems to support marketing automation. Based on these initiatives, management estimates the US net product revenue potential by 2025 at around \$100 million. In addition, royalty revenues from the Norgine license agreement in Europe are also expected to grow steadily.

Selling, general and administrative costs in 2022 will likely increase due to new commercial and marketing initiatives while R&D expenditures (i.e., both the amount charged to the statement of profit and any amounts capitalised) for the year will be broadly in line with the amounts incurred in 2021.

The Group's current cash availability should extend into the third quarter of 2022. However, management expects to secure new financing in the near term which would extend the Group's cash runway.

Hans-Peter Rudolf
Chief Financial Officer

21 June 2022





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

Risk management framework

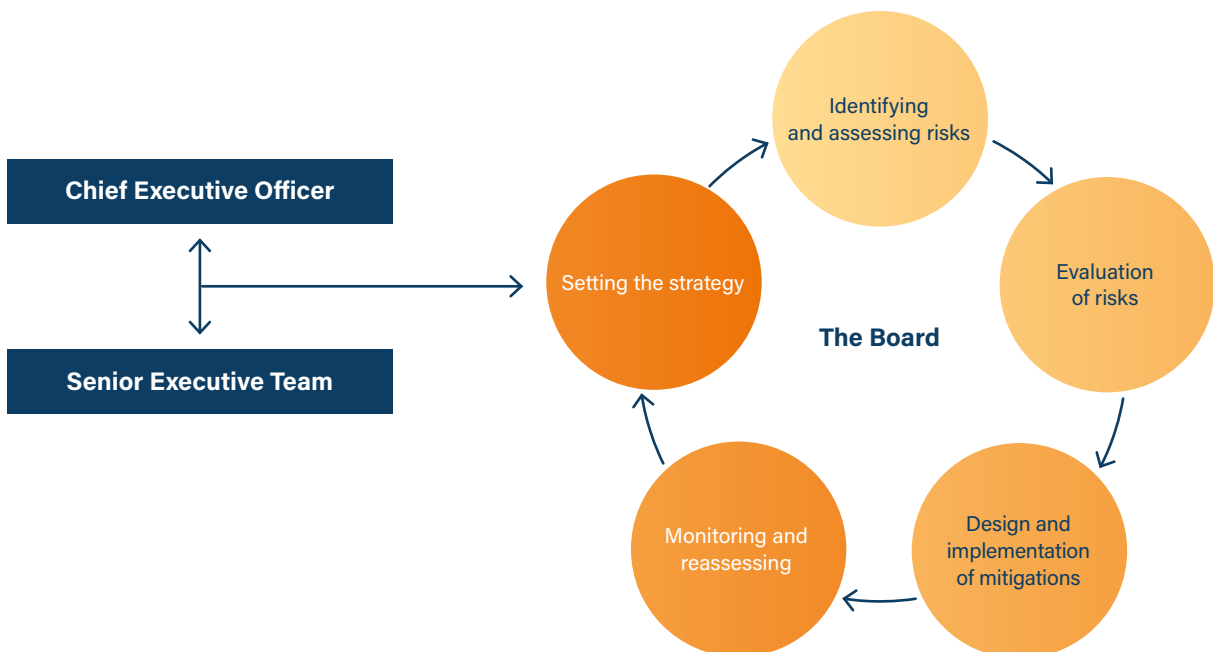
The management of risk is a key responsibility of the Board of Directors. The Board ensures that the key risks are understood and appropriately managed in light of the Group's strategy and objectives, and that an effective internal risk management process, including internal controls, is in place to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

The key policy objectives include:

- Establishing the importance of risk management in the successful operation of the business;
- Ensuring that the risk appetite of the Board is fully understood by the Senior Executive Team;

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

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





The current principal risks are:

Key



No change



Increased



Decreased



New risk

Risk description	Change	Potential impact	Mitigation
Failure to execute on US launch of Accrufer[®], including slow ramp-up or non-achievement of peak sales		Material adverse impact on the Group's financial condition and prospects.	Experienced commercial team leads US launch; launch and commercial activities are monitored closely.
Inability to secure payer coverage on time or for enough insured lives or at too high of a discount		Lower than expected net revenues and cash flows negatively impact Group's financial condition and financial outlook.	High-level focus and attention by Senior Executive Team on key commercial payer relationships.
Costs of launching and promoting Accrufer[®] in the US are significantly greater than planned		Higher than expected costs could lead to requirement for further funding.	Close monitoring of actual-to-budgeted results, plus updating of rolling forecasts; exploration of alternative financing options.
Commercialisation partners fail to achieve potential of Accrufer[®]/ Feraccru[®]		Shield will under-deliver shareholder value as royalties and sales milestones will not be maximised.	Commercialisation of out-licensing agreements includes performance measures to enable Shield to monitor the performance of partners.
Disruption to product supply		Failure to supply product to the US and to commercialisation partners could undermine sales potential.	The Group holds substantial quantities of raw materials and has clearly defined agreements with its CMO suppliers.
Failure to protect IP		If a patent were to be successfully challenged, it could limit the commercial value of Accrufer [®] /Feraccru [®] .	The Company actively monitors its patents and robustly defends challenges to them.
Ability to attract and retain key staff and members of management team		Shield's ability to commercialise Accrufer [®] in the US and manage its relationships with suppliers and commercialisation partners could be undermined by failure to retain or recruit key employees.	The Group endeavours to offer attractive remuneration and working environment to employees.
COVID-19 disrupts business operations		Employees may need to self-isolate or become ill; meetings with third parties or supply chain could be disrupted.	Employees can work from home, meetings can be held by video conference and the Company holds substantial quantities of raw materials inventory. Recent lockdowns had minimal impact on business.



Corporate governance

Board of Directors



Greg Madison
Chief Executive Officer

Tenure
One year

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 \$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
Four 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).

Committee membership



Peter Llewellyn-Davies
Non-Executive Director

Tenure
Six 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 Accelerate Partners and President of the Austrian biotech industry association BIOTECH AUSTRIA and CEO of Apeiron Biologics AG and invIOs Holding AG.

Committee membership





Key

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



Dr Christian Schweiger, MD, PhD
Non-Executive Director

Tenure

Two 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.

Committee membership



Fabiana Lacerca-Allen
Non-Executive Director

Tenure

One year

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.

Committee membership



Anders Lundstrom
Non-Executive Director

Tenure

One year

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 membership





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.



Hans Peter Hasler
Chairman

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	Tim Watts ⁽ⁱ⁾	
CEO	Greg Madison ⁽ⁱⁱ⁾	
Independent NED	Peter Llewellyn-Davies	Chair of Audit Committee. Member of Nomination Committee.
Independent NED	Rolf Hoffmann ⁽ⁱⁱⁱ⁾	Chair of Remuneration Committee. Member of Nomination Committee.
NED	Dr Christian Schweiger	Member of Nomination Committee. Member of Remuneration Committee.
Independent NED	Fabiana Lacerca-Allen ^(iv)	Member of Audit Committee. Member of Nomination Committee.
Independent NED	Anders Lundstrom ^(v)	Chair of Remuneration Committee. Member of Nomination Committee.

(i) Resigned 30 September 2021

(ii) Appointed 18 June 2021

(iii) Resigned 17 June 2021

(iv) Appointed 10 May 2021

(v) Appointed 10 May 2021



Tim Watts resigned as CEO on 1 June 2021 and from the Board on 30 September 2021. Between the dates of 1 June 2021 and 30 September 2021 Tim Watts served as an Executive Director.

Greg Madison was appointed as CEO on 1 June 2021 and formally joined the Board on 18 June 2021.

Rolf Hoffmann resigned as Independent Non-Executive Director on 18 June 2021. Rolf had been serving on the Board since his appointment on 6 April 2018.

Fabiana Lacerca-Allen and Anders Lundstrom were appointed as Independent Non-Executive Directors on 10 May 2021.

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:

2021 meetings	Number of meetings	Attendance
Main Board	5	All Directors attended
Audit Committee	4	All Committee members attended
Remuneration Committee	3	All Committee members attended
Nomination Committee	1	All Committee members attended

Due to the significant matters facing the Company during 2021, the Non-Executive Directors met frequently with the CEO and Company Secretary during the year.

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

Independence of Non-Executive Directors

A majority of the Company's Directors are Non-Executive Directors and 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 26% of Shield's issued share capital). Although Peter Llewellyn-Davies was put forward for election by W. Health, he was nevertheless appointed independently and does not represent W. Health.

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

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. New Directors received a formal induction following their appointment.

Re-election of Directors and term of service

Details of the proposed re-election of Directors and the terms of their service contracts/letters of appointment are provided within the Directors' remuneration report on page 32.

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 27 and 28.

Risk management and internal control

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

Remuneration

The role of the Board and its Remuneration Committee in establishing a policy on Executive remuneration and an explanation of the level and components of remuneration are provided in the Directors' remuneration report on pages 29 to 35.

Engagement with stakeholders

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

General meetings

Details of the Annual General Meeting (AGM) are provided in the Directors' report on page 37. 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

21 June 2022



Monitoring risk and reporting



Peter Llewellyn-Davies
Audit Committee Chair

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.

2021 membership and attendance

Peter Llewellyn-Davies	●●●●
Hans Peter Hasler	●
Fabiana Lacerca-Allen	●●●

The Audit Committee

The Audit Committee’s responsibilities include:

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

Membership and activities of the Audit Committee

The current members of the Audit Committee are Peter Llewellyn-Davies (Chairman) and Fabiana Lacerca-Allen. Fabiana Lacerca-Allen was appointed as a member of the Committee on 18 June 2021 taking over from Hans Peter Hasler. The Committee met formally on four occasions during 2021.

In April 2021 the Committee met to receive the report from KPMG on the audit of the 2020 financial results, and to review the draft preliminary results announcement and the draft 2020 Annual Report. The key audit issues discussed at the meeting were:

- The valuation of intangible assets, in particular that of PT20 – the Committee concluded that no impairment was required, based on a risk-adjusted analysis of the commercial prospects for PT20 which had been prepared by management;
- The valuation of the investment in the parent company books of the carrying value of its subsidiaries – the Committee concluded that the carrying value was justified by the commercial prospects for Feraccru® which were supported by the licence agreements with Norgine and ASK Pharm to commercialise Feraccru® in Europe and China and the US approval of Accrufer®; and



Membership and activities of the Audit Committee continued

- Going concern – the Group’s latest cash flow forecast demonstrated sufficient cash resources after the £27.6 million fundraise, completed in March 2021, to last for at least twelve months following the date of approval of the financial statements. On this basis the Committee concluded that it was appropriate to prepare the 2020 financial statements on the going concern basis.

In August 2021 the Committee met to consider the draft announcement of the half-year financial results. The main issues discussed were revenue recognition, the valuation of PT20 and going concern. Regarding going concern, management pointed out that actual cash spent over the course of the last few months was significantly lower than projected. Additionally, management identified several potential cash-preserving measures, which further limit cash spending going forward, and extend the projected cash runway to the end of the second quarter of 2022. Consequently, the Committee concluded that the use of the going concern basis of preparation was appropriate for the interim results.

The Committee met again in November 2021. The main topics discussed were:

- KPMG’s plan for the 2021 audit. It was noted that key issues for 2021 would continue to include the valuation of intangible assets, in particular PT20, the parent company’s investment in subsidiaries and going concern; and
- Review of the latest risk register and the updated financial position and prospects procedures (FPPP) Board memorandum, both of which had been prepared by management and circulated to the full Board.

In March 2022 the Audit Committee met to receive the report of the auditor and the outcome of the audit process. The key matters for discussion were the valuation of intangible assets and going concern.

External audit

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

The Senior Statutory Auditor for 2021 was Stuart Burdass, who initially assumed this role for the 2020 audit.

The Audit Committee approves any non-audit services provided by the external auditor, with consideration given to the threats posed to independence and safeguards in place. All such services were approved during the year.

Internal audit

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

Peter Llewellyn-Davies
Audit Committee Chair

21 June 2022



Committed to best practice



Anders Lundstrom
Remuneration Committee Chair

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

2021 membership and attendance

Rolf Hoffmann	●●
Hans Peter Hasler	●●●
Anders Lundstrom	●

On behalf of the Board of Directors, I am pleased to present the Directors' remuneration report for the year ended 31 December 2021. 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 was appointed Committee Chair on 18 June 2021 taking over from Rolf Hoffmann, who resigned on 18 June 2021.

The Committee meets at least once a year and met three times during the course of 2021. It has responsibility for:

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

Aon Solutions UK Limited 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.



Key remuneration principles

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

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

Executive remuneration in 2021

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 are provided on pages 31 and 34.

Looking forward to 2022

The CEO's bonus opportunity and share options award opportunity for 2022 are expected to be up to 75% of salary and 100% of salary respectively, with each award subject to the achievement of performance conditions and pro-rated for length of service during the year.

Board changes

On 1 June 2021 Tim Watts resigned as CEO of Shield Therapeutics plc. Greg Madison was appointed as CEO following the resignation of Tim Watts. On 18 June 2021, Greg Madison was appointed to the Board of Directors.

On 10 May 2021, both Fabiana Lacerca-Allen and Anders Lundstrom were appointed to the Board of Directors as Non-Executive Directors.

On 18 June 2021 Rolf Hoffmann did not stand for re-election as Non-Executive Director.



Executive Directors' remuneration policy

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

Element and purpose	Operation	Maximum opportunity
Fixed remuneration		
Basic salary		
To provide a competitive base salary for the market and size of the Company in order to attract and retain Executive Directors of a suitable calibre.	Usually reviewed annually, taking account of: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> Private medical insurance. 	No overall maximum has been set, but the level of benefits provided is determined taking into account the overall cost to the Company. Other benefits may be provided to reflect individual circumstances, such as relocation expenses.
Retirement benefits		
To provide an appropriate level of retirement benefit (or cash allowance equivalent).	Executive Directors are eligible to participate in the Group defined contribution pension scheme. In appropriate circumstances, Directors may be permitted to take benefits as a salary cash supplement (which will ordinarily be reduced to take account of the employer National Insurance contributions).	Contributions for 2021 and 2022 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 maximum bonus opportunity is 75% of base salary.
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 recruitment awards, awards are made based on a percentage of salary at the time of onboarding and will vest twelve 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.

During 2021 there were several matters which required the Non-Executive Directors to have a greater level of involvement in the day-to-day business of the Company and, in certain instances, to commit substantially more time and effort in supporting management and communicating with major shareholders than would ordinarily be expected of them. As a consequence of this extra commitment, Mr Hasler, Mr Hoffmann, Mr Llewellyn-Davies and Dr Schweiger each received additional fees of £10,000 during H1 2021 over and above their normal Directors' fees.

These payments are shown on page 33.

Directors' service contracts

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

Name	Position	Notice period	Notes
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 2021 and 2020.

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 32

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

(v) Anders Lundstrom was appointed on 10 May 2021

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

Directors' remuneration – year ended 31 December 2020

Name	Salary/fees £000	Benefits £000	Bonus £000	Pensions £000	Total remuneration 2020 £000
Executive Directors					
Tim Watts ^(vii)	219	—	—	24	243
Carl Sterritt ^(viii)	119	—	115	12	246
Non-Executive Directors					
Hans Peter Hasler	97	—	—	—	97
Peter Llewellyn-Davies	68	—	—	—	68
Rolf Hoffmann	65	—	—	—	65
Dr Christian Schweiger ^(ix)	20	—	—	—	20
James Karis ^(x)	47	—	—	—	47
	635	—	115	36	786

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

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

(ix) Dr Christian Schweiger was appointed on 26 June 2020

(x) James Karis resigned on 18 June 2020

No Director waived any emoluments in respect of the year.

**Retention and Performance Share Plan (RPSP) options granted in 2021 (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 2021 included the following awards to the CEO.

Name	Number of options	Vesting date
Greg Madison (performance award)	620,696	By 14 June 2024
Greg Madison (recruitment award)	1,000,000	By 14 June 2022

As at 31 December 2021, Greg Madison held 1,620,696 options. No other Director holds any options. All options are exercisable at a nominal price of £0.015 per share. No amounts were paid on grant.

The previous CEO Tim Watts held 625,000 options which were tested at 31 December 2021. In accordance with the performance conditions all options lapsed.

2021 annual bonus (audited)

The CEO was awarded a bonus of \$221,264 in respect of 2021, however the Board has agreed to defer any bonus payments in respect of 2021 until such time the Board deems it appropriate for payment.

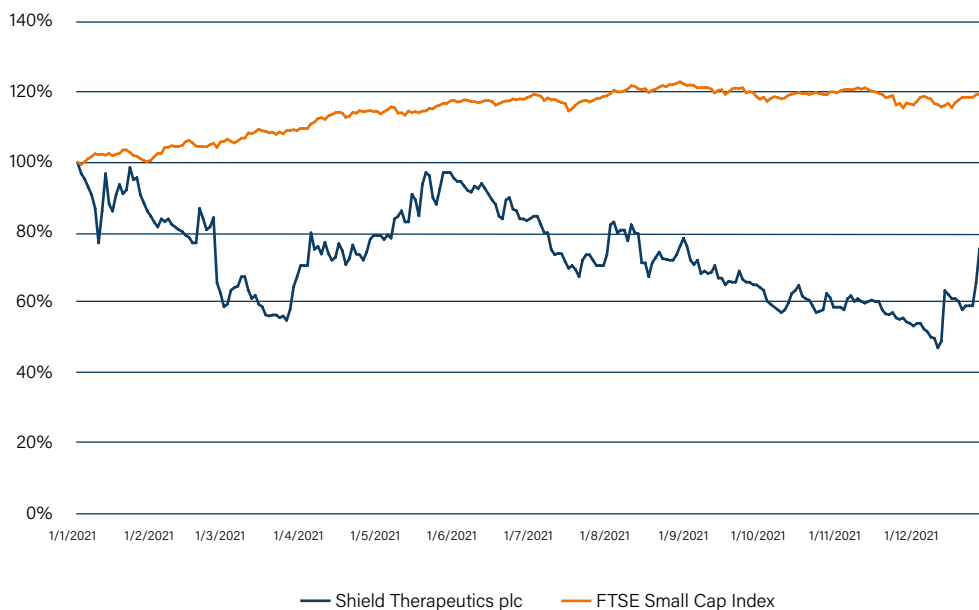
Directors' shareholdings

The table below discloses the interests of any Directors serving during the year in the shares of the Company at 31 December 2021.

Name	Shares at 31 December 2021	% of share capital
Dr Christian Schweiger	5,665,580	2.62%
Tim Watts	728,500	0.3%
Hans Peter Hasler	500,000	0.23%
Peter Llewellyn-Davies	20,000	0%

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 2021 was £0.4450. The highest mid-market price of the Ordinary Shares during the year was £0.6260 and the lowest price was £0.2701.

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

Anders Lundstrom
Remuneration Committee Chair
21 June 2022



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 2021.

Principal activities

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

Strategic report

The strategic report is set out on pages 2 to 21. 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 2021 were related primarily to the commercialisation of Accrufer® in the US which was launched in June 2021. This included:

- The appointment of key hires in the US.
- Comprehensive tender process to select partners for supply and distribution in US.
- Securing contracts to ensure payer coverage for Accrufer®.

In order to support the US launch strategy various funding strategies were evaluated in the early part of 2021 with Shield announcing an equity fundraise in February 2021 which was approved by the shareholders in March 2021.

The Company entered into two out-licensing agreements for the commercialisation of Accrufer® in foreign territories. These were with Korea Pharma Co., Ltd. for the commercialisation of Accrufer® in the Republic of Korea and with KYE Pharmaceuticals Inc. for the commercialisation of Accrufer® in Canada.

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

The Group employed between 27 and 32 staff during 2021. The Chief Executive Officer and the other members of the Senior Executive Team interact daily with all employees. Management has implemented employee policies and procedures which are appropriate for the size of the Group.

Apart from its shareholders and employees the Group's main stakeholders are Norgine BV and Beijing Aosaikang Pharmaceutical Co., Ltd., with which the Group has signed licence development and commercialisation agreements relating to Feraccru®/Accrufer®. The agreements contain formal provisions for relationships between Shield and the licence partners but the Board and management also recognise the importance of establishing and maintaining good, less formal relationships with these stakeholders. The Chief Executive Officer and Senior 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 46. The Group's loss after taxation for the year was £19,336,000.

The Directors do not recommend the payment of a dividend in respect of the year ended 31 December 2021.



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 (appointed 18 June 2021)

Peter Llewellyn-Davies

Dr Christian Schweiger

Fabiana Lacerca-Allen (appointed 10 May 2021)

Anders Lundstrom (appointed 10 May 2021)

Rolf Hoffmann (resigned 17 June 2021)

Tim Watts (resigned 30 September 2021)

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.

Research and development

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

Political donations

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

Financial instruments

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

Corporate governance report

The Company's corporate governance report can be found on pages 22 to 38 of the Annual Report. The corporate governance report forms part of this Directors' report and is incorporated into it by cross-reference.

Major interests

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

W. Health LP	25.91%
AOP Orphan International AG	13.11%
Hargreaves Lansdown	9.63%

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 2.00pm on Wednesday 27 July 2022.

By order of the Board

Greg Madison
Chief Executive Officer

21 June 2022



Corporate governance

Statement of Directors' responsibilities

in respect of the Annual Report and the financial statements

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

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

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

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

- Select suitable accounting policies and then apply them consistently;
- Make judgments and estimates that are reasonable, relevant and reliable;
- State whether they have been prepared in accordance with 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

21 June 2022



Independent auditor's report

to the members of Shield Therapeutics plc

1. Our opinion is unmodified

We have audited the financial statements of Shield Therapeutics plc ("the Company") for the year ended 31 December 2021 which comprise the consolidated statement of profit and loss and other comprehensive income, the group and company balance sheets, the group and company statements of changes in equity, the group and company statements of cash flows, and the related notes, including the accounting policies in note 2.

In our opinion:

- the financial statements give a true and fair view of the state of the Group's and of the parent Company's affairs as at 31 December 2021 and of the Group's loss for the year then ended;
- the Group financial statements have been properly prepared in accordance with UK-adopted international accounting standard;
- the parent Company financial statements have been properly prepared in accordance with UK-adopted international accounting standard, and as applied in accordance with the provisions of the Companies Act 2006; and
- the financial statements have been prepared in accordance with the requirements of the Companies Act 2006.

Basis for opinion

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

Overview		
Materiality:	£0.6m (2020: £0.4m)	
group financial statements as a whole	3.1% (2020: 4.3%) of group loss before tax	
Coverage	100% (2020: 100%) of group loss before tax	
Key audit matters		vs 2020
Recurring risks	Going concern	▲
	Recoverability of intangible assets	◀▶
	Parent company: Recoverability of investments in subsidiaries	◀▶



2. Material uncertainty related to going concern

The risk	Our response
<p>Going concern Refer to page 28 (Audit Committee Report).</p> <p>We draw attention to note 2 to the financial statements which indicates that the cash resources of the Group will cease to be sufficient in the absence of further funding received from the commercialisation of the Group's Feraccru® asset, or other forms of finance such as debt finance or royalty finance, the success and timing of which are uncertain.</p> <p>These events and conditions, along with the other matters explained in note 2, constitute a material uncertainty that may cast significant doubt on the group's and the parent company's ability to continue as a going concern.</p> <p>Our opinion is not modified in respect of this matter.</p>	<p>Disclosure quality The financial statements explain how the Board has formed a judgment that it is appropriate to adopt the going concern basis of preparation for the Group and parent Company.</p> <p>That judgment is based on an evaluation of the inherent risks to the Group's and Company's business model and how those risks might affect the Group's and Company's financial resources or ability to continue operations over a period of at least a year from the date of approval of the financial statements.</p> <p>The risk most likely to adversely affect the Group's and Company's available financial resources over this period was that expected cash inflows from signing agreements with new partners in the US or alternative sources of finance are not secured.</p> <p>The risk for our audit was whether or not those risks are such that they amount to a material uncertainty that may have cast significant doubt about the ability to continue as a going concern. If so, that fact is required to be disclosed (as has been done) and , along with a description of the circumstances, is a key financial statement disclosure.</p> <p>The financial statements explain how the Board has formed a judgment that it is appropriate to adopt the going concern basis of preparation for the group and parent company.</p>
	<p>We considered whether these risks could plausibly affect the liquidity in the going concern period by assessing the directors' sensitivities over the level of available financial resources indicated by the Group's financial forecasts taking account of severe, but plausible, adverse effects that could arise from these risks individually and collectively.</p> <p>Our procedures included:</p> <ul style="list-style-type: none"> – Historical comparisons: We assessed the directors' previous forecasts against actual outcomes to form a view of the directors' forecasting accuracy; – Sensitivity analysis: We considered sensitivities over the level of available financial resources indicated by the Group's financial forecasts, including revenue cash flows, taking account of reasonably possible (but not unrealistic) adverse effects that could arise, individually and collectively; – Benchmarking assumptions: We challenged the appropriateness of the key assumptions, such as the revenue assumptions, used in the cash flow projections by reference to our knowledge of the business and quotes from external suppliers. We also assessed the projections and assumptions by reference to the general market conditions and post year end trading and cash flows; – Assessing transparency: We assessed the completeness and accuracy of the matters covered in the going concern disclosure by reference to our audit findings from the above procedures and our understanding of the Group's business and strategies.

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

Key audit matters are those matters that, in our professional judgment, were of most significance in the audit of the financial statements and include the most significant assessed risks of material misstatement (whether or not due to fraud) identified by us, including those which had the greatest effect on: the overall audit strategy; the allocation of resources in the audit; and directing the efforts of the engagement team. These matters were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters. Going concern is a significant key audit matter and is described in section 2 of our report. In arriving at our audit opinion above, the other key audit matters, in decreasing order of audit significance, were as follows:



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

The risk		Our response
<p>Group: Recoverability of intangible assets (£26.9 million; 2020: £27.3 million).</p> <p>Refer to page 28 (Audit Committee Report), page 55 (accounting policy) and page 63 (financial disclosures)</p>	<p>Forecast-based assessment</p> <p>These intangible assets relate to the Group's two drug CGUs (Feraccru® and PT20) and their possibility of impairment is a significant estimate as the drugs are at a relatively early stage in their lifecycle. The valuation of these drugs are also the key consideration in assessing the recoverability of the parent company's investment in subsidiaries (see below).</p> <p>The estimated recoverable amount of the CGUs containing the assets relating to the drugs is subjective due to the inherent uncertainty involved in forecasting and discounting future cash flows.</p> <p>The cash flows include amounts in respect of the inflows from a combination of anticipated royalties and forecast sales, and other payments from current or prospective licensees and outflows of the estimated costs to progress the commercialisation of these assets.</p> <p>The effect of these matters is that, as part of our risk assessment for audit planning purposes we determined that the value in use of both CGUs had a high degree of estimation uncertainty, with a potential range of reasonable outcomes greater than our materiality for the financial statements as a whole, and possibly many times that amount. The financial statements (note 14) disclose the sensitivity estimated by the Company.</p>	<p>We performed the tests below rather than seeking to rely on any of the group's controls because the nature of the balance is such that we would expect to obtain audit evidence primarily through the detailed procedures described.</p> <p>Our procedures included:</p> <ul style="list-style-type: none"> – Our sector experience: We evaluated and challenged the assumptions used, in particular those relating to forecast receipts from licensees, forecast sales, and the discount rate applied to discount the cashflows; – Benchmarking assumptions: We compared the Group's assumptions to externally derived data in relation to key inputs such as projected market growth and discount rates, and compared estimated royalty rates with those already agreed by the Group and other similar licence agreements in the sector; – Sensitivity analysis: We performed breakeven analysis on the key assumptions noted above; – Assessing transparency: We assessed whether the disclosures about the sensitivity of the outcome of the impairment assessment to changes in key assumptions reflected the risks inherent in the forecast-based assessment of recoverability.
<p>Parent company: Recoverability of parent company's investment in subsidiaries and debt due from Group entities</p> <p>Investments – £105.3 million; (2020: £104.7 million).</p> <p>Debt due from Group entities – £60.1 million (2020: £41.5 million).</p> <p>Refer to page 27 (Audit Committee Report), page 56 (accounting policy) and page 64 (financial disclosures).</p>	<p>Forecast-based assessment</p> <p>The carrying amount of the parent company's investments in subsidiaries and debt due from Group entities is significant and at risk of irrecoverability as the subsidiary companies are currently loss-making. The estimated recoverable amount of these balances is subjective due to the inherent uncertainty in forecasting and discounting future cash flows.</p> <p>The effect of these matters is that, as part of our risk assessment, we determined that the recoverable amount of the cost of investment in subsidiaries has a high degree of estimation uncertainty, with a potential range of reasonable outcomes greater than our materiality for the financial statements as a whole, and possibly many times that amount. The financial statements (note 14) disclose the sensitivity estimated by the Company.</p>	<p>We performed the tests below rather than seeking to rely on any of the company's controls because the nature of the balance is such that we would expect to obtain audit evidence primarily through the detailed procedures described.</p> <p>Our procedures included:</p> <ul style="list-style-type: none"> – Test of detail: Comparing the carrying amount of 100% of the investments with the relevant subsidiaries' draft balance sheet to identify whether their net assets, being an approximation of their minimum recoverable amount, were in excess of their carrying amounts and covered the debt owed. – Assessing transparency: Assessing whether the disclosures about the sensitivity of the outcome of the impairment assessment to changes in key assumptions reflected the risks inherent in the forecast-based assessment of recoverability.



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

Materiality for the group financial statements as a whole was set at £600,000 (2020: £400,000), determined with reference to a benchmark of group loss before tax, of which it represents 3.1% (2020: 4.3% of normalised group loss before tax by averaging over the last four years due to fluctuations in the business cycle). Materiality has increased because the group loss before tax has increased.

Materiality for the parent company financial statements as a whole was set at £60,000 (2020: £50,000), determined with reference to a benchmark of loss before tax, of which it represents 5.7% (2020: 5.3% of normalized loss before tax).

In line with our audit methodology, our procedures on individual account balances and disclosures were performed to a lower threshold, performance materiality, so as to reduce to an acceptable level the risk that individually immaterial misstatements in individual account balances add up to a material amount across the financial statements as a whole.

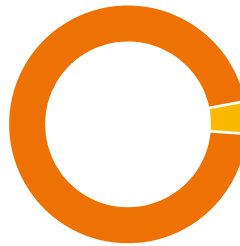
Performance materiality was set at 75% (2020: 75%) of materiality for the financial statements as a whole, which equates to £450,000 (2020: £300,000) for the group and £45,000 (2020: £37,500) for the parent company. We applied this percentage in our determination of performance materiality because we did not identify any factors indicating an elevated level of risk.

We agreed to report to the Audit Committee any corrected or uncorrected identified misstatements exceeding £30,000 (2020: £20,000), in addition to other identified misstatements that warranted reporting on qualitative grounds.

Of the group's 6 (2020: 5) reporting components, we subjected 4 (2020: 3) to full scope audits for group purposes and 2 (2020: 2) to specified risk-focused audit procedures. The latter were not individually financially significant enough to require a full scope audit for group purposes.

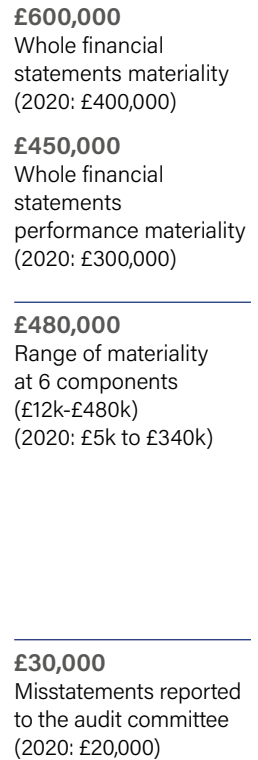
Group loss before tax

£19.6 million
(2020: £9.3 million
normalised group loss
before tax)



Loss before tax
Group materiality

Group materiality £0.6 million (2020: £0.4 million)



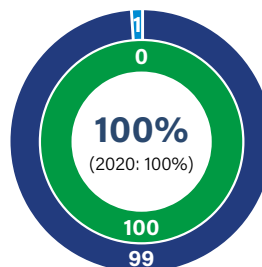
Group revenue



Group loss before tax



Group total assets



- Full scope for group audit purposes 2021
- Specified risk-focused audit procedures 2021
- Full scope for group audit purposes 2020
- Specified risk-focused audit procedures 2020



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

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

The Group team carried out all of the work on the 6 reporting components. We used component materialities, which range from £12,000 to £480,000 (2020: £5,000 to £340,000), having regard to the mix of size and risk profile of the Group across the components.

The scope of the audit work performed was predominately substantive as we placed limited reliance upon the Group's internal control over financial reporting.

5. Going concern basis of preparation

The Directors have prepared the financial statements on the going concern basis as they do not intend to liquidate the Group or the Company or to cease their operations, and as they have concluded that the Group's and the Company's financial position means that this is realistic for at least a year from the date of approval of the financial statements ("the going concern period"). As stated in section 2 of our report, they have also concluded that there is a material uncertainty related to going concern.

An explanation of how we evaluated management's assessment of going concern is set out in section 2 of our report.

Our conclusions based on this work:

- we consider that the Directors' use of the going concern basis of accounting in the preparation of the financial statements is appropriate;
- we have nothing material to add or draw attention to in relation to the directors' statement in Note 2 to the financial statements on the use of the going concern basis of accounting, and their identification therein of a material uncertainty over the Group and Company's ability to continue to use that basis for the going concern period; and
- we found the going concern disclosure in note 2 to be acceptable.

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

Identifying and responding to risks of material misstatement due to fraud

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

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

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

As required by auditing standards, we perform procedures to address the risk of management override of controls, in particular the risk that Group management may be in a position to make inappropriate accounting entries and the risk of bias in accounting entries such as the recoverability of Intangible assets and the recoverability of the parent company's investment in subsidiaries. On this audit we do not believe there is a fraud risk related to revenue recognition because revenue recognised around the year end is not material and not considered to be susceptible to management manipulation.

We did not identify any additional fraud risks.

We performed procedures including:

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



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

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

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

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

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

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

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

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

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

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

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

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

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

Strategic report and directors' report

Based solely on our work on the other information:

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



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

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

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

We have nothing to report in these respects.

9. Respective responsibilities Directors' responsibilities

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

Auditor's responsibilities

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

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

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

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

Stuart Burdass (Senior Statutory Auditor) for and on behalf of KPMG LLP, Statutory Auditor

Chartered Accountants
Quayside House
110 Quayside
Newcastle upon Tyne
NE1 3DX
21 June 2022



Financial statements

Consolidated statement of profit and loss and other comprehensive income

for the year ended 31 December 2021

	Notes	2021 £000	2020 £000
Revenue	5	1,519	10,387
Cost of sales		(980)	(1,354)
Gross profit		539	9,033
Other operating income		111	—
Operating costs – selling, general and administrative expenses	7	(20,023)	(8,608)
Operating profit/(loss) before research and development expenditure		(19,373)	425
Research and development expenditure	6	(579)	(2,579)
Operating loss		(19,952)	(2,154)
Financial income	9	395	269
Financial expense	9	(8)	(1)
Loss before tax		(19,565)	(1,886)
Taxation	11	229	(744)
Loss for the year		(19,336)	(2,630)
Attributable to			
Equity holders of the parent		(19,336)	(2,630)
Other comprehensive income			
Items that are or may be reclassified subsequently to profit or loss:			
Foreign currency translation differences – foreign operations		1,396	(16)
Total comprehensive expenditure for the year		(17,940)	(2,646)
Attributable to			
Equity holders of the parent		(17,940)	(2,646)
Total comprehensive expenditure for the year		(17,940)	(2,646)
Earnings per share			
Basic and diluted loss per share	10	£(0.09)	£(0.02)



Group balance sheet

at 31 December 2021

	Notes	2021 £000	2020 £000
Non-current assets			
Intangible assets	13	26,851	27,266
Property, plant and equipment	12	304	32
		27,155	27,298
Current assets			
Inventories	15	1,635	1,379
Trade and other receivables	16	2,930	619
Current tax asset	11	576	292
Cash and cash equivalents	17	12,117	2,940
		17,258	5,230
Total assets		44,413	32,528
Current liabilities			
Trade and other payables	18	(3,114)	(1,471)
Other liabilities	19	(110)	(753)
Lease liabilities	24	(156)	(28)
		(3,380)	(2,252)
Total liabilities		(3,380)	(2,252)
Net assets		41,033	30,276
Equity			
Share capital	21	3,238	1,764
Share premium	22	114,583	88,352
Merger reserve	22	28,358	28,358
Currency translation reserve	22	1,449	53
Retained earnings	22	(106,595)	(88,251)
Total equity		41,033	30,276

Financial statements

These financial statements were approved by the Board of Directors on 21 June 2022 and were signed on its behalf by:

Greg Madison

Director

Company registered number: 09761509



Financial statements

Company balance sheet

at 31 December 2021

	Notes	2021 £000	2020 £000
Non-current assets			
Investments	14	105,285	104,731
Trade and other receivables	16	60,088	41,472
		165,373	146,203
Current assets			
Trade and other receivables	16	69	39
Cash and cash equivalents	17	10,559	1,741
		10,628	1,780
Total assets		176,001	147,983
Current liabilities			
Trade and other payables	18	(644)	(276)
Other liabilities	19	(3)	—
Total liabilities		(647)	(276)
Net assets		175,354	147,707
Equity			
Share capital	21	3,238	1,764
Share premium	22	114,583	88,352
Merger reserve	22	117,323	117,323
Retained earnings	22	(59,790)	(59,732)
Total equity		175,354	147,707

The parent company's loss for the year was £1,054k (FY2020: £1,117k). These financial statements were approved by the Board of Directors on 21 June 2022 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 2021

	Issued capital £000	Share premium £000	Merger reserve £000	Currency translation reserve £000	Retained earnings £000	Total £000
Balance at 1 January 2020	1,758	88,352	28,358	69	(86,392)	32,145
Loss for the year	—	—	—	—	(2,630)	(2,630)
Other comprehensive income:						
Foreign currency translation differences	—	—	—	(16)	—	(16)
Total comprehensive expense for the year	—	—	—	(16)	(2,630)	(2,646)
Transactions with owners, recorded directly in equity						
Equity-settled share-based payment transactions	6	—	—	—	771	777
Balance at 31 December 2020	1,764	88,352	28,358	53	(88,251)	30,276
Loss for the year	—	—	—	—	(19,336)	(19,336)
Other comprehensive income:						
Foreign currency translation differences	—	—	—	1,396	—	1,396
Total comprehensive expense for the year	—	—	—	1,396	(19,336)	(17,940)
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	(106,595)	41,033



Financial statements

Company statement of changes in equity

for the year ended 31 December 2021

	Issued capital £000	Share premium £000	Merger reserve £000	Retained earnings £000	Total £000
Balance at 1 January 2020	1,758	88,352	117,323	(59,401)	148,032
Loss for the year	—	—	—	(1,117)	(1,117)
Total comprehensive expense for the year	—	—	—	(1,117)	(1,117)
Transactions with owners, recorded directly in equity					
Equity-settled share-based payment transactions	6	—	—	786	792
Balance at 31 December 2020	1,764	88,352	117,323	(59,732)	147,707
Loss for the year	—	—	—	(1,055)	(1,055)
Total comprehensive expense for the year	—	—	—	(1,055)	(1,055)
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	(59,790)	175,354



Group statement of cash flows

for the year ended 31 December 2021

	2021 £000	2020 £000
Cash flows from operating activities		
Loss for the year	(19,336)	(2,630)
Adjustments for:		
Depreciation and amortisation	2,207	2,705
Equity-settled share-based payment expenses	992	771
Financial income	(395)	(269)
Financial expense	42	1
Unrealised foreign exchange gains/(losses)	1,396	(11)
Income tax	(229)	744
	(15,323)	1,311
Increase in inventories	(256)	(431)
Increase in trade and other receivables	(2,879)	(264)
Increase/(decrease) in trade and other payables	1,643	(2,075)
(Decrease)/increase in other liabilities	(643)	140
Change in lease assets and liabilities (new leased assets)	128	8
Income tax received/(paid)	592	(89)
Net cash flows from operating activities	(16,738)	(1,400)
Cash flows from investing activities		
Financial income	13	3
Acquisitions of intangible assets	(9)	(23)
Acquisitions of tangible assets	(372)	—
Capitalised development expenditure	(1,683)	—
Net cash flows from investing activities	(2,051)	(20)
Cash flows from financing activities		
Interest paid	(42)	(1)
Leases – interest payment	(3)	(4)
Proceeds from equity raise	27,679	—
Proceeds of share options exercised	26	6
Total cash outflow for leases	(76)	(48)
Net cash flows from financing activities	27,584	(47)
Net increase/(decrease) in cash	8,795	(1,467)
Effect of exchange rate fluctuations on cash held	382	266
Cash and cash equivalents at 1 January	2,940	4,141
Cash and cash equivalents at 31 December	12,117	2,940



Financial statements

Company statement of cash flows

for the year ended 31 December 2021

	2021 £000	2020 £000
Cash flows from operating activities		
Loss for the year	(1,055)	(1,117)
Adjustments for:		
Equity-settled share-based payment expenses	442	109
Financial income	(895)	(395)
	(1,508)	(1,403)
Decrease in trade and other receivables	(30)	29
Decrease in trade and other payables	372	(77)
Net cash flows from operating activities	(1,166)	(1,451)
Cash flows from investing activities		
Financial income	497	395
Repayment of loans to Group undertakings	1,486	1,005
Loans made to Group undertakings	(20,102)	—
Net cash flows from investing activities	(18,119)	1,400
Cash flows from financing activities		
Proceeds of share option exercise	26	6
Proceeds from equity raise	27,679	—
Net cash flows from financing activities	27,705	6
Net increase/(decrease) in cash	8,420	(45)
Effect of exchange rate fluctuations on cash held	398	—
Cash and cash equivalents at 1 January	1,741	1,786
Cash and cash equivalents at 31 December	10,559	1,741



Notes (forming part of the financial statements)

for the year ended 31 December 2021

1. General information

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

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

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

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

2. Accounting policies

The consolidated and parent company financial statements have been prepared and approved by the Directors in accordance with 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 historical cost basis. The functional currency of the Company is GBP. The consolidated financial statements are presented in GBP and all values are rounded to the nearest thousand (£000), except as otherwise indicated.

Company income statement

As permitted by Section 408 of the Companies Act 2006, the Company has not presented its own income statement. The loss for the financial year per the accounts of the Company was £1.0 million. The total comprehensive expenditure for the year comprises the net loss and is wholly attributable to the equity holders of Shield Therapeutics plc; therefore, no statement of comprehensive income has been disclosed.

Basis of preparation

Going concern

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

At 31 December 2021 the Group held £12.1m of cash. Since year-end, Shield secured an exclusive license agreement with KYE Pharmaceuticals Inc. for the development and commercialisation of Accrufer[®] in Canada, resulting in £0.15m being received as an upfront payment. In addition, the Group is starting to receive cash deposits related to Accrufer[®] product sales. The Group's unaudited cash balance at 30 April 2022 was £5.7 million.

The Directors have considered the funding requirements of the Group through the preparation of detailed cash flow forecasts for the period to December 2023. Under current business plans, the current cash resources will extend into the third quarter of 2022. As a result, additional revenue generating transactions or financing would therefore be needed by that time to allow the business plans to continue.

The Group is currently considering various forms of finance, such as debt finance and royalty finance underpinned by the expected net product revenues generated in the US over the next few years. However, there can be no guarantee that any of these opportunities will be successfully concluded. Based on the status of the various finance considerations, the Directors believe that it remains appropriate to prepare the financial statements on a going concern basis. However, the above matters indicate the existence of a material uncertainty related to events or conditions which may cast significant doubt on the Group's and the Company's ability to continue as a going concern and, therefore, that the Group and Company may be unable to realise their assets and discharge their liabilities in the normal course of business.

The financial statements do not include any adjustments that would result from the basis of preparation being inappropriate.

Basis of consolidation

The consolidated financial statements comprise the financial statements of the Group and its subsidiaries as at 31 December 2021.

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

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



2. Accounting policies continued

Foreign currency

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

Revenue

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

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

- Execution of the licence – revenue from both contracts was recognised at the time the agreements were signed;
- Event-based milestones such as completion of the paediatric clinical study, approval of the product in China and the achievement of sales thresholds – these comprise variable consideration and, as such, revenue is only recognised when it is highly probable that such revenue will not be reversed in future. No revenue has been recognised in respect of these milestones in either 2019 or 2020; and
- Sales-based royalties – these are attributable to the licence and revenue is recognised when sales occur.

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 health care providers 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, health care providers 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 statement of comprehensive income in the period in which it is incurred.

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

Employee benefit costs

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



2. Accounting policies continued

Share-based payments

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

Finance income and costs

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

Taxation

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

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

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

Intangible assets

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

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

Amortisation is charged as follows:

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

Impairment of intangible assets

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

Property, plant and equipment

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

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

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

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

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

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



2. Accounting policies continued

Investments in subsidiaries

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

Inventories

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

Financial assets and liabilities

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

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

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

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

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

3. Estimates and judgments

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

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

Going concern

The Board has formed a judgment that it is appropriate to adopt the going concern basis of preparation for the Group and parent company. This judgment is based on an evaluation of the Group's cash flow forecasts and risks to its business model and how those risks might affect the Group's and Company's financial resources or ability to continue operations over a period of at least twelve months from the date of approval of the financial statements. The Directors consider it appropriate to adopt the going concern basis of accounting in preparing the financial statements for the reasons set out on page 53, and note that these reasons give rise to a material uncertainty which may cast significant doubt on the Group's and the Company's ability to continue as a going concern.

Development expenditure

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

Development expenditure in 2021, such as the development of a formulation for the paediatric clinical study, have not been capitalised as there is considerable technical uncertainty as to whether the formulation and the paediatric study will lead to approval of the product for use in children.

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

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



3. Estimates and judgments continued

Estimate of recoverable amount of intellectual property acquired with Phosphate Therapeutics Limited – £15.9 million; investments in Company balance sheet of £26.8 million

The valuation of intellectual property acquired with Phosphate Therapeutics Limited in 2016 is based on cash flow forecasts for the underlying product, PT20 and an assumed appropriate cost of capital and other inputs, such as the size of the market in major markets, in order to arrive at a value in use for the asset. The realisation of its value is ultimately dependent on the positive outcome of a PT20 Phase III clinical study followed by regulatory approval and successful commercialisation of the asset. Whilst earlier PT20 clinical studies provide grounds for confidence that the Phase III study would be successful, this cannot be guaranteed. Work on the development of a suitable commercial formulation of the drug product is ongoing. In the event that commercial returns are lower than current expectations this may lead to an impairment. Recoverability of intangible assets from the PT20 CGU is a significant source of estimation. See Note 13 for sensitivity analysis of key assumptions in this valuation.

Estimate of recoverable amount of intellectual property associated with Feraccru® – intangible assets of £10.9 million; investments in Company balance sheet of £78.4 million

The valuation of intellectual property associated with Feraccru® (including patents, development costs and the Company's investment in Shield TX (Switzerland) AG is based on cash flow forecasts for the underlying business and an assumed appropriate cost of capital and other inputs in order to arrive at a fair value for the asset. The realisation of its value is ultimately dependent on the successful commercialisation of the asset. In the event that commercial returns are lower than current expectations this may lead to an impairment. No impairment has been recognised to date. See Note 14 for sensitivity analysis of key assumptions in this valuation. The Group does not expect a reasonable range of sensitivities in the assumptions used to give rise to material differences within the recoverability of Feraccru® however, in the event of multiple changes in assumptions relating to the ability to successfully commercialise the products this could lead to an impairment.

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:

Annual improvements to IFRS 2018-2020

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

IAS 16 (Amended) – Property, Plant and Equipment: Proceeds Before Intended Use

IAS 37 (Amended) – Onerous Contracts – Cost of Fulfilling a Contract

IFRS 3 (Amended) – Reference to Conceptual Framework

IFRS 17 – Insurance Contracts

The Directors do not expect that the adoption of the amendments, interpretations and annual improvements list above (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.
- PT20 – development of the Group's secondary asset.

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



Financial statements

Notes (forming part of the financial statements) continued

for the year ended 31 December 2021

5. Segmental reporting continued

	Feraccru® 2021 £000	PT20 2021 £000	Central and unallocated 2021 £000	Total 2021 £000	Feraccru® 2020 £000	PT20 2020 £000	Central and unallocated 2020 £000	Total 2020 £000
Revenue	1,519	—	—	1,519	10,387	—	—	10,387
Operating (loss)/profit	(18,294)	(159)	(1,499)	(19,952)	424	(2,047)	(531)	(2,154)
Financial income				395				269
Financial expense				(8)				(1)
Tax				229				(744)
Loss for the year				(19,336)				(2,630)

The revenue analysis in the table below is based on the country of registration of the fee-paying party, £0.5 million (2020: £9.7 million) of revenue is derived from licence upfront and milestone payments from commercial partners. The remainder, £0.9million (2020: £0.7 million) is derived from royalties and £0.1 million net product revenue from Accrufer® sales in the US (2020: £Nil).

	Year ended 31 December 2021 £000	Year ended 31 December 2020 £000
Europe	908	729
Asia	550	9,658
USA	61	—
	1,519	10,387

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

	Year ended 31 December 2021 £000	Year ended 31 December 2020 £000
Customer A	—	9,658
Customer B	908	729
Customer C	550	—
Other customers	61	—
	1,519	10,387

As at 31 December 2021	Feraccru® £000	PT20 £000	Central and unallocated £000	Total £000
Segment assets	14,069	15,767	14,577	44,413
Segment liabilities	(11,899)	(14)	8,533	(3,380)
Total net assets	2,170	15,753	23,110	41,033
Depreciation, amortisation and impairment	753	1,454	—	2,207
Capital expenditure	372	—	—	372
Capitalised development costs	1,683	—	—	1,683

As at 31 December 2020	Feraccru® £000	PT20 £000	Central and unallocated £000	Total £000
Segment assets	11,573	17,605	3,350	32,528
Segment liabilities	(1,267)	(41)	(944)	(2,252)
Total net assets	10,306	17,564	2,406	30,276
Depreciation, amortisation and impairment	671	2,034	—	2,705
Capital expenditure	—	—	—	—
Capitalised development costs	—	23	—	23

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



6. Expenses and auditor's remuneration

	Year ended 31 December 2021 £000	Year ended 31 December 2020 £000
Loss for the year has been arrived at after charging:		
Research and development expenditure	579	2,579
Fees payable to Company's auditor and its associates for the audit of parent company and consolidated financial statements	61	70
Fees payable to Company's auditor and its associates for other services:		
The audit of Company's subsidiaries	47	30
Corporate finance transactions	—	—
Tax compliance services	4	3
Other services	—	—

7. Operating costs - selling, general and administrative expenses

Operating costs comprise:

	Year ended 31 December 2021 £000	Year ended 31 December 2020 £000
Selling costs	10,262	281
General administrative expenses	7,554	5,622
Depreciation and amortisation	2,207	2,705
	20,023	8,608

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	
	2021 Number	2020 Number
R&D	5	5
Medical	2	2
Commercial	8	1
Management and administration	8	8
	23	16

The number of staff employed by the Group at 31 December 2021 was 22 (31 December 2020: 15).

The aggregate payroll costs of these persons were as follows:

	2021 £000	2020 £000
Wages and salaries	4,118	3,076
Share-based payments (see Note 23)	992	786
Other employee benefits	18	61
Pensions	76	78
	5,204	4,001



Financial statements

Notes (forming part of the financial statements) continued

for the year ended 31 December 2021

8. Staff numbers and costs continued

Key management compensation information is as follows:

	2021 £000	2020 £000
Wages and salaries	1,765	1,580
Share-based payments	564	616
Other employee benefits	7	61
Pensions	51	56
	2,387	2,313

Details of directors remuneration information is shown on page 33 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 33.

9. Financial income and expenses

	Year ended 31 December 2021 £000	Year ended 31 December 2020 £000
Financial income		
Net foreign exchange gains	382	266
Total interest income on financial assets measured at amortised cost	13	3
	395	269

	Year ended 31 December 2021 £000	Year ended 31 December 2020 £000
Financial expense		
Net foreign exchange losses	(34)	—
Total interest expense on financial liabilities measured at amortised cost	—	—
Bank charges	(8)	(1)
	(42)	(1)

10. Loss per share

	2021			2020		
	Loss £000	Weighted shares 000	Loss per share £	Loss £000	Weighted shares 000	Loss per share £
Basic and diluted	(19,336)	204,024	(0.09)	(2,630)	117,234	(0.02)

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

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

The diluted loss per share is identical to the basic loss per share in both years, as potential dilutive shares are not treated as dilutive since they would reduce the loss per share. At the date of approval of the report 7,390,922 of share options were in issue under the Company's share option plans (see Note 23) which potentially provide 7,390,922 additional Ordinary Shares (approximately 3.4% of the current share capital).



11. Taxation

Recognised in the income statement:

	Year ended 31 December 2021 £000	Year ended 31 December 2020 £000
Current income tax – UK	188	292
Current income tax – overseas	(55)	(966)
Current income tax – adjustments in respect of prior years	96	(70)
Deferred tax	—	—
Total tax credit/(charge)	229	(744)

Reconciliation of total tax credit:

	Year ended 31 December 2021 £000	Year ended 31 December 2020 £000
Loss for the year	(19,336)	(2,630)
Taxation	229	(744)
Loss before tax	(19,565)	(1,886)
Standard rate of corporation tax in the UK	19%	19%
Tax using the UK corporation tax rate	(3,717)	(358)
Expenses not deductible for tax purposes	147	117
R&D tax credits – current year	(25)	(292)
Adjustments in respect of prior years	(77)	70
Foreign taxation suffered	55	(966)
Differences in foreign tax rate	7	—
Unrelieved tax losses carried forward and other temporary differences not recognised for deferred tax	3,839	685
Total tax credit/(charge)	229	(744)

Factors affecting the future tax charge

The UK corporation tax rate remains unchanged at 19%. The unrecognised UK deferred tax asset as at 31 December 2020 has been calculated based on this rate. The March 2021 Budget announced that a rate of 25% would apply with effect from 1 April 2023, which was enacted on 24 May 2021. This will increase the company's future tax charge accordingly. The unrecognised deferred tax asset as at 31 December 2021 has been calculated based on these rates, reflecting the expected timing of reversal of the related timing differences (2020: 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.

	2021 £000	2020 £000
Unutilised Swiss tax losses to carry forward	—	—
Potential deferred tax asset thereon	—	—
Unutilised German tax losses to carry forward	—	25
Potential deferred tax asset thereon	—	4
Unutilised UK tax losses to carry forward	54,689	35,062
Potential deferred tax asset thereon	13,672	6,662
Total potential deferred tax asset	13,672	6,666

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 £0.6 million at 31 December 2021 (2020: £0.4 million) relates to the anticipated R&D tax credit claim in respect of the 2021 and 2020 financial year.



Financial statements

Notes (forming part of the financial statements) continued

for the year ended 31 December 2021

12. Property, plant and equipment

Group	2021 £000	2020 £000
Cost		
1 January	84	78
Additions	372	56
Disposals	—	(50)
31 December	456	84
Accumulated depreciation		
1 January	52	52
Charge for the period	100	50
Disposals	—	(50)
31 December	152	52
Net book value	304	32

Included within property, plant and equipment are £156,000 (2020: £28,000) 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 2020	2,055	9,943	27,047	39,045
Additions – externally purchased	—	—	23	23
Additions – internally developed	—	—	—	—
Disposals	—	—	—	—
Balance at 31 December 2020	2,055	9,943	27,070	39,068
Additions – externally purchased	9	1,683	—	1,692
Additions – internally developed	—	—	—	—
Disposals	—	—	—	—
Balance at 31 December 2021	2,064	11,626	27,070	40,760
Accumulated amortisation				
Balance at 1 January 2020	574	982	7,591	9,147
Charge for the period	94	527	2,034	2,655
Disposals	—	—	—	—
Balance at 31 December 2020	668	1,509	9,625	11,802
Charge for the period	65	588	1,454	2,107
Disposals	—	—	—	—
Balance at 31 December 2021	733	2,097	11,079	13,909
Net book value				
31 December 2021	1,331	9,529	15,991	26,851
31 December 2020	1,387	8,434	17,445	27,266

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

	2021 £000	2020 £000
Feraccru®	10,860	9,821
Phosphate Therapeutics Limited	15,991	17,445
	26,851	27,266



13. Intangible assets continued

Management has reviewed for impairment the carrying value of the intangible assets as at 31 December 2021. The intangible assets relate to two CGUs, being the Feraccru® business and the Phosphate Therapeutics Limited business. The recoverable amount for Feraccru® has been determined based on value-in-use calculations, using pre-tax cash flow projections for the period of the patents, until 2034. The recoverable amount for PT20 has been determined based on value-in-use calculations using projections of the licensing income which could be derived from the product until 2034, being the current patent life of the product including five years' supplementary patent protection. Management has considered the potential impact of the coronavirus pandemic but does not believe it will materially adversely affect the prospects for either Feraccru® or PT20 due to the ongoing worldwide patient need for treatment for iron deficiency and hyperphosphatemia respectively and the long patent lives of both products. The following key assumptions have been included in the value-in-use calculations:

Feraccru®

The value in use has been calculated based on royalty income forecast to arise from the commercialisation licence agreements with Norgine BV covering Europe, Australia and New Zealand and with Beijing Aosaikang Pharmaceutical Co. Ltd covering China, Taiwan, Hong Kong and Macau, 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, assuming Accrufer® is launched by the end of the second quarter 2021, and 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. The discount rate has not changed since the previous year as the change in risk is reflected in the cash flows which recognise the risks associated with a Shield-led launch of Accrufer® compared with the out-licensing model assumed in 2019. Sensitivity analysis shows that sales in the US would need to be reduced by around 75% from management's base case assumptions, with no reduction in costs, before an impairment of the carrying value of the intangible asset would be required. The Group therefore does not expect a reasonable range of sensitivities in the assumptions used to give rise to material differences within the recoverability of Feraccru®, however in the event of multiple changes in assumptions relating to the ability to successfully commercialise the products this could lead to an impairment.

Phosphate Therapeutics Limited

The value in use of PT20, Phosphate Therapeutics Limited's main asset, has been based on cash flow forecasts of assumed out-licensing income which could be derived from the product PT20 until 2034, being the current patent life of the asset with an additional five years' supplementary patent protection. Sales forecasts have been derived from third-party market projections for the phosphate binder global market and assume that PT20 can reach around 20% of the iron-based phosphate binder market by the end of its patent life. The resulting sales forecast has been cross-referenced to sales of existing comparable products. Commercialisation of PT20 is contingent on the successful outcome of a Phase III clinical study, which cannot be guaranteed, and subsequent regulatory approval. Once the product is approved, the value in use is further dependent on successfully out-licensing the asset to a commercialisation partner and the generation of sufficient sales over the patent life with product launch in the US assumed in 2025, and Europe, Japan and China assumed in 2026. A discount factor of 15% has been applied, reflecting the inherent uncertainty attached to obtaining marketing authorisation for the drug and its subsequent commercial success under an anticipated out-licensing business model. Using a 15% discount rate, management's base case sales forecasts would need to be reduced by 40% before triggering an impairment of the carrying value of the intangible asset. Please note that the valuation of PT20 is sensitive to changes in the discount factor applied. Alternatively, using the unadjusted base case sales forecasts, a licence deal with no upfront payment, no development or sales milestones and a royalty of only 9%, which collectively would be well below a market-standard agreement, would still support the intangible asset valuation. Using a discount rate of 18.3% or higher would result in an impairment. Whilst the sensitivity analysis performed indicates the carrying value is supportable, as noted above, there are several key assumptions in the impairment review of the PT20 asset, including an assumption that the asset will be successfully taken through the clinical trials process, and high level assessments of the global market for such a treatment, and an assumption of the market penetration.



Financial statements

Notes (forming part of the financial statements) continued

for the year ended 31 December 2021

14. Investments

Company	2021 £000	2020 £000
Cost		
1 January	165,131	164,454
Additions	554	677
Disposals	—	—
31 December	165,685	165,131
Accumulated impairment		
1 January and 31 December	(60,400)	(60,400)
Net book value		
31 December	105,285	104,731
1 January	104,731	104,054

Other additions of £0.6 million (2020: £0.7 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 2021 and 31 December 2020

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

* Investment held indirectly

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

	2021 £000	2020 £000
Shield TX (Switzerland) AG	78,373	77,967
Shield Therapeutics Inc.	148	—
Phosphate Therapeutics Limited	26,764	26,764
	105,285	104,731

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

Shield TX (Switzerland) AG

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



14. Investments continued

Phosphate Therapeutics Limited

The Company's carrying value of Phosphate Therapeutics Limited is supported by the value in use of PT20, the main asset of the subsidiary. The value in use of PT20, Phosphate Therapeutics Limited's main asset, has been assessed and tested for impairment as described in Note 13. Using a 15% discount rate, management's base case sales forecasts would need to be reduced by 12% before triggering an impairment of the carrying value of the Company's carrying value. Alternatively, using the unadjusted base case sales forecasts, a licence deal with no upfront payment or approval milestone, which collectively would be well below a market-standard agreement, would still support the intangible asset valuation. Whilst the sensitivity analysis performed indicates the carrying value is supportable, as noted above, there are several key assumptions in the impairment review of the PT20 asset, including an assumption that the asset will be successfully taken through the clinical trials process, and high-level assessments of the global market for such a treatment, and an assumption of the market penetration.

15. Inventories

Group	2021 £000	2020 £000
Raw materials	1,344	1,379
Finished goods	291	—
	1,635	1,379

The cost of inventories recognised as an expense and included in cost of sales was £492,000 (2020: £480,000). Cost of sales includes royalties payable to Vitra Pharmaceuticals Limited.

16. Trade and other receivables

	Group		Company	
	2021 £000	2020 £000	2021 £000	2020 £000
Trade receivables	816	219	—	—
Other receivables	381	145	69	39
Prepayments	1,733	255	—	—
Amounts due from Group undertakings	—	—	60,088	41,472
	2,930	619	60,157	41,511

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	
	2021 £000	2020 £000	2021 £000	2020 £000
Non-current	—	—	60,088	41,472
Current	2,930	619	69	39
	2,930	619	60,157	41,511

At the year end no trade receivables were past due or impaired (2020: £Nil).



Financial statements

Notes (forming part of the financial statements) continued

for the year ended 31 December 2021

17. Cash and cash equivalents

	Group		Company	
	2021 £000	2020 £000	2021 £000	2020 £000
Cash at bank and in hand	12,117	2,940	10,559	1,741

18. Trade and other payables

	Group		Company	
	2021 £000	2020 £000	2021 £000	2020 £000
Trade payables	1,311	395	372	—
Accruals	1,803	1,076	272	276
	3,114	1,471	644	276

19. Other liabilities

	Group		Company	
	2021 £000	2020 £000	2021 £000	2020 £000
Taxation and social security	49	672	3	—
Other payables	61	81	—	—
	110	753	3	—

20. Financial instruments and financial risk management

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

The Group had the following financial instruments at 31 December:

	2021 £000	2020 £000
Cash and cash equivalents (Note 17)	12,117	2,940
Trade and other receivables	2,930	619
Trade and other payables	3,114	1,471
Lease liabilities	110	28

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

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

	2021 £000	2020 £000
Sterling	1,997	1,807
US Dollar	9,781	821
Swiss Franc	49	44
Euro	290	268
	12,117	2,940

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



20. Financial instruments and financial risk management continued

Financial risk factors

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

(a) Foreign exchange risk

In 2021 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:

Change in GBP vs. EUR rate		Effect on loss before tax	
		Year ended 31 December 2021 £000	Year ended 31 December 2020 £000
EUR	+5.00%	(14)	(13)
	-5.00%	14	13
USD	+5.00%	(466)	(39)
	-5.00%	466	39

(b) Interest rate risk

The Group's policy is to maximise interest receivable on deposits, subject to maintaining access to sufficient liquid funds to meet day-to-day operational requirements and preserving the security of invested funds. With the current low level of bank interest rates, interest receivable on bank deposits in 2021 was £13,000 (2020: £5,000). If interest rates had been 1% higher in 2021 the impact on cash interest received would have been £134,000 (2020: £34,000).

Interest payable arises principally on the Group's leases. If interest rates had been 1% higher in 2021 the impact on cash interest paid would have been £1,000 (2020: £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

	2021		2020	
	Number 000	£000	Number 000	£000
At 1 January	117,620	1,764	117,189	1,758
Exercise of share options	985	15	431	6
Issuance of shares pursuant to placing	97,280	1,459	—	—
Issuance of shares pursuant to subscription	—	—	—	—
At 31 December	215,885	3,238	117,620	1,764

985,104 share options were exercised during the year (2020: 431,533).

**22. Reserves**

The Group's balance sheet contains the following reserves:

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

23. Share-based payments

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

The schemes which the Group operates are:

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

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

The number of options outstanding at the start and end of both 2020 and 2021, the movements through both years, and the expense charged to the Group financial statements were as follows:

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	—
BSP	Cash	—	—	—	—	—	—	—
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



23. Share-based payments continued

2020

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

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

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

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

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

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

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

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

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



Financial statements

Notes (forming part of the financial statements) continued

for the year ended 31 December 2021

23. Share-based payments continued

In March 2021, 307,438 share options were granted under the RPSB 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 RPSB 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 RPSB 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 RPSB 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 RPSB 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 RPSB 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.

All of the share options schemes are equity-settled.

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

	December 2021 Black Scholes	September 2021 Black Scholes	June 2021 Monte Carlo	June 2021 Black Scholes	June 2021 Black Scholes	March 2021 Black Scholes
Weighted average share price	£0.29	£0.40	£0.58	£0.58	£0.58	£0.34
Exercise price	£0.015	£0.015	£0.015	£0.015	£0.58	£0.34
Expected volatility	59%	59%	59%	59%	59%	59%
Expected option life	1 year	1 year	3 years	1 year	3 years	1 year
Expected dividends	Nil	Nil	Nil	Nil	Nil	Nil
Risk-free interest rate (based on UK government bonds)	0.70%	0.70%	0.70%	0.70%	0.70%	0.70%
Fair value at measurement date	£0.29	£0.40	£0.21	£0.58	£0.58	£0.34

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	2021	2020
Net book value property, plant and equipment owned	148	4
Net book value right-of-use assets	156	28
Total	304	32
Lease liabilities	2021	2020
Less than one year	57	28
Greater than one year	99	—
Total	156	28
Amounts recognised in profit or loss	2021	2020
Interest on lease liabilities	3	1
Expenses relating to short term leases	73	48
Total	76	49

During 2021 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 and retained earnings. There have been changes to the capital requirements each year as the Group has required regular suitable levels of capital injections to fund development. As mentioned above the Board periodically monitors the capital structure of the Group. The table below details the net capital structure at the relevant balance sheet dates.

	2021	2020
	£000	£000
Cash and cash equivalents	12,117	2,940

26. Related party transactions

During the year the Company had intercompany loan balances with some of its subsidiaries as follows; Shield TX (UK) Limited £54,122,044 due to the Company (2020: £36,450,295 due to the Company), Shield TX (Switzerland) AG £2,753,482 due to the Company (2020: £2,136,610 due to the company) and Phosphate Therapeutics Limited £382,734 due to the Company (2020: £353,142 due to the Company).

27. Subsequent events

As announced on 5 January 2022, the Group entered into an exclusive license agreement with KYE Pharmaceuticals Inc. for the development and commercialisation of Accrufer® in Canada. Under this agreement, Shield will receive an upfront payment of £0.15 million and is eligible to receive £0.85 million in development and sales milestones. For the term of the agreement, Shield will also receive double-digit royalties on net sales of Accrufer®.



Glossary

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



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