RNS Number : 7244Q
Shield Therapeutics PLC
30 June 2022

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

Business Update, Final Results and Financing Agreement

Shield Provides a Business Update, its Final Results for the Year Ended 31 December 2021 and announces a financing agreement of US$10 million

London, UK, 30 June 2022: Shield Therapeutics plc (LSE: STX), a commercial stage pharmaceutical company focused on the commercialization of Accrufer®/Feraccru® (ferric maltol), a novel, oral iron therapy differentiated from other conventional irons by its efficacy, well-tolerated formulation, and broad indication, today reports a business update covering recent developments, its audited final results for the year ended 31 December 2021 and details of a financing transaction of US$10 million through a shareholder loan from AOP Orphan International AG ('AOP'). Upon completion this transaction will extend the Company's cash runway to approximately the end of calendar 2022.

Shield had a transformational 2021, successfully launching Accrufer® in the US, with strong growth in revenue and demand, and achieving a solid start to the financial year. The Company executed 100% growth in prescriptions for the first months of 2022 whilst focusing on the Company's three main priorities: increasing awareness of Accrufer®, generating clinical experience and expanding payor coverage.

Current Business Updates

- **100% increase in total Accrufer® prescriptions in Q1 '22 as compared to Q4 '21**, exceeding 3,900 total prescriptions during the first quarter, with a small 30-person sales team.
  - Women's Health practitioners, a rapidly growing segment treating women with underlying diseases leading to iron deficiency, now represents over 50% of Accrufer® prescriptions.
  - Continued high Accrufer® demand from the General Practitioners representing the balance of prescriptions.
  - **Estimated 20 million people in the US** with anaemia reflecting a huge medical need**.**
- **100 million or ~40% of eligible lives now have coverage for Accrufer®** by US payers across commercial and Medicaid segments, dramatically expanding access for patients and growing further.
- **>1,100 Health Care Providers** have been introduced to Accrufer® by participating in Shield sponsored programmes from January to April.
- **700 New First Time Writers of Accrufer®** from January to April, indicating growing awareness and interest by healthcare providers.
- **FDA approval of Accrufer® product shelf life increased from 24 to 36 months** providing additional flexibility in manufacturing and storage timelines.
- **Phase 3 paediatric study in the US and UK on track with over 50% of sites active.**
- **Out-licensing agreement for Accrufer®/Feraccru® with KYE Pharmaceuticals Inc. ("KYE") in Canada in January 2022.** In March 2022, KYE submitted their documentation for approval in the Canadian market, expected mid-2023.

Greg Madison, CEO of Shield Therapeutics, stated: "*I am extremely proud of the team here at Shield and the incredible work they have done. Twelve months ago, awareness of Accrufer® and its clinical application was low along with the Company's profile so it's rewarding to stand here today with a rapidly growing business highlighted by increasing prescriptions, expanding payer coverage, growing awareness and first-time writers. That, coupled with a dynamic new commercial leadership team who bring not only expertise but passion and belief that we can alter the dynamics of how patients are treated for iron deficiency, with or without anaemia. Based on all our collective insights, we are even more confident today about Accrufer® becoming the oral iron of choice, and the potential for significant value creation. The team here at Shield will continue to work tirelessly in our pursuit to ensure the millions of patients seeking treatment for their iron deficiency, will have the opportunity to experience the benefits of Accrufer®.*"

Financing

Shield has agreed a financing transaction, through an executed binding letter of intent, which will, when completed, extend the Group's cash runway until approximately the end of calendar 2022 through a shareholder loan in the amount of US$10 million from AOP Orphan International AG ("AOP"), a shareholder owning 13.1% of the Company's issued share capital (registered in the name of MaRu AG).

The loan facility will be structured to be drawn down by 1 August 2022. Interest of 7.0% above the 12-month USD-LIBOR is payable monthly in arrears. The shareholder loan will be secured against the US intellectual property rights associated with Accrufer® and will be repayable in cash in the event that Shield secures a further debt or equity financing for no less than approximately US$30 million or, in any event, by 31 December 2023. The lenders will have the right, but not the obligation, to convert any outstanding loan balances into new ordinary shares in Shield at any time at a 10% discount to the average closing middle market price for the preceding ten business days or, in the event of a new equity raise, on the same terms as all other investors subscribe. An arrangement fee of 2% is payable to the lenders on signing the formal loan documentation. Execution of the formal loan documentation will be subject to Aim Rule 13.

As a result of the loan being convertible into Shield ordinary shares, it is subject to the approval of Shield shareholders. A general meeting of Shield is expected to be convened for the last week of July 2022 for the purpose of obtaining this approval.

Prior to agreeing the shareholder loan, the Company initiated efforts to raise US$30 million in equity which if completed would have provided access to a larger non-dilutive debt facility offered in the form of a non-binding term sheet from a financial institution. However, due to the extremely challenging equity market conditions it became apparent that it was unlikely such an equity financing could be closed at this time.

The Company has continued to engage with various parties in relation to potential financing opportunities and other strategic partnerships, which in combination with the US$10 million loan expected from AOP, has led Shield to re-assess the optimal level and structure of its future funding required to drive sales growth of Accrufer® in the US. That assessment is ongoing and further announcements will be made in due course.

2021 Operational highlights

- **US Commercialisation**: US Accrufer® sales reached approximately 2,500 prescriptions in the six months following the US launch in July 2021. This achievement was accomplished in context of limited awareness of Accrufer® by US healthcare providers at launch due to no prior market development and no payer coverage until the end of December 2021.
- **Reimbursement**: No payer coverage established until the end of 2021, when four major contracts were signed creating access heading into 2022.
- **Growth in the EU**: Feraccru® volume in Europe increased by 60% in 2021 compared to 2020 through efforts of our partner, Norgine BV. The growth was due to increased demand in Germany, where packs sold increased by more than 20% over the prior year.
- **Expanded Global Commercial Partnering**: Shield licensed Accrufer®/Feraccru® to Korea Pharma Co., Ltd. in the Republic of Korea.
- **Progression of Clinical Studies by Our Commercial Partners**: Our partner, Beijing Aosaikang Pharmaceutical Co., Ltd. ("ASK Pharma"), completed a pharmacokinetics study requirement in China and started enrolment in the Phase 3 registrational trial.
- **Label Expansion Opportunities**: Shield initiated a Phase 3 paediatric study in the US and UK.
- **Strengthened Leadership Team:** Greg Madison (Chief Executive Officer, 'CEO'), Hans-Peter Rudolf (Chief Financial Officer, 'CFO') and Dr José Menoyo (Chief Medical Officer, 'CMO') joined the team.

2021 Financial highlights

- Revenues of £1.5 million (2020: £10.4 million).
  - With first payer contracts signed in December 2021, limited prescription sales in six months following the launch benefited from commercial reimbursement.
- Loss for the year of £17.9 million (2020: £2.6 million).
  - The loss in 2021 increased by £15.3 million compared to the loss in 2020, primarily due to a £11.4 million increase in operating costs related to the US launch activities, plus one-time net revenues of £9.4 million in 2020 from the upfront payment received on the signing of the Chinese license agreement.
- Net cash of £12.1 million (2020: £2.9 million).

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.

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About Accrufer®/Feraccru®

Accrufer®/Feraccru® (ferric maltol) is a novel, stable, non-salt based oral therapy for adults with iron deficiency, with or without anaemia. 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 specialty pharmaceutical company with a focus on addressing iron deficiency with its lead product Accrufer®/Feraccru® (ferric maltol). The Group has launched Accrufer® in the US and Feraccru® is commercialized in the UK and European Union by Norgine B.V., who 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 commercialization 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, 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 our views to change.

Chairman's Statement

Despite the continued challenges thrown at us by the COVID-19 pandemic, Shield had a transformational 2021 which included the successful completion of a £27.6 million (net) 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 of improving patients' lives all over the world.

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.

During 2021 Shield appointed three key hires who are based in our Boston Office: Greg Madison joined the team in May as Chief Executive Officer. Greg's proven experience and leadership skills are key to support the ongoing launch in the USA. I am confident that the Company is equipped with the team to deliver on the large US market opportunity for Accrufer®. In addition to Greg, 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 across his three year tenure.

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. The Company is pleased to report that at the year-end 60 million commercial lives were covered and ensuring patient coverage is achieved from the other major pharmacy benefit managers (PBMs) continues to be core focus. This further increased to 100 million commercial lives post period end.

In addition, the paediatric Phase III study was initiated by the end of 2021 and our business development team continues to pursue out-license and other opportunities for Accrufer®/Feraccru® to further drive sales growth and 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 Lacerca-Allen. Our compliance programme incorporates the Office of Inspector General'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 that we are 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 that 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, Non-Executive Chairman

Chief Executive Officer's statement

I joined the Shield organisation as CEO in May 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 a broad label were all factors that stood out as 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 Sates, 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 by the end of 2021. This increased to 100 million commercial lives post period end, and we expect access to continue to grow as we move through 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 further 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 (OB/GYN) 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. GP's and OB/GYN in Germany/UK routinely prescribe a lot of oral iron and express the same dissatisfaction around tolerability and are actively seeking effective and well tolerated oral irons in lieu of sending patients to get an IV infusion or switching from one oral iron to another in the quest for one which they can better tolerate.

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. Our partner has 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 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 one month to 17 years. This study encompasses sites both in the US and UK, and if successful, it adds 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 twelve 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

Financial review

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 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 not reimbursed but subsidised through patient assistance programs. Payer coverage through agreements with various pharmacy benefit managers only became 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 setup 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 £0.6 million (2020: £2.6 million), excluding capitalised development expenditure of £1.7 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 amounted to £12.1 million (31 December 2020: £2.9 million) and at 31 May 2022 to £4.2 million (unaudited).

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 £12.1 million 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 £0.15 million 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 31 May 2022 was £4.2 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 cash resources at 31 May 2022 would extend into the third quarter of 2022. Based on the new shareholder loan expected to be received from AOP in the amount of US$10 million, the Group's cash runway would be extended until approximately the end of calendar 2022. To allow the business plans to continue beyond that point in time, the Company will continue to engage with various parties pursuing various financing and strategic opportunities. Even though there can be no guarantee that any of these opportunities will be successfully concluded, the Directors believe that it remains appropriate to prepare the financial statements on a going concern basis based on the status of these discussions. Nevertheless, 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.

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, including the new shareholder loan which is expected to be received, should extend until approximately the end of calendar 2022 and further financing and strategic opportunities are being actively pursued.

Hans-Peter Rudolf, Chief Financial Officer

Following below are the consolidated statement of profit and loss and other comprehensive income, the Group balance sheet, the Group statement of changes in equity and the Group statement of cash flows. Refer to Shield's 2021 Annual Report, available on the Company's website at www.shieldtherapeutics.com, for the relevant notes and disclosures.

Consolidated statement of profit and loss and other comprehensive income

for the year ended 31 December

	2021	2020
	£000	£000
Revenue	**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	**(20,023)**	(8,608)
Operating profit/(loss) before research and development expenditure	**(19,373)**	425
Research and development expenditure	**(579)**	(2,579)
Operating loss	**(19,952)**	(2,154)
Financial income	**395**	269
Financial expense	**(8)**	(1)
Loss before tax	**(19,565)**	(1,886)
Taxation	**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	**£(0.09)**	£(0.02)

Group balance sheet

at 31 December

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

Group statement of changes in equity
for the year ended 31 December

	Issued capital £000	Share premium £000	Merger reserve £000	Currency translation reserve £000	Retained earnings £000	Total £000
Balance at 1 January 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**

Group statement of cash flows
for the year ended 31 December

	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)
(Decrease)/increase in trade and other payables	**1,643**	(2,075)
Increase/(decrease) in other liabilities	**(643)**	140
Change in lease assets and liabilities	**128**	8
Income tax (paid)/received	**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 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

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