RNS Number : 6120X
Shield Therapeutics PLC
27 April 2023

Shield Therapeutics plc
("Shield" or the "Company" or the "Group")

Business Update and Unaudited Results

Total U.S. Accrufer® prescriptions increased to more than 25,000 in 2022
& 12% sequential rise in Q1 2023 over Q4 2022

Strong progress made on implementation of collaborative U.S. Sales Agreement with Viatris for Accrufer®

Funded to support operations through to cash flow break-even by end of 2024

London, UK, 27 April, 2023: Shield Therapeutics plc (LSE: STX), a commercial stage pharmaceutical company focused on the commercialisation of its innovative oral iron therapy for iron deficiency, Accrufer®/Feraccru® (ferric maltol), announces its unaudited preliminary results for the year ended 31 December 2022 and reports a business update covering recent developments, including significant Q1 2023 Accrufer® growth.

Current Business Updates
US commercial update: Shield has made substantial progress across the following areas since the start of 2023:

Expansion of commercial organisation and field sales team - Following the announcement of the collaborative sales agreement with Viatris in late December, new territory maps were finalised and the recruiting, hiring and training of the 100-sales professionals and 12 Regional Sales Managers (RSM's) began. This combined sales team of 100 (50/50 Shield and Viatris) will promote Accrufer® to the 12,000+ highest prescribers in their respective territories. The hiring and training have consisted of four phases:

- **Phase 1:** In January, Shield hired 16 direct sales representatives (of the former 22 contract sales representatives), who began promoting in their new territories immediately.
- **Phase 2:** Training of the existing Viatris sales representatives was completed at the end of January and they began promoting in their new territories in February. Collectively, between the two organisations, 30 sales representatives were promoting Accrufer® as of 1 February.
- **Phase 3:** New-Hire training classes were completed by the end of March resulting in a total of 66 sales representatives promoting Accrufer® as of 1 April.
- **Phase 4:** A final New-Hire training class is currently taking place and in total, Shield will have hired and trained 49 (out of 50) sales representatives and all six RSM's by the end of April. Recruiting efforts continue to fill the final vacant territory.
- **Going forward**: This combined sales and commercial organisation of Shield and Viatris will join together at a U.S. National Sales Meeting in early May and 98 sales representatives will be promoting Accrufer® in their respective territories by the middle of next month.
- **New Chief Commercial Officer**: Andy Hurley joined the Executive Leadership team as Chief Commercial Officer in April 2023, bringing a proven track record of delivering successful product launches and a strong background of commercial leadership experience.
- **Strong growth in U.S. Accrufer® prescriptions led by increases in March 2023:** Prescriptions for the first quarter of 2023 continued to increase and amounted to over 10,500 with a significant acceleration in March, contributing 38% of total quarterly volume, showing the initial impact of the additional sales force by both companies.

	Month on month growth			Q1 2023 growth over Q4 2022
	Jan 2023	Feb 2023	Mar 2023	
Total Prescriptions	+3%	+1%	+21%	**+12%**

Volume				
New Prescription Volumes	+7%	+3%	+18%	**+11%**
First Time Prescribers	-9%	+41%	+71%	**+24%**

Shield's Chief Executive Officer, Greg Madison, commented: *"It has been an extremely busy and productive first quarter of 2023 as we focused our attention on the implementation of our new agreement with Viatris. Creating brand new sales territories and the recruiting, hiring and training of our 50 sales representatives and new managers has been our primary focus. Our internal team has done an amazing job, and I am extremely pleased that not only are we on track for completion of our stated goal by early May, but by the quality and experience of the people we have been able to attract and hire into our organisation.*

"Early Q1 2023 indicators are encouraging and show that our new U.S. commercial strategy with Viatris for Accrufer® is gaining good traction. March provided a strong conclusion to Q1 2023 and a springboard for the rest of the year as we see notable upticks across several key performance areas such as first time prescribers and new prescriptions. We achieved this with less than one third of our combined targeted sales team promoting Accrufer®, including some of whom are just a month out of training. The combination of a complete sales team from Shield and our partner, Viatris, plus a strong Q1 and standout March, gives us confidence in the 2023 growth outlook for Accrufer®.

"Our strong start to 2023 builds on Shield's very successful 2022. We notably advanced our strategy to make Accrufer® the oral iron of choice in the U.S. Robust increases in Accrufer® prescriptions, completion of the Viatris agreement and our £30 million financing set Shield up for a strong future, with the resources to support our planned operations to cash flow break even, expected in Q4 2024."

Final Unaudited Results

Operational Highlights

- Over 25,000 prescriptions written for Accrufer® during 2022 with strong and consistent quarter on quarter growth
- Of the 2,230 Health Care Providers (HCPs) who have prescribed Accrufer® in 2022, over 70% were first time prescribers mainly by Women's health practitioners and General Practitioners
- Broad reimbursement coverage now covers over 100 million patients via US payers across Commercial and Medicaid segments, enabling greater access for patients
- Multi-year collaborative sales agreement with Viatris in December 2022 secured to co-commercialise Accrufer® in the U.S
- Net sales of Feraccru® in Germany and UK by Norgine increased by c.10%
- In Canada, our partner KYE Pharmaceuticals filed for regulatory approval with Health Canada in 2022 and expect full approval in H2 2023
- Enrolment in our pivotal trial continues in China, although enrolment progress has been impacted by local COVID-19 pandemic measures
- In the Republic of Korea, Korea Pharma, gained clarity and feedback from authorities on the regulatory and clinical pathway to gain approval for ferric maltol
- FDA Approval of Accrufer®'s improved shelf life to 48 months enhances manufacturing and storage timelines, making the product more accessible and user-friendly
- Ongoing Phase 3 Paediatric study will expand the label and market opportunity for Accrufer® and completes the fulfilment of all FDA post-marketing commitments
- A presentation at the American College of Gastroenterology Annual Scientific Meeting highlighted an early and sustained response in patients with inflammatory bowel disease with IDA who were treated with Accrufer®/Feraccru® ferric maltol, a very under-served group of patients
- New Corporate website (https://www.shieldtherapeutics.com/) and branding logo was launched

Financial Highlights

- Total Revenue increased to £4.5 million (FY21: £1.5 million), excluding Viatris upfront payment of £4.2 million:
  - *Net product revenue of £2.9 million from sales of Accrufer® in the US (FY21: £0.1 million)*
  - *Royalty revenue of £1.4 million from product sales in Europe (FY21: £0.9 million)*
  - *Upfront payment of £0.2 million from KYE Pharmaceuticals on signing of the license agreement for commercialisation in Canada (FY21: £0.5 million from Korea Pharma)*
  - *Total revenue excludes upfront payment of £4.2 million (or US$5.0 million), received upon execution of co-promote arrangement with Viatris, which was expected to be recognised as revenue in 2022, however, following discussions with the Company's auditors, £0.7 million of that payment was recorded in other operating income*

in 2022 and £3.5 million will be recognised in other operating income in 2023 (matching timing of when costs are incurred to build out commercial infrastructure to support the Viatris partnership)

- Operating loss before impairment and research & development expenditure of £24.6 million (2021: £19.5 million)
  - *Increased by £5.1 million, as expected and primarily due to continuing development of commercial operations in US*
- Fully funded following total new financing of c. £36.6 million (or US$44.9 million), net of related costs (including proceeds from convertible shareholder loan in August 2022 and gross funds received post period end). This is expected to provide resources to support operations through cash-flow breakeven expected by Q4 2024:
  - *New convertible shareholder loan from AOP Health of £8.0 million (US$9.8 million)*
  - *Upfront payment on execution of Viatris co-promote arrangement of £4.2 million (US$5.0 million)*
  - *Amendment to shareholder loan from AOP Health of £8.2 million (US$10.0 million)*
  - *Equity placing and open offer of £16.2 million (US$20.1 million)*
- Cash on hand of £2.8 million at 31 December 2022 and £19.2 million at 31 March 2023.

The information contained within this announcement is deemed by the Company to constitute inside information as stipulated under the Market Abuse Regulation (EU) No. 596/2014 (as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018). Upon the publication of this announcement via the Regulatory Information Service, this inside information is now considered to be in the public domain.

For further information please contact:

Shield Therapeutics plc	www.shieldtherapeutics.com
Greg Madison, CEO	+44 (0) 191 511 8500
Hans-Peter Rudolf, CFO	
Nominated Adviser and Joint Broker	
Peel Hunt LLP	
James Steel/Oliver Duckworth	+44 (0)20 7418 8900
Joint Broker	
finnCap Ltd	
Geoff Nash/George Dollemore/Alice Lane/Nigel Birks/Harriet Ward	+44 (0)20 7220 0500
Financial PR & IR Advisor	
Walbrook PR	
Paul McManus/Lianne Applegarth/Alice Woodings	+44 (0)20 7933 8780 or shield@walbrookpr.com
Investor Contact (US Advisor)	
LifeSci Advisors, LLC	
John Mullaly	+1 617 429 3548 or jmullaly@lifesciadvisors.com

About Accrufer®/Feraccru®

Accrufer®/Feraccru® (ferric maltol) is a novel, stable, non-salt based oral therapy for adults with iron deficiency, with or without anemia. Accrufer®/Feraccru® has a novel mechanism of absorption compared to other oral iron therapies and has been shown to be an efficacious and well-tolerated therapy in a range of clinical trials. More information about Accrufer®/Feraccru®, including the product label, can be found at: www.accrufer.com and www.feraccru.com

About Shield Therapeutics plc

Shield is a commercial stage pharmaceutical company focused on the commercialisation of Accrufer®/Feraccru® (ferric maltol), an innovative oral iron therapy for iron deficiency differentiated from other irons by its efficacy, broad label and well-tolerated formulation. The Group has launched Accrufer® in the US with an exclusive, multi-year collaboration agreement with Viatris, Inc. Feraccru® is commercialised in the UK and European Union by Norgine B.V., that also have the marketing rights in Australia and New Zealand. Shield also has an exclusive license 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, and with KYE Pharmaceuticals Inc. in Canada.

Accrufer®/Feraccru® has patent coverage until the mid-2030s
Accrufer®/Feraccru® are registered trademarks of the Shield Group

Forward-Looking Statements
This press release contains forward-looking statements. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements. These forward-looking statements are based on management's current expectations and include statements related to the commercial strategy for Accrufer®/Feraccru®. These statements are neither promises nor guarantees, but involve known and unknown risks and uncertainties, many of which are beyond our control, that may cause actual results and performance or achievements to be materially different from management's expectations expressed or implied by the forward-looking statements, including, but not limited to, risks associated with the Group's business and results of operations, competition and other market factors. The forward-looking statements made in this press release represent management's expectations as of the date of this press release, and except as required by law, the Group disclaims any obligation to update any forward-looking statements contained in this release, even if subsequent events cause its views to change.

Chairman and Chief Executive Officer's joint statement

We have made tremendous progress as an organisation and 2022 was a transformational year for our Company across many different areas. We have secured an important co-commercialisation agreement with Viatris, which dramatically expands the commercial resources for our product Accrufer® in the US.

With a much larger field sales organisation being rapidly assembled (100 dedicated sales people collectively vs 30-person contract sales team in 2022), plus additional resources on the marketing and payer/reimbursement side, we believe this represents a substantial growth opportunity for Accrufer® prescriptions and revenues. In addition, we announced a financing of the Company prior to the year end, providing the necessary financial capital to expand our operations in conjunction with the Viatris agreement, and based on our financial models, we still expect to reach cash flow break-even by Q4 2024. It was a challenging year for the financial markets, and we were very pleased to conclude these transactions early in 2023. Following these events, 2023 becomes a year of execution across a number of key areas, first and foremost the expansion of our field teams, which we expect to conclude by 1 May 2023.

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

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

Iron deficiency, with or without anaemia, continues to be a prevalent issue in the US, with over 13 million prescriptions of oral iron written every year, the vast majority over the counter (OTC) iron. Physicians and patients alike routinely comment on the challenges associated with these irons, namely around poor effectiveness driven by tolerability, discontinuations, and lack of efficacy. As a result, health care providers (HCPs) have relatively

unfavourable impressions of oral irons. As the only FDA approved oral iron to treat iron deficiency regardless of the aetiology, we are in a unique and competitive position to change the way physicians think about oral iron.

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

In December 2022, we signed a multi-year, exclusive co-commercialisation agreement with Viatris, which will dramatically expand the commercial resources for Accrufer®. The collaboration has expanded the commercial footprint and sales and marketing resources with Viatris' well established prescriber relationships, best-in-class digital marketing, direct to patient capabilities and extensive market access experience. We believe this collaboration will result in an acceleration of awareness, prescriptions and revenues which we believe will allow Shield to be cash flow positive by Q4 2024. This agreement increases the number of field sales representatives from 22 in Q4 2022 to 100 by 1 May 2023. This increases the number of HCPs the collective team can call on, from approximately 3,300 in 2022 to over 12,000 in 2023 once these new sales representatives are fully trained and in the field. We should also see a benefit from smaller geographies resulting in increased opportunities for our field sales team to engage with HCPs. Importantly, Accrufer® will be the only product promoted by this combined sales force, resulting in 100% of its focus and effort. Importantly, in terms of momentum, of the 2,230 HCPs who prescribed Accrufer® in 2022, over 70% were first time prescribers.

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

The partnership with Viatris is off to a great start. Work on expanding the sales commenced early in 2023 with the aim of to having all 100 sales representatives hired and trained by 1 May 2023. As this new team begins calling on its high-volume HCPs, we firmly believe that we will start seeing the effects of its efforts during the second half of 2023.

Europe/Australia

Norgine, our partner with responsibility for Europe and Australia, saw 10% growth in Feraccru® volume during 2022. Germany now represents approximately 72% of the total unit sales of Feraccru® for Norgine, followed by the UK with c.18%. There remains a significant opportunity for Feraccru® in key markets such as Germany and the UK; however, there is work to be done in order to maximise the value. The area of opportunity lies in women's health. OB/GYN clinicians are consistently high prescribers of oral iron products for their patients with iron deficiency. We will continue to work with Norgine in helping shift its focus to this important customer segment.

Global partnerships and development

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

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

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

Our people and culture

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

The Shield team would like to recognise the service and dedication, in memoriam, of our Chief Medical Officer, Dr. José Menoyo who died unexpectedly of natural causes on 2 January 2023. We will always remember Dr. Menoyo's joyful heart and outstanding contribution, with sincerest gratitude.

Outlook

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

Hans Peter Hasler, Non-Executive Chairman
Greg Madison, Chief Executive Officer

Chief Financial Officer's review

Revenue

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

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

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

Royalty revenue from Norgine, Shield's license partner in Europe, increased from £0.9 million in 2021 to £1.4 million in 2022 on the back of a 10% increase in total packs sold. Germany now accounts for c.72% of the total net sales of Feraccru® in Europe, followed by the United Kingdom with c.18%. Norgine began expanding its call reach into Women's Health practitioners in Germany at the end of 2022, which is expected to have a further positive impact on future sales volumes.

Cost of sales

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

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

Selling, general and administrative expenses

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

Impairment of intangible assets

Following the completion of the collaborative sales agreement for Accrufer® in the United States with Viatris and the equity fundraise in January 2023, the Group carried out a review of the recoverable amount of its intangible assets. As a result of this review, the Directors concluded that the Group should concentrate the use of its resources on the commercial development of Accrufer®/Feraccru® and the ongoing paediatric study.

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

Research and development

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

Financial income

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

Tax

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

Balance sheet

Intangible assets at 31 December 2022 were £11.8 million (31 December 2021: £26.9 million), comprised of £10.8 million (31 December 2021: £9.5 million) capitalised Feraccru® development costs, in particular the AEGIS-H2H study and the paediatric pharmacokinetic study and £1.0 million (31 December 2021: £1.3 million) capitalised Feraccru® patent and trademark cost, incurrent to strengthen the Group's intellectual property. All capitalised expenditure related to Phosphate Therapeutics licences have been written off in the current year (31 December 2021: £16.0 million).

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

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

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

Cash at 31 December 2022 was £2.8 million (31 December 2021: £12.1 million), which includes the Viatris upfront payment but does not include the £16.4 million net of expenses from the equity fundraise, completed on 5 January 2023, and the £8.2 million (or US$10 million) from the increase in the convertible shareholder loan with AOP Health, drawn on 12 January 2023. Cash at 31 March 2013 was £19.2 million and the rate of cash burn is expected to reduce through the second half of the year when the expanded sales team is fully recruited and established.

Non-current liabilities are comprised of the convertible shareholder loan from AOP Health, which is repayable by 31 December 2026. The fair value of the conversion feature of this loan, which will be revalued at each balance sheet date, has been separated from the value of the loan principal amount in accordance with IFRS 9. At 31 December 2022, the fair value of the conversion feature was £0.5 million and the remaining loan balance was £5.5 million. These balances do not yet reflect the additional £8.2 million (or US$10 million), which the Company drew down on 12 January 2023.

Trade and other payables increased from £3.5 million at 31 December 2021 to £9.5 million at 31 December 2022 as a result of the larger trading volumes in the US. Additionally, the balance at 31 December 2022 includes £3.5 million (31 December 2021: £Nil) of the Viatris upfront payment, received in 2022, but to be recognised in 2023. This payment had been expected to be recognised as revenue in 2022, however, following discussions with the Company's auditors, an amount of £3.5 million had to be deferred and will be recognised in other operating income in 2023.

Cash flow

Net cash outflow in 2022 was £12.2 million, decreasing the cash on hand from £12.1 million at 31 December 2021 to £2.8 million at 31 December 2022, excluding a positive effect of exchange rate fluctuations on cash balances in the amount of £2.9 million.

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

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

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

Going concern

At 31 December 2022, the Group held £2.8 million in cash. Since year-end, the Group completed an equity fundraise which raised £16.4 million net of expenses, and it drew £8.2 million (or US$10 million) on the convertible shareholder loan with AOP Health in connection with an amendment to the original loan agreement, dated 1 August 2022, raising the Group's cash balance at 31 March 2023 to £19.2 million.

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

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

Financial outlook

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

The collaboration will result in a 100-person sales team which will promote Accrufer® to over 12,000 HCPs that write the majority of oral iron prescriptions in the US. Shield and Viatris are each hiring a team of 50 dedicated sales professionals as part of the collaboration agreement. Shield's recruitment of the new sales team is well under way with virtually all 50 representatives hired and on track to be trained by 1 May 2023.

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

With the support of the Viatris partnership, management estimates that Accrufer® has the potential to generate combined net product revenues of c. US$150 million by the year ending 31 December 2025 and it expects the Group to turn cash flow positive by the end of 2024. Nearer term the Company expects to deliver strong growth in prescription numbers in 2023, in line with the 125,000 to 160,000 range provided at the time of the December 2022 financing, with a significant weighting to the second half when the 100-person sales team will be in situ for the entire period.

Annual operating expenses for Shield are expected to be in the range of US$40-45 million in the year ending 31 December 2023 and are expected to remain approximately at this level until the year ending 31 December 2025 assuming Accrufer® prescriptions and revenues build as expected. The costs of servicing interest on the convertible shareholder loan will be around £1.7 million (or US$2.0 million) per annum, however no interest is payable on the £8.2 million (or US$10 million) extension during 2023.

Hans-Peter Rudolf, Chief Financial Officer

Unaudited consolidated statement of profit and loss and other comprehensive income
for the year ended 31 December 2022

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

Unaudited Group balance sheet
at 31 December 2022

	2022 £000	2021 (Restated) £000
Non-current assets		
Intangible assets	**11,783**	26,851
Property, plant and equipment	**197**	304
	11,980	27,155
Current assets		
Inventories	**1,457**	1,635
Trade and other receivables	**5,380**	2,929
Current tax asset	**436**	576
Cash and cash equivalents	**2,821**	12,117
	10,094	17,257

Total assets	**22,074**	44,412
Non-current liabilities		
Convertible shareholder loan	**(5,542)**	-
Fair value of loan conversion feature	**(466)**	-
	(6,008)	-
Current liabilities		
Trade and other payables	**(9,489)**	(3,455)
Other liabilities	**(1,061)**	(110)
Lease liabilities	**(89)**	(156)
	(10,639)	(3,721)
Total liabilities	**(16,647)**	(3,721)
Net assets	**5,427**	40,691
Equity		
Share capital	**(3,891)**	(3,238)
Share premium	**(116,263)**	(114,583)
Merger reserve	**(28,358)**	(28,358)
Currency translation reserve	**(3,635)**	(1,449)
Deposit for shares	**82**	-
Accumulated deficit	**146,638**	106,937
Total equity	**(5,427)**	(40,691)

Unaudited Group statement of changes in equity

for the year ended 31 December 2022

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

Unaudited Group statement of cash flows

for the year ended 31 December 2022

	2022 £000	2021 (Restated) £000
Cash flows from operating activities		
Loss for the year	**(40,444)**	(19,678)
Adjustments for:		
Depreciation and amortisation	**2,362**	2,207
Equity-settled share-based payment expenses	**743**	992
Financial income	**(721)**	(395)

Financial expense	**389**	42
Impairment of intangible assets	**14,708**	-
Income tax	**362**	(229)
	(20,601)	(17,061)
Decrease/(increase) in inventories	**178**	(256)
Increase in trade and other receivables	**(2,451)**	(2,879)
Increase in trade and other payables	**6,030**	1,985
Increase in other liabilities	**951**	(643)
Income tax received	**(354)**	592
Net cash flows from operating activities	**(18,247)**	(18,262)
Cash flows from investing activities		
Financial income	**200**	13
Additions to intangible assets	**-**	(9)
Additions to tangible assets	**(53)**	(372)
Capitalised development expenditure	**(1,842)**	(1,683)
Net cash flows from investing activities	**(1,695)**	(2,051)
Cash flows from financing activities		
Interest paid	**(334)**	(42)
Leases - interest payment	**(4)**	(3)
Change in lease assets and liabilities (new leased assets)	**(63)**	128
Proceeds from equity raise	**-**	27,679
Proceeds from convertible shareholder loan	**8,228**	-
Deposit for shares	**(82)**	-
Proceeds of share options exercised	**87**	26
Total cash outflow for leases	**(125)**	(76)
Net cash flows from financing activities	**7,707**	27,712
Net (decrease)/increase in cash	**(12,235)**	7,399
Effect of exchange rate fluctuations on cash held	**2,939**	1,778
Cash and cash equivalents at 1 January	**12,117**	2,940
Cash and cash equivalents at 31 December	**2,821**	12,117

This information is provided by RNS, the news service of the London Stock Exchange. RNS is approved by the Financial Conduct Authority to act as a Primary Information Provider in the United Kingdom. Terms and conditions relating to the use and distribution of this information may apply. For further information, please contact rns@lseg.com or visit www.rns.com.

RNS may use your IP address to confirm compliance with the terms and conditions, to analyse how you engage with the information contained in this communication, and to share such analysis on an anonymised basis with others as part of our commercial services. For further information about how RNS and the London Stock Exchange use the personal data you provide us, please see our Privacy Policy.

END

FR MZGZDLVMGFZM