Shield Therapeutics plc

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

Preliminary Results for the Year Ended 31 December 2017

London, UK, 11 April 2018. Shield Therapeutics plc (LSE:STX), a commercial stage, pharmaceutical company delivering innovative specialty pharmaceuticals to address patients' unmet medical needs, with an initial focus on addressing iron deficiency with its approved product, Feraccru®, today announces its preliminary Group results for the year ended 31 December 2017.

Highlights (including post period)

Operational

- Feraccru was out licensed across additional markets via agreements with AOP for Scandinavia and EWO pharma for Switzerland
    - Pre-approval notification for Feraccru received from the Swiss regulatory authority in June 2017
- Progress across clinical trials:
    - Feraccru AEGIS-H2H IIIb study progressing, with results expected in the second half of 2018
    - Recruitment of paediatric pharmaco-kinetic study completed with data available during 2018
    - Completion of recruitment into AEGIS-CKD pivotal Phase III study of Feraccru in the treatment of IDA in patients with Chronic Kidney Disease (CKD), results issued post year end
- Grants received for Feraccru's Composition of Matter patent in significant additional territories including the US, Europe, Australia and Canada providing broad protection through to 2035
- Application submitted to the European Medicines Agency (EMA) to extend the label for Feraccru to adult patients with iron deficiency (ID)

Financial

- Revenue of £637,000 (2016: £304,000) was recorded during the year
- Net loss of £19.6 million (2016: £15.0 million)
- Adjusted net loss* of £17.0 million (2016: £9.4million)
- Net cash of £13.3 million (2016: £21.0 million), which includes net proceeds raised during the year via the Warrant exercise, subscription and placing of £11.9 million

*Adjusted net loss is defined as net loss adjusted for exceptional items (see Note 9).

Post period:

- The number of patients being treated with Feraccru in the initial target markets of Germany and the UK have continued to increase month on month through the first few months of 2018
- In March 2018, the European Commission (EC) adopted the EMA's Decision to extend the approved indication for Feraccru (Ferric Maltol) to include treatment of all adults with iron deficiency (ID) with or without anaemia, thereby increasing Feraccru's commercial opportunity increasing the eligible patient population

- Previously Feraccru had only been approved and marketed in Europe for the treatment of Iron Deficiency Anaemia (IDA) in adult patients with Inflammatory Bowel Disease (IBD), a market opportunity of c. 330,000 patients. The label expansion in Europe represents a market opportunity of c. 40 million patients with iron deficiency

- AEGIS-CKD pivotal Phase III study of Feraccru:
  - In February 2018, an initial top line analysis indicated that Feraccru had failed to meet the study's primary endpoint
  - In March 2018, Shield conducted its detailed analyses of the data from the double-blind period of the AEGIS-CKD study which identified that the initial reporting of top line data had been confounded by a number of patient-specific events that the Company believed directly and adversely impacted the primary endpoint analysis. It also highlighted that, with these data points removed, the primary and secondary endpoint of the study would have been met
  - The Company presented these analyses to the FDA in a previously scheduled pre-NDA submission meeting in March 2018 and subsequent final minutes of this meeting were received in early April
  - These minutes form the official record of this meeting with the FDA and provided Shield with the necessary guidance to progress submission without the need to conduct additional pivotal clinical trials in CKD patients
  - The NDA will be submitted as soon as possible in 2018 and the work will be funded within the Company's current cash resources
  - Further routine analyses of the dataset will continue to deepen the Company's understanding of the positive impact of Feraccru on IDA in CKD patients

Following the initial top-line results from the AEGIS-CKD pivotal Phase III study of Feraccru, the Group announced a Business and Trading update and confirmed that a cost rationalisation programme was being implemented to significantly conserve the Company's available financial resources. It also confirmed that the Board would be leading a full review of Shield's strategic options. The outcome of the FDA's deliberations on its submissions has helped inform the Group's ongoing strategic review.

Commenting on the preliminary results, Carl Sterritt, CEO of Shield Therapeutics plc, said: *"Expansion of Feraccru's commercial activities in 2017, through an increase in promotional events, improved market access and sales people in the field saw awareness and use of the product increase, even within Feraccru's initial narrow label which existed through Q1-2018.*

"We have been making progress in Germany and the UK, continuing to bring the substantial benefits of Feraccru to patients. Product awareness is growing*, and more patients than ever are benefitting from Feraccru. During the first months of 2018 we have continued to see positive month-on-month growth in demand for Feraccru in both Germany and the UK. With the approval of a broad label to treat iron deficiency, the potential for Feraccru to become a mainstay of therapy for patients with this debilitating condition is very real. In addition, we continue to successfully out-license Feraccru in additional markets, with further discussions ongoing. Looking forwards, we have engaged a third party to evaluate ways of more rapidly leveraging the value of Feraccru in Europe and together we are considering a range of partnering structures. These could likely include upfront payments which would further extend the Company's cash runway, together with sales-based royalties that would provide revenue throughout the life of a partnering agreement.*

"The Composition of Matter patent grants for Feraccru in major pharmaceutical markets now also provides broad protection of Feraccru's intellectual property through to 2035, further adding to the value of Feraccru.

Post period in March 2018, following the Company's submission of an application to the EMA to broaden the label for Feraccru in Europe, we were delighted that the European Commission rapidly adopted the

CHMP's recommendation to extend the approved indication for Feraccru to include treatment of all adults with iron deficiency with or without anaemia, providing Feraccru with a much larger commercial opportunity through a very significant increase in patients who could potentially be treated with Feraccru. This was an important step for Shield as it should result in Feraccru being used earlier in the evolution of disease in patients affected by this debilitating condition.

"After the unexpected and disappointing initial top-line results from the AEGIS-CKD pivotal Phase III study of Feraccru in February, I am reassured that we have rapidly been able to understand what occurred in the study to prepare a data package which underpinned a constructive pre-NDA meeting with the FDA. Having now considered their formal feedback, we are confident in moving forward with our original plan to finalise and submit a New Drug Application to FDA as quickly as possible."

Summary and outlook

As a result of the Company taking positive actions to preserve cash following the initial AEGIS-CKD study top-line results reporting, the Board believes that the Company has sufficient cash resources to fund the business until at least the end of Q4 2018. However, as this is being primarily achieved through a significant reduction in Shield's own headcount and promotional activities related to Feraccru, with further cost containment remaining an ongoing priority, this is likely to impact sales of Feraccru. However, we are evaluating ways of maintaining Feraccru's share of voice in the marketplace to continue to build on the solid progress made to date.

The outcome of the FDA's deliberations on the Company's submissions has helped provide guidance to the Group's ongoing strategic review and some initial decisions have been shared below. The Board will continue to update shareholders on further decisions in respect of the Company's future strategy. Beyond this, another key event for 2018 will be readout of the AEGIS-H2H IIIb study, due in H2 2018, which is within the extended cash runway. If successful, this will primarily be used to support broader pricing and reimbursement activities in Europe.

While these significant post-period developments dominate our agenda, the Board continues to evaluate the Group's options and focus on ensuring value is realised for its shareholders.

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About Shield Therapeutics plc
Shield Therapeutics is a commercial stage pharmaceutical company, delivering innovative specialty pharmaceuticals to address patients' unmet medical needs. Our clear purpose is to help our patients become people again, by enabling them to enjoy the things that make the difference in their everyday lives. The Group has a marketed product, Feraccru®, for the treatment of all adults with iron deficiency with or without anaemia which has exclusive IP rights until the mid-2030's. For more information please visit www.shieldtherapeutics.com.

This announcement is released by Shield Therapeutics plc and contains inside information for the purposes of the Market Abuse Regulation (EU) 596/2014 ("**MAR**") and is disclosed in accordance with the Company's obligations under Article 17 of MAR. The person who arranged for the release of this announcement on behalf of Shield Therapeutics plc was Carl Sterritt, Chief Executive Officer.

Chairman's statement

2017 was another year of solid progress for Shield, the results of which, however, have been significantly affected by post period events. The Company's focus in 2017 continued to be to raise awareness of Feraccru, grow sales in the UK and Germany and recruit into the ongoing clinical trials of Feraccru as rapidly as possible. Progress on those fronts had been positive, with more than twenty specialist staff driving product recognition and sales in Germany and the UK by the end of 2017.

Financing the business has been one of the Company's key objectives. In June the Group completed a successful Warrant exercise, subscription and placing raising net proceeds of £11.9 million, which augmented the balance sheet and further enabled the Company to execute on its strategic plans ahead of the AEGIS-CKD data read out. Extending the cash runway post the AEGIS-CKD data has required a significant emphasis on cost containment and as a consequence, Shield has rationalised its commercial structure and other functions, all of these actions have extended the Group's cash runway at least through to the end of Q4 2018 which critically is expected to enable the Company to deliver a number of key value enhancing events including filing of the NDA and results of the head to head study.

The market environment

Our assets
Market environment
Our lead asset Feraccru, and pipeline, are well positioned to benefit from the current market dynamics where we see continued political interest in both Europe and the US regarding drug pricing due to patient, prescriber and payor pressure. Success in today's market requires an evidence-based proposition where value is key, and several trends appear to be reshaping the marketplace[1] that include an aging population, with an increase in chronic disease placing even greater pressure on stretched healthcare budgets. This increases demands from payors for real-world evidence from studies measuring the pharmaco-economic performance of a therapy through the use of electronic medical records, providing data to support outcomes-based pricing along with mandatory treatment guidelines that can constrain a physician's choice of treatment.

Feraccru lead product:
The Company's lead product, Feraccru, is ideally positioned to benefit from the market dynamics and evolving treatment pathways. Feraccru can remove cost from the healthcare system by reducing the requirement for intravenous iron therapies in patients who are intolerant of salt-based oral iron products.

[1] Source: PwC Pharma 2020 series

Fewer patients requiring intravenous therapy can in turn reduce the administrative, financial and patient inconvenience burdens that accompany such treatments. Together, we believe these attributes make Feraccru an attractive asset in today's ever-changing and increasingly value-based market.

Strategy

Through 2017 the Company has been building the foundations to achieve its vision and ambitions to become an international pharmaceutical company focused on identifying, developing and commercialising innovative specialty pharmaceuticals that address patients' unmet medical needs. Key elements of this strategy were:

- Seek a broad label for Feraccru in Europe
- Maximise the commercial potential of Feraccru in key European markets
- Prepare Feraccru for a New Drug Application (NDA) in the US
- Evaluate potential ways of commercialising Feraccru in the US, either through a strategic partner or self-commercialisation
- Acquire or in-license additional clinical or commercial-stage product candidates that have the potential to address patients' unmet medical needs

Following the disappointing initial top-line AEGIS CKD results, the strategic focus for the coming year has had to be significantly revised. We as a Board, are seeking to achieve the best possible outcome for stakeholders. We believe that the best approach is to continue to focus on Feraccru and increasing market penetration via the broad EU label and geographic expansion and we will evaluate partnering options to help us achieve Feraccru's full potential. We have made clear progress with the recent EC approval for the broad label in Europe for Feraccru. It can now be used in the treatment of iron deficiency in adults, and with clarity on the outcome of the AEGIS-CKD study, we have been able to have constructive discussions with and received guidance from the FDA that has given the Company the confidence to now move forward with the submission of an NDA for Feraccru as soon as possible. We also await the outcome of the AEGIS-H2H IIIb study, due in H2 2018. All of these events contribute to our strategic review around the future direction of the business.

Governance

As a Board, we are committed to the principles of good corporate governance. During the period, we have undertaken an annual update to our governance and risk management processes and the Group's risk management plan to ensure that they remain appropriately aligned to the size of the Company. The availability of sufficient financial resources continues to be the greatest risk. Further details are provided in the Audit, Risk and Corporate Governance Reports of the Annual Report.

As a growing company, the quality and integrity of our people remains fundamental to the way we do business and to our future success. The Board recognises the importance the Company places on its values and delivering on its purpose by aligning efforts with and committing to a set of clearly identified core values.

The Company's Corporate Governance Report can be found on pages 25 to 26 of the Annual Report. Ever since the Company's listing as an AIM-quoted company, the Board has maintained a regular review of its effectiveness and of the wider governance structure of the Group. As an AIM-quoted company, Shield Therapeutics is not currently required to comply with the UK Corporate Governance Code but following a recent update to the AIM Rules for Companies the Company has decided to apply the UK Corporate Governance Code and will assess any departures from the Code and the reasons for doing so by the implementation date of 28 September 2018. As set out in the Corporate Governance Report, as the Group continues to grow, we will maintain this evaluation and take the governance steps necessary to support the Group's development.

Board Changes
In September, Joanne Estell resigned her Board position as Chief Financial Officer and Company Secretary to pursue other business interests outside the healthcare sector. I would like to thank Joanne for her contribution to the Company. We were fortunate and pleased to be able to make an internal appointment for this role and Dr Karl Keegan was appointed interim Chief Financial Officer. Karl had been with Shield as Director of Corporate Development and previously worked closely with the CEO and the rest of the Board on all aspects of the Group's operations and strategy development and, as a member of Shield's Leadership Team.

At the beginning of April 2018 (post period), the Board was delighted to announce Rolf Hoffmann has joined the Board of Shield Therapeutics. His extensive experience and knowledge of the pharmaceutical industry and its key stakeholders in major markets will be helpful in defining the Company's future strategy and we look forward to Rolf playing a full and active role in these discussions and beyond.

People
Shield Therapeutics has always strived to be a company that people want to work with and for. The Board and I would like to thank all of Shield's employees and its partners who have continued to show tremendous commitment and worked hard to deliver our corporate objectives and goals through a transformational period for the Group. The decisions the Board and Management had to take immediately after receipt of the initial top-line results of the Phase III AEGIS-CKD study to reduce the operational activity and headcount of the business were particularly difficult, but completely necessary to protect our financial resources. The Board and I offer our sincere gratitude to all those who have been affected and who have shown continued commitment in difficult times.

Andrew Heath
Chairman, Shield Therapeutics plc

Chief Executive Officer's statement and Financial Review

Introduction
Notwithstanding the very significant negative impact and ongoing fallout of the early February announcement of the initial topline data from the AEGIS-CKD study, the last 15 months have been a period of laying stronger business foundations, consolidation and solid progress for Shield Therapeutics and our lead asset, Feraccru.

Along with good progress with Feraccru's clinical development, Shield had continued to make clear progress with the commercialisation activities of Feraccru and having gained ground in Germany and the UK, the Company has continued to make progress in bringing the substantial benefits of Feraccru to more patients in these territories. Product awareness has grown consistently, and more patients than ever are benefitting from Feraccru therapy. Reassuringly this growth has continued post the announcement of the initial topline result of the AEGIS-CKD study. In addition, we have continued to successfully out-license Feraccru in additional markets, with additional discussions ongoing.

This year the Company received significant new patent grants for Feraccru's Composition of Matter Patent in Europe and the US, which now provides broad commercial protection through to 2035. Receipt of these is a valuable step forward for the Company as it considers its strategic options.

Post period in March 2018, we were pleased that the European Commission approved the extended indication for Feraccru to include treatment of all adults with ID with or without anaemia. This is an important step for Shield by providing Feraccru with a much greater commercial opportunity through a significantly larger patient population who could potentially benefit from Feraccru therapy as previously it

was only approved and marketed in Europe for the treatment of iron deficiency anaemia (IDA) in adult patients with inflammatory bowel disease (IBD).

After the unexpected and disappointing initial top-line results from the AEGIS-CKD pivotal Phase III study of Feraccru in February, the Company announced a Business and Trading update and confirmed the implementation of a cost rationalisation programme and the Board implemented a full review of Shield's strategic options. I am reassured that we have rapidly been able to understand what occurred in the study to produce the initial and confusing topline result. This has enabled us to take appropriate and well-controlled steps to prepare a data package that underpinned a constructive pre-NDA meeting with the FDA and led to the recent receipt of the final minutes of this meeting. These provided Shield with the necessary guidance to decide to progress with the submission of an NDA for Feraccru as soon as possible and without the need to conduct additional pivotal clinical trials.

The outcome of the FDA's deliberations has certainly helped inform the Group's ongoing strategic review, not least allowing us to confirm that the Company will submit an NDA as soon as possible in 2018. Further updates on our announced activities around partnering Feraccru in Europe will be shared in a timely manner.

Feraccru – initial focus on targeting IDA patients with IBD in UK and Germany

The Company's lead product, Feraccru, is a novel non-salt, oral formulation of ferric iron, which was first approved in Europe in 2016 and Shield is now able to market the product for the treatment of ID, in all adult patients. It is estimated that more than 40 million individuals in Europe alone suffer from ID. The strategic review has recognised the importance of accelerating the positive sales momentum in Europe and as announced, we have engaged a third party to facilitate progressing potential partnering arrangements.

Germany

Following the appointment of Andreas Off, a General Manager with more than 20 years of in-market experience with specialty pharmaceuticals, to lead Shield's German operations, the management team became fully active in 2017 and the field-based sales force expanded later in the year following some hiring challenges through the summer months and was well on its way to reaching a headcount of 20 sales representatives during the first half of 2018 before we took the resource conserving decisions to reduce operational capabilities in February 2018. However, Feraccru uptake has continued to increase in the immediate aftermath, but it is clear that with a larger share of voice and people on the ground we would expect further increases in uptake in this important and well-funded market.

The in-country sales teams had been focused on conversion of physician interest into prescription sales. Feraccru benefited from more pre-launch awareness (Shield had more hospitals in Germany actively involved in key pre-approval clinical trials of Feraccru) as well as somewhat stronger pricing in this territory. These elements, combined with the benefits Feraccru provides to patients, prescribers and payors, have led to continued progress in uptake during 2017 with pack sales per month increasing by over 400% from January 2017 to December 2017, with this trend continuing in the post period timeframe.

UK

As previously reported the commercial dynamics of the UK market remain significantly different to those in Germany. Initial focus in the UK has been on achieving the required formulary access with hospitals and clinical commissioning groups (CCGs) that enables prescriber usage demand to be fulfilled. Reimbursement activities continue and by the end of 2017 we had made submissions to formularies that accounted for approximately 65% of the patient opportunity (increased from 31% at 31 December 2016), exceeding our stated target of 60%. Encouragingly we continue to improve Feraccru's prescribing status in those areas where formulary has been granted and by the end of 2017 we had over 100 centres in the UK ordering per month, compared to 48 at the end of 2016. Finally, in the UK during 2017 pack sales per month increased by over 400%.

Tangible progress is being made with the NHS and UK prescriber interest in Feraccru is increasing. The label expansion, AEGIS-CKD data and AEGIS-H2H data are all expected to have further positive impact in 2018 and we remain confident that appropriate investment in manpower and activities would create an attractive market for Feraccru in the UK. We will evaluate partnering options to help us achieve Feraccru's full potential.

Delivering on Shield's out-licensing strategy

Geographic expansion of Feraccru outside the Group's stated core markets is an important element of Shield's broader commercialisation strategy and good progress was made in this respect in 2017.

The Group concluded an update to and expansion of the existing agreement with AOP Pharmaceuticals which provided for improved commercial terms in existing territories and the addition of commercial rights to Feraccru in Scandinavia. This expanded agreement accelerated access to near-term revenues in this market region and allowed Shield to better focus its resources on the core European markets.

In July, Shield entered into an exclusive agreement for Feraccru in Switzerland with Ewopharma AG. Under the terms of the agreement, Shield continues to manage all regulatory aspects of Feraccru's initial marketing authorisation, supply product to Ewopharma, provide product training and marketing support for the brand. Ewopharma has responsibility for maintaining Feraccru's marketing authorisation and managing commercialisation of the planned future label expansion, with support from Shield, as well as all aspects of pricing, reimbursement, marketing and distribution. Switzerland is a well-developed market for the treatment of Iron Deficiency Anaemia (IDA), currently contributing almost 15% of total European IV iron sales from a little more than 2% of the population.

Regulatory approval of Feraccru is expected imminently in Switzerland, having received a pre-approval notification from the Swiss regulatory authority in June 2017 and the Board believes Feraccru will be an important product for Ewopharma. With its existing expertise in the IDA market, together with a focus on gastroenterology, Ewopharma is well positioned to rapidly and effectively launch Feraccru into the Swiss market.

As recently announced, Shield is also working with Torreya Partners to explore ways of accelerating the realisation of Feraccru's potential in Europe and more distant geographies. We have been encouraged by the level of interest shown in the initial stages of our European partnering activities for Feraccru. To date this includes receipt a non-binding proposal from a potential partner, which includes an upfront payment as part of the proposal (as is typical in deals in this sector), that the Company would use to provide a cash runway into 2019. Although there can be no certainty that such an agreement will be concluded, this indicates there is clear interest and as progress is made, updates on these activities will be provided.

Clinical progress to support broader commercialisation of Feraccru

AEGIS-CKD pivotal Phase III study of Feraccru

The Feraccru AEGIS-CKD study is a pivotal Phase III trial with a primary endpoint evaluating haemoglobin response to Feraccru (ferric maltol, 30mg twice daily) compared to placebo in the treatment of IDA in patients with chronic kidney disease (CKD). Top-line data was based on the 16-week primary endpoint, with 167 subjects enrolled in 30 renal centres across the US.

Post period in February, initial top line results showed that Feraccru had seemingly failed to meet the study's primary endpoint of demonstrating a statistical difference in change of haemoglobin from baseline compared to placebo at 16 weeks (0.45 v 0.15 g/dL, p=0.1686). The response at 8 weeks demonstrated separation of the treatment arms (0.53 v 0.0 g/dL, p = 0.0009), which was not sustained to week 16. Patient

drop-out rate was low over the 16 weeks and similar in both arms - 10 (9%) in the Feraccru arm versus 7 (12.5%) placebo, reconfirming the strong tolerability profile of Feraccru.

Subsequently, following a blinded review of all enrolled subjects who completed the initial 16-week placebo-controlled portion of the study, a small number of patients in both treatment arms were identified as experiencing pre-specified events that could have led to withdrawal but, as permitted in the study protocol, with Investigator discretion they remained in the study. The Company believes the inclusion of data from these patients, post these confounding events, significantly impacted the haematology-focused primary endpoint of the pivotal study. Consequently, further analyses of the data from the full trial population have been conducted using a multiple imputation methodology in the pre-specified statistical analysis of the Intention to Treat (ITT) population, which correctly dealt with the confounding data.

As a result of these revised analyses, patients treated with Feraccru demonstrated a statistically significant response (p=0.0149) in haemoglobin levels after 16 weeks of treatment compared to placebo (difference 0.52g/dl (CI 0.102, 0.930) and statistically significant results were achieved across a range of secondary iron parameters (TSAT, Ferritin levels, serum iron levels). The response at 8 weeks also demonstrated separation of the treatment arms (0.49 v 0.03 g/dL, p = 0.0052). The Company believes there is a clear and robust rationale for the analyses of the dataset as outlined and following constructive discussions with FDA is now moving forward with the submission of an NDA for Feraccru as soon as possible and without conducting any additional clinical trials.

Feraccru AEGIS-H2H IIIb study – primary endpoint data anticipated in H2 2018
The AEGIS-H2H Phase 3b study is designed as a non-inferiority trial comparing the efficacy and safety of Feraccru to the market-leading latest generation form of IV iron (Ferinject/Injectafer, ferric carboxymaltose). The data from the study will primarily be used to support pricing and reimbursement negotiations in those markets that seek comparator data and the primary endpoint data from the study is expected to be available in the second half of 2018.

CHMP positive opinion for Feraccru® (Ferric Maltol) for the treatment of Iron Deficiency in adults
Post period, in March 2018, the European Commission authorised a significant extension of the approved label for Feraccru. The Company's lead asset is now approved and can be marketed in Europe for the treatment of iron deficiency, in all adult patients.

This is an important step for Shield and for patients suffering with iron deficiency be that with or without anaemia. Iron deficiency causes significant morbidity and failure to be able to treat it adequately with current therapies can cause the disease to progress to iron deficiency anaemia. The WHO has identified that iron deficiency is a globally important health issue significantly impacting the lives of up to 2 billion people, albeit the majority of these are due to nutritional issues.

The new market opportunity for Feraccru in Europe significantly expands from the current 330,000 patients with IDA in IBD we have previously reported, to a much broader patient population opportunity, with over 40 million[2] people in the EU estimated to be iron deficient. With Feraccru being protected by a broad composition of matter patent through to 2035, this is a valuable step forward for the Company as it considers its strategic options.

Other trials and data collection efforts
In 2017, Shield initiated a number of data collection projects to support marketing activities and pricing and reimbursement applications for Feraccru. This includes a patient registry in Germany which could be

[2] *Levi, M., Rosselli, M., Simonetti, M., Brignoli, O., Cancian, M., Masotti, A., Pegoraro, V., Cataldo, N., Heiman, F., Chelo, M., Cricelli, I., Cricelli, C. and Lapi, F. (2016), Epidemiology of iron deficiency anaemia in four European countries: a population-based study in primary care. Eur J Haematol, 97: 583–593. doi:10.1111/ejh.12776

expanded across Europe and a real-world evidence study across a number of UK prescribing centres involving patients receiving commercial Feraccru. As well as generating supportive data for the use of Feraccru, involvement in such programmes more directly increases the prescriber's knowledge of the product being assessed and of Shield Therapeutics.

The Group's first paediatric pharmaco-kinetic study of Feraccru has now completed recruitment with Shield observing a high degree of interest and involvement from the participating centres. Data from this study is also expected in 2018 and will help the Group design the small paediatric Phase 3 study that the EMA requires to enable Feraccru to be marketed for the treatment of IDA in children.

Further strengthening of the intellectual property protection of Feraccru

Shield continued to strengthen its IP position regarding Feraccru. Following the UK grant notification in October 2016 for the composition of matter patent for Feraccru, Australian and Canadian patent grants were received in March and April 2017, respectively. In May 2017, the European Patent Office also notified Shield that it intended to grant the patent across its jurisdiction, followed most recently with notification of allowance of grant from the US Patent Office in September. The result of these positive opinions is that the active substance of Feraccru is now broadly protected through to late 2035 in the USA, Europe, Australia, and Canada thereby adding a significant number of years to the peak sales opportunity for Feraccru in these commercially important markets. Applications and prosecutions continue in other commercially relevant markets.

Financial Review

During the year to December 2017 the Group maintained its focus on the commercialisation of Feraccru. Spend on research and development activities, together with commercial teams, continued to grow. June 2017 also saw gross funds raised of £12.4 million through the combination of an exercise of Warrants, institutional placing and subscription for shares.

Revenue

Revenue of £637,000 (2016: £304,000) was recorded during the year, as the Group continued its progress with commercialisation. Of this amount £70,000 (2016: £240,000) relates to sales in the UK and £567,000 (2016: £64,000) to sales in Europe.

Selling, general and administrative expenses

Selling costs increased to £9.1 million (2016: £4.2 million) during the year, as the Group developed its commercial activities in Europe. General administrative expenses of £5.2 million (2016: £4.6 million) reflected the increase in headcount in this area. Depreciation and amortisation of £2.4 million (2016: £1.9 million) is principally in relation to the intellectual property acquired with Phosphate Therapeutics Limited during 2016.

Research and development expenditure

The statement of profit and loss includes research and development expenditure of £4.7 million, incurred in relation to the Group’s phase III AEGIS-CKD study, together with additional costs associated with the Marketing Authorisation Approval.

Costs of £3.2 million were also capitalised in relation to the Group’s H2H phase 3b and paediatric studies and CMC costs relating to the scale up of manufacturing activity.

Tax

The tax credit of £1.4 million in the statement of profit and loss relates to cash claimed in respect of R&D credits for the 2016 financial year.

Loss per share
The basic loss per share for 2017 was £0.17 (2016: £0.15). After adding back exceptional items (see Note 11) the adjusted loss per share was £0.15 (2016: £0.09). Details of the loss per share calculations are provided at Note 11.

Balance sheet
Net assets at 31 December 2017 were £41.2 million (2016: £48.4 million), including cash of £13.3 million (2016: £21.0 million) and intangible assets of £30.0 million (2016: £29.0 million). This followed the receipt of net fundraising proceeds during the year of £11.9 million.

£23.3 million (2016: £25.3 million) of the intangible assets balance relates to the acquisition of intellectual property with Phosphate Therapeutics Limited and £5.4 million (2016: £2.5 million) to the capitalisation of development costs in relation to the Group's clinical studies, with the remaining balance of £1.3 million (2016: £1.1 million) relating to patents and trademarks.

Cash flow
Cash burn (net cash flow from operating and investing activities) during the year was £19.6 million, primarily in relation to ongoing commercialisation and research and development activities. The Group also raised net funding proceeds of £11.9 million during the year, resulting in a net cash outflow of £7.7 million.

Foreign exchange management
The Group takes a conservative position with regard to foreign exchange and does not currently take out forward contracts, as the timing and extent of future cash flow requirements denominated in foreign currencies are difficult to predict. Part of the IPO funds receipt was in Euros and this had the benefit of providing a significant level of natural hedging against foreign exchange movements. Future currency needs are continually monitored, and currency purchases will be considered when the extent and timing of such needs are known.

Going concern
As described in Note 5 the Directors have prepared the financial statements on a going concern basis, however uncertainty remains regarding the source and timing of funding to support the Group's commercialisation efforts and its going concern status. The auditors have issued an emphasis of matter in this respect.

This strategic report was approved on 10 April 2018, by order of the Board.

Carl Sterritt
CEO, Shield Therapeutics plc

Consolidated statement of profit and loss and other comprehensive income

for the year ended 31 December 2017

	Note	**2017 £000**	2016 £000
Revenue	8	**637**	304
Cost of sales		**(155)**	(100)
Gross profit		**482**	204
Operating costs – selling, general and administrative expenses		**(16,722)**	(10,675)
Other operating income		**-**	40
Operating loss before research and development expenditure		**(16,240)**	(10,431)
Research and development expenditure		**(4,711)**	(2,029)
Operating loss		**(20,951)**	(12,460)
Analysed as:			
Operating loss before exceptional items		**(18,380)**	(10,303)
Exceptional items	9	**(2,571)**	(2,157)
Operating loss		**(20,951)**	(12,460)
Net foreign exchange (losses)/gains		**(41)**	270
Net foreign exchange losses on financial instruments	2	**-**	(1,059)
Net loss on financial instruments designated as fair value through profit or loss	2	**-**	(2,398)
Financial income		**15**	58
Financial expense		**(17)**	(14)
Loss before tax		**(20,994)**	(15,603)
Taxation	12	**1,406**	587
Loss for the year		**(19,588)**	(15,016)
Attributable to:			
Equity holders of the parent		**(19,588)**	(15,016)
Other comprehensive income			
Items that are or may be reclassified subsequently to profit or loss:			
Foreign currency translation differences – foreign operations		**(41)**	112
Total comprehensive expenditure for the year		**(19,629)**	(14,904)
Attributable to:			
Equity holders of the parent		**(19,629)**	(14,904)
Total comprehensive expenditure for the year		**(19,629)**	(14,904)
Earnings per share			
Basic and diluted loss per share	11	**£(0.17)**	£(0.15)
Non-GAAP measure			
Adjusted loss per share	11	**£(0.15)**	£(0.09)

Group balance sheet

at 31 December 2017

	Note	**2017 £000**	2016 £000
Non-current assets			
Intangible assets	13	**29,961**	28,984
Property, plant and equipment		**13**	19
		29,974	29,003
Current assets			
Inventories		**125**	418
Trade and other receivables		**1,572**	1,985
Cash and cash equivalents		**13,299**	20,978
		14,996	23,381
Total assets		**44,970**	52,384
Current liabilities			
Trade and other payables		**(3,501)**	(3,827)
Other liabilities		**(262)**	(161)
		(3,763)	(3,988)
Total liabilities		**(3,763)**	(3,988)
Net assets		**41,207**	48,396
Equity			
Share capital	14	**1,746**	1,622
Share premium		**88,338**	77,963
Warrants reserve		**-**	2,760
Merger reserve		**28,358**	28,358
Currency translation reserve		**32**	73
Retained earnings		**(77,267)**	(62,380)
Total equity		**41,207**	48,396

These financial statements were approved by the Board of Directors on 10 April 2018 and were signed on its behalf by:

Carl Sterritt
Director
Company registered number: 09761509

Group statement of changes in equity

for the year ended 31 December 2017

	Share capital £000	Share premium £000	Warrants reserve £000	Merger reserve £000	Currency translation reserve £000	Retained earnings £000	Total £000
Balance at 1 January 2016	690	-	-	28,358	(39)	(47,652)	(18,643)
Loss for the year	-	-	-	-	-	(15,016)	(15,016)
Other comprehensive income:							
Foreign currency translation differences	-	-	-	-	112	-	112
Total comprehensive income/(expense) for the year	-	-	-	-	112	(15,016)	(14,904)
Transactions with owners, recorded directly in equity							
Share issue – IPO	325	26,487	2,760	-	-	-	29,572
Share options exercised	309	25,011	-	-	-	-	25,320
Phosphate Therapeutics Limited acquisition	298	26,465	-	-	-	-	26,763
Equity-settled share-based payment transactions	-	-	-	-	-	288	288
Balance at 31 December 2016	1,622	77,963	2,760	28,358	73	(62,380)	48,396
Loss for the year	-	-	-	-	-	(19,588)	(19,588)
Other comprehensive income:							
Foreign currency translation differences	-	-	-	-	(41)	-	(41)
Total comprehensive expense for the period	-	-	-	-	(41)	(19,588)	(19,629)
Transactions with owners, recorded directly in equity							
Share issue – exercise of Warrants	108	10,235	(2,760)	-	-	2,760	10,343
Share issue – placing	15	-	-	-	-	1,381	1,396
Share issue – subscription	1	140	-	-	-	-	141
Equity-settled share-based payment transactions	-	-	-	-	-	560	560
Balance at 31 December 2017	**1,746**	**88,338**	**-**	**28,358**	**32**	**(77,267)**	**41,207**

Group statement of cash flows

for the year ended 31 December 2017

	2017 £000	2016 £000
Cash flows from operating activities		
Loss for the year	**(19,588)**	(15,016)
Adjustments for:		
Depreciation and amortisation	**2,437**	1,936
Loss on derivative financial instruments	**-**	2,398
Equity-settled share-based payment expenses	**560**	288
Financial income	**(15)**	-
Financial expense	**17**	-
Unrealised foreign exchange losses	**39**	984
Income tax	**(1,406)**	-
	(17,956)	(9,410)
Decrease/(increase) in inventories	**293**	(418)
Increase in trade and other receivables	**(171)**	(377)
Decrease in trade and other payables	**(409)**	(154)
Increase in other liabilities	**101**	103
Financial income	**15**	-
Financial expense	**(17)**	-
Income tax received	**1,993**	-
Net cash flows from operating activities	**(16,151)**	(10,256)
Cash flows from investing activities		
Acquisitions of intangible assets	**(235)**	(528)
Capitalised development expenditure	**(3,173)**	(2,639)
Acquisition of property, plant and equipment	**-**	(8)
Cash acquired with Phosphate Therapeutics Ltd	**-**	177
Net cash flows from investing activities	**(3,408)**	(2,998)
Cash flows from financing activities		
Proceeds of Warrants exercise	**10,792**	-
Proceeds of placing	**1,500**	-
Proceeds of subscription	**144**	-
Share issue costs	**(556)**	-
Proceeds of IPO	**-**	32,500
IPO costs	**-**	(2,427)
Other costs	**-**	(501)
Share options exercised	**-**	3,935
Net cash flows from financing activities	**11,880**	33,507
Net (decrease)/increase in cash	**(7,679)**	20,253
Cash and cash equivalents at 1 January	**20,978**	725
Cash and cash equivalents at 31 December	**13,299**	20,978

Notes

for the year ended 31 December 2017

1. General information

The financial information set out above has been prepared in accordance with the recognition and measurement criteria of International Financial Reporting Standards as adopted by the EU (Adopted IFRSs).

The financial information set out above does not constitute the company's statutory accounts for the years ended 31 December 2017 or 2016 but is derived from those accounts. Statutory accounts for 2016 have been delivered to the registrar of companies, and those for 2017 will be delivered in due course. The auditor has reported on those accounts; their reports were (i) unqualified and (ii) did not contain a statement under section 498 (2) or (3) of the Companies Act 2006; though in 2017 it did include a reference to a matter to which the auditor drew attention by way of emphasis without qualifying their report in relation to going concern.

These results were approved by the Board of Directors on 10 April 2018.

2. Fundraising

During the year the Company raised gross proceeds of £12.4 million through the combination of an exercise of Warrants, institutional placing and subscription for shares. In addition, £36.4 million was raised in the prior financial year through the Company's IPO and an exercise of shareholder options. Details of these transactions are provided below.

AIM listing

Shield Therapeutics plc was admitted to AIM on 26 February 2016 with a placing price of £1.50 per share for the additional 21.7m new shares issued pursuant to the placing. The Company's Shares and Warrants (see below) commenced trading on 26 February 2016. £32.5 million gross was raised through the listing process and £2.4 million of issue costs were incurred in the process.

On 26 February 2016 debt with a fair value of £21.4 million was converted to equity and this included certain options converted to equity at an exercise price of £3.9 million. As a consequence of this transaction, reserves increased by £25.3 million and the Group became debt free. Fair value costs of £2.4 million and foreign exchange translation costs of £1.1 million were charged to the statement of profit and loss during the prior year as a consequence of the fair value remeasurement of the debt prior to its conversion.

Exercise of Warrants

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

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

Placing

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

Subscription

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

Expenses of £0.5 million were incurred in the course of the exercise of Warrants, placing and subscription. These were charged to the share premium account.

3. Acquisition of Phosphate Therapeutics Limited

On 26 February 2016 Shield Therapeutics plc acquired 100% of the share capital of Phosphate Therapeutics Limited in consideration for 19,887,791 shares in the Company with a fair value of £27 million. All of the intangible assets value associated with this transaction has been allocated to the intellectual property acquired with Phosphate Therapeutics Limited.

4. Merger of Swiss entities

During 2016 the Group merged its Swiss legal entities, Shield Holdings AG, Iron Therapeutics Holdings AG and Iron Therapeutics (Switzerland) AG, with effect from 31 August 2016. Following completion of the merger process Shield Holdings AG and Iron Therapeutics (Switzerland) AG have been dissolved. The surviving entity, Iron Therapeutics Holdings AG changed its name to Shield TX (Switzerland) AG and now contains the assets formerly held by the dissolved Swiss entities.

5. Accounting policies

The consolidated and parent company financial statements have been prepared and approved by the Directors in accordance with International Financial Reporting Standards as adopted by the EU ("Adopted IFRSs").

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

Going concern

In June 2017 the Company succeeded in raising gross proceeds of £12.4 million through the combination of an exercise of Warrants, institutional placing and subscription for shares. At the year end the Group held £13.3 million of cash and net assets of £41.2 million.

The Directors have considered the funding requirements of the Group through the preparation of detailed cash flow forecasts for the period to December 2019. In doing so, the Directors have reviewed the operational forecasts, which were updated, following a cost saving programme undertaken in March 2018, which resulted in a lower cost base going forwards. Under current business plans the current cash resources ("cash runway") will exist to Q4 2018.

Based on this, additional funding is expected to be required by December 2018 in order to support the Group's and the Company's going concern status. The Directors are undertaking a strategic review of the business and following the recent significant expansion of Feraccru's European marketing authorisation to include all adult patients with iron deficiency, the Directors are evaluating ways of more rapidly leveraging the value of Feraccru in Europe and have engaged a third party to help to facilitate this process.

The Directors are also considering a variety of partnering structures that, if successfully concluded, would likely include an upfront payment which would further extend the Group's cash runway. In addition, such a partnering transaction would provide the Group with ongoing sales-based royalties throughout the life of the partnering agreement. In addition, in March 2018, the Group received a non-binding proposal from a potential partner which would, via an upfront payment as part of this arrangement (as is typical in deals in this sector), ensure sufficient resources to fund ongoing operations until at least Q2 2019.

Following feedback from the US FDA the Directors are now progressing with completing and submitting a New Drug Approval ("NDA") for Feraccru in 2018 and will now re-assess the commercialisation options for Feraccru in the US, and will continue to explore ways of commercialising Feraccru in the US for example through a joint venture or traditional partnering arrangement. These arrangements would also consist of an upfront payment.

However, there can be no guarantee that sufficient funding will be available from the potential options being considered, referred to above.

In the event that the Group does not successfully agree terms on at least one of the strategic options within the next 12 months, the Directors consider that the Group would be able to further reduce its development programmes to ensure its cash resources are sufficient for a period to at least Q4 2019, which is more than 12 months from the date of approval of this annual report and accounts.

Based on the above factors the Directors believe that it remains appropriate to prepare the financial statements on a going concern basis. However, the above factors give rise to a material uncertainty which may cast significant doubt on the Group's and the Company's ability to continue as a going concern and, therefore, to continue realising its assets and discharging its liabilities in the normal course of business. The financial statements do not include any adjustments that would result from the basis of preparation being inappropriate.

5. Accounting policies (continued)

Basis of consolidation

The consolidated financial statements comprise the financial statements of the Group and its subsidiaries as at 31 December 2017.

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

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

Foreign currency

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

The assets and liabilities of foreign operations, including goodwill and fair value adjustments arising on consolidation, are translated to the Group's presentation currency, Sterling, at foreign exchange rates ruling at the balance sheet date. The revenues and expenses of foreign operations are translated at an average rate for the year where this rate approximates to the foreign exchange rates ruling at the dates of the transactions.

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

Classification of financial instruments issued by the Group

Following the adoption of IAS 32, financial instruments issued by the Group are treated as equity only to the extent that they meet the following two conditions:

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

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

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

Non-derivative financial instruments

Non-derivative financial instruments comprise trade and other receivables, cash at bank and in hand, restricted cash, loans and borrowings, and trade and other payables.

Trade and other receivables

Trade and other receivables are recognised initially at fair value. Subsequent to initial recognition they are measured at amortised cost using the effective interest method, less any impairment losses.

Trade payables, other payables and other liabilities

Trade and other payables are recognised initially at fair value. Subsequent to initial recognition they are measured at amortised cost using the effective interest method.

Cash and cash equivalents

Cash and cash equivalents comprises cash balances in the bank and restricted cash.

5. Accounting policies (continued)

Inventories

Inventories are stated at the lower of cost and net realisable value. Cost is determined using standard costing techniques. The cost of finished goods comprises raw materials, direct labour, other direct costs and related production overheads. Net realisable value is the estimated selling price in the ordinary course of business, less applicable variable selling expenses. In arriving at net realisable value provision is made for any obsolete or damaged inventories.

Embedded derivatives

Derivatives embedded in host contracts are accounted for as separate derivatives and recorded at fair value if their economic characteristics and risks are not closely related to those of the host contracts and the host contracts are not held for trading or designated at fair value through the profit or loss. These embedded derivatives are measured at fair value with changes in fair value recognised in profit or loss.

Intangible assets

Research and development

Expenditure on research activities is recognised as an expense in the statement of profit and loss.
Expenditure on development activities directly attributable to an intangible asset is capitalised when the following conditions are met:

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

The Group considers that Marketing Authorisation Approval (MAA) regulatory approval in the relevant jurisdiction confirms these criteria.
Internally developed intangible assets are recorded at cost and subsequently measured at cost less accumulated amortisation and accumulated impairment losses.
Capitalised directly attributable development costs include clinical trial costs, Chemistry, Manufacturing and Controls (CMC) costs and contractor costs. Internal salary costs have not been capitalised as they are not considered to directly relate to bringing the asset to its working condition and employee costs are not allocated by project.
Expenditure in relation to patent registration and renewal of current patents is capitalised and recorded as an intangible asset. Registration costs are continually incurred as the Group registers these patents in different countries. Patent assets are stated at cost less accumulated amortisation and accumulated impairment losses.

Amortisation is charged to the statement of profit and loss on the straight-line basis. Amortisation commences when patents are issued, or in the case of other capitalised development expenditure when substantive revenue is being generated from products. Amortisation is charged as follows:

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

Impairment of assets

An impairment review is carried out annually for assets not yet in use. An impairment review is carried out for assets being amortised or depreciated when a change in market conditions and other circumstances indicates that the carrying value may not be recoverable. The recoverable amount is the higher of an asset's fair value less costs to sell and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows.

5. Accounting policies (continued)

Property, plant and equipment

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

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

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

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

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

Revenue

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

Revenue is recognised in the consolidated statement of profit and loss and other comprehensive income when the risks and rewards associated with the ownership of goods are transferred to the customer. This is deemed to occur when the customer collects and loads the product, resulting in the legal transfer of title.
Milestone payments under licensing agreements are recognised as revenue in the consolidated statement of profit and loss upon achievement of the milestone targets, as defined in the licensing agreement, unless the group has substantial ongoing performance obligations associated with the milestone still to deliver and the payment is not fixed or non-refundable.

Other operating income

Other operating income is measured at the fair value of consideration received or receivable for management services supplied to related parties. Income is recognised when the service has been delivered.

Expenses

Financial income and expense

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

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

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 periods.

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

Share-based payments

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

- including any market performance conditions;
- excluding the impact of any service and non-market performance vesting conditions; and
- including the impact of any non-vesting conditions.

5. Accounting policies (continued)

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

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

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

6. Critical accounting judgments and key sources of estimation uncertainty

In the application of the Group's accounting policies, which are described in Note 5, management is required to make judgments, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources.

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

Going concern

Judgment has been applied as to whether sufficient funding will be forthcoming in order to enable the continuation of the Company. As described in Note 5 the Directors have reviewed operational forecasts and followed a cash saving programme, extending the cash runway to Q4 2018. Additional funding is expected to be required to support the Company's going concern status and the Directors are currently considering a variety of partnering structures which if successfully concluded would lead to an upfront payment, further extending the Company's cash runway. In the event that such an agreement is not reached the Group's intangible and other assets may be impaired.

Valuation of intellectual property acquired with Phosphate Therapeutics Limited - £23.3 million

The valuation of intellectual property acquired with Phosphate Therapeutics Limited during the prior year 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 regulatory approval and successful commercialisation of the asset. Work on the development of a suitable commercial formulation of the drug product is ongoing and a strategic commercial/co-development partner for the asset is being sought in order to provide the funding required to successfully commercialise the asset. In the event that commercial returns are lower than current expectations or partner or alternative funding is not available this may lead to an impairment. No impairment has been recognised to date (see Note 13).

Valuation of intellectual property associated with Feraccru – intangible assets £6.6 million; investments in company balance sheet £103.0 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. A strategic commercial partner for the asset is currently being sought in Europe in order to provide the funding required to successfully commercialise the asset. In the event that commercial returns are lower than current expectations or partner or alternative funding is not available this may lead to an impairment. No impairment has been recognised to date (see Note 13).

Deferred tax assets

Estimates of future profitability are required for the decision whether or not to create a deferred tax asset. To date no deferred tax assets have been recognised.

Notes (continued)

for the year ended 31 December 2017

7. New standards and interpretations

The Group has adopted the following standards, amendments and interpretations in these financial statements for the first time. The adoption of these pronouncements has not had a material impact on the Group's accounting policies, financial position or performance:

- Currently none endorsed.

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

- IFRS 9 Financial instruments.
- IFRS 15 Revenue from contracts with customers.
- IFRS 16 Leases.

The Group is continuing to assess the impact of IFRS 9, IFRS 15 and IFRS 16 and does not expect their introduction to have a material impact.

8. 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 supply 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.

	2017				2016			
	Feraccru £000	**PT20 £000**	**Central and unallocated £000**	**Total £000**	Feraccru £000	PT20 £000	Central and unallocated £000	Total £000
Revenue	**637**	**-**	**-**	**637**	304	-	-	304
Operating loss	**(16,718)**	**(2,047)**	**(2,186)**	**(20,951)**	(9,179)	(14)	(3,267)	(12,460)
Net foreign exchange (losses)/gains				**(41)**				270
Foreign exchange losses on financial instruments				**-**				(1,059)
Net loss on financial instruments designated as fair value through profit or loss				**-**				(2,398)
Financial income				**15**				58
Financial expense				**(17)**				(14)
Tax				**1,406**				587
Loss for the year				**(19,588)**				(15,016)

The revenue analysis in the table below is based on the country of registration of the fee paying party.

	2017 £000	2016 £000
UK	**70**	240
Europe	**567**	64
	637	304

8. Segmental reporting (continued)

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

	2017 £000	2016 £000
Customer A	**-**	160
Customer B	**497**	113
Customer C	**93**	31
Other customers	**47**	-
	637	304

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

Year ended 31 December 2016	Feraccru® £000	PT20 £000	Central and unallocated £000	Total £000
Segment assets	6,450	25,394	20,540	52,384
Segment liabilities	(3,645)	(129)	(214)	(3,988)
Total net assets	2,805	25,265	20,326	48,396
Depreciation, amortisation and impairment	172	1,764	-	1,936
Capital expenditure	8	-	-	8
Capitalised development costs	2,639	-	-	2,639

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

9. Exceptional and non-recurring items

Exceptional items are separately disclosed on the basis that the Directors believe this is necessary to enable a fuller understanding of the performance of the Group. The Directors define exceptional items as:

- Material items that are unusual by size or incidence – this includes costs related to the IPO, including those related to complex financial instruments that expired at IPO; or
- Non-cash charges which, whilst recurring in nature, at this stage in the Group's development, are of a disproportionate size relative to the Group's other expenditure – this includes the amortisation of the Phosphate Therapeutics licences and share-based payment charges.

	2017 £000	2016 £000
Phosphate Therapeutics Ltd. intellectual property amortisation	**2,011**	1,702
Share-based payments charge	**560**	288
Non-recurring legal and professional fees	**-**	167
Exceptional items charged within operating loss	**2,571**	2,157
FX movement on share options	**-**	1,059
Fair value remeasurement of share options	**-**	2,398
Total exceptional items	**2,571**	5,614

Notes (continued)

for the year ended 31 December 2017

10. Staff numbers and costs

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

	2017 Number	2016 Number
R&D	**6**	7
Medical	**6**	2
Commercial	**17**	8
Finance and administration	**18**	12
	47	29

The aggregate payroll costs of these persons were as follows:

	2017 £000	2016 £000
Wages and salaries	**5,150**	3,221
Share-based payments	**560**	288
Other employee benefits	**272**	199
Pensions	**206**	108
	6,188	3,816

11. Loss per share

	Year ended 31 December 2017			Year ended 31 December 2016		
	Loss £000	**Weighted shares 000**	**Loss per share £**	Loss £000	Weighted shares 000	Loss per share £
IFRS – basic and diluted	**(19,588)**	**112,358**	**(0.17)**	(15,016)	101,160	(0.15)
Adjusted – basic and diluted	**(17,017)**	**112,358**	**(0.15)**	(9,402)	101,160	(0.09)
Proforma adjusted – basic and diluted	**(17,017)**	**112,358**	**(0.15)**	(9,402)	108,135	(0.09)

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 1,499,614 of share options were in issue under the Company's LTIP, CSOP and Retention Share Plan (RSP), which are considered non-dilutive and potentially provide 1,499,614 additional Ordinary Shares (approximately 1.3% of the current share capital). The level of options exercisable under the LTIP is dependent on the achievement of targets against the Compound Annual Growth Rate in the Company's share price over the vesting period.

The adjusted loss is calculated after adding back exceptional and non-recurring items as illustrated in the table below, in order to illustrate the underlying performance of the business.

The adjusted loss is calculated using the weighted average number of Ordinary Shares in issue during the year.

The adjusted proforma loss per share is calculated using the number of Ordinary Shares in issue following the IPO, and is presented to show how the loss per share would appear had the post-IPO level of Ordinary Shares been in place for the full year.

11. Loss per share (continued)

The table below reflects the income used in the basic, diluted and adjusted (non-GAAP) EPS computations:

	2017 £000	2016 £000
Loss for the year as used for calculating basic EPS	**(19,588)**	(15,016)
Phosphate Therapeutics Ltd. intellectual property amortisation	**2,011**	1,702
Share-based payments charge	**560**	288
Fair value remeasurement of share options	**-**	2,398
FX movement on share options	**-**	1,059
Non-recurring legal and professional fees	**-**	167
Loss attributable to ordinary equity holders of the parent adjusted for the effect of one-off and exceptional items as used for calculating Adjusted EPS	**(17,017)**	(9,402)

12. Taxation

Recognised in the income statement:

	2017 £000	2016 £000
Current income tax – adjustments in respect of prior years	**1,406**	587
Deferred tax	**-**	-
Total tax credit	**1,406**	587

Reconciliation of total tax credit:

	2017 £000	2016 £000
Loss for the year	**(19,588)**	(15,016)
Taxation	**1,406**	587
Loss before tax	**(20,994)**	(15,603)
Standard rate of corporation tax in the UK	**19.25%**	20.00%
Tax using the UK corporation tax rate	**(4,041)**	(3,121)
Expenses not deductible for tax purposes	**111**	9
Adjustments in respect of prior years	**1,408**	(567)
Unrelieved tax losses carried forward and other temporary differences not recognised for deferred tax	**3,928**	3,132
Total tax credit	**1,406**	587

A R&D credit of £Nil (2016: debit of £20,000) was also included as a credit within operating costs during the year.

Factors affecting future tax charge
Reductions in the UK corporation tax rate from 20% to 19% (effective from 1 April 2017) and to 17% (effective from 1 April 2020) were substantively enacted on 6 September 2016. This will reduce the Group's future current tax charge accordingly. The deferred tax assets and liabilities at 31 December 2017 have been calculated based on these rates.

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.

12. Taxation (continued)

	2017 £000	2016 £000
Unutilised Swiss tax losses to carry forward	**16,187**	17,799
Potential deferred tax asset thereon	**2,020**	2,128
Unutilised German tax losses to carry forward	**109**	90
Potential deferred tax asset thereon	**16**	27
Unutilised UK tax losses to carry forward	**34,320**	21,920
Potential deferred tax asset thereon	**5,637**	3,725
Total potential deferred tax asset	**7,673**	5,880

13. Intangible assets

Group	**Patents and trademarks £000**	**Development costs £000**	**Phosphate Therapeutics licences £000**	**Total £000**
Cost				
Balance at 1 January 2016	689	-	-	689
Additions – externally purchased	528	-	-	528
Additions – internally developed	-	2,639	-	2,639
Acquisition with Phosphate Therapeutics Limited	-	-	27,047	27,047
Effects of movements in foreign exchange	223	-	-	223
Balance at 31 December 2016	1,440	2,639	27,047	31,126
Additions – externally purchased	235	-	-	235
Additions – internally developed	-	3,173	-	3,173
Balance at 31 December 2017	**1,675**	**5,812**	**27,047**	**34,534**
Accumulated amortisation				
Balance at 1 January 2016	176	-	-	176
Charge for the period	113	115	1,702	1,930
Effects of movements in foreign exchange	36	-	-	36
Balance at 31 December 2016	325	115	1,702	2,142
Charge for the period	92	327	2,012	2,431
Balance at 31 December 2017	**417**	**442**	**3,714**	**4,573**
Net book values				
31 December 2017	**1,258**	**5,370**	**23,333**	**29,961**
31 December 2016	1,115	2,524	25,345	28,984

13. Intangible assets (continued)

At the year end management reviewed the carrying value of the intangible assets for impairment. The intangible assets relate to two cash-generating units, being the Feraccru business and the Phosphate Therapeutics Limited business. The recoverable amount has been determined based on value-in-use calculations, using pre-tax cash flow projections for the period of the patents. The following key assumptions have been included in the value-in-use calculations.

Feraccru

- The value in use has been calculated based on product sales which expire in 2035, being the current patent life of the asset.
- Anticipated sales are based on a third party assessment provided to the Company.
- A discount factor of 12%, reflecting the Marketing Authorisation already obtained for the drug and commercial progress to date.

Phosphate Therapeutics Limited

- The value in use has been calculated based on product sales which expire in 2029, being the current patent life of the asset.
- Anticipated sales are based on a third party assessment provided to the Company.
- A discount factor of 20%, reflecting the inherent uncertainty attached to obtaining Marketing Authorisation for the drug.

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

	2017 £000	2016 £000
Feraccru	**6,628**	3,639
Phosphate Therapeutics Limited	**23,333**	25,345
	29,961	28,984

Management has identified one key assumption, which if increased to the following rate would result in the recoverable amount in respect of the assets reducing so as to equal their carrying amount.

	Feraccru	Phosphate Therapeutics Limited
Discount rate	15%	26.8%

The Company had no intangible assets (2016: £Nil).

14. Share capital

	Number 000	£000
At 1 January 2017	108,135	1,622
Exercise of Warrants	7,194	108
Issuance of Shares pursuant to placing	1,000	15
Issuance of Shares pursuant to subscription	97	1
At 31 December 2017	**116,426**	**1,746**

See Note 2 for details of share capital issued during the course of the year.

15. Post balance sheet events

No adjusting post balance sheet events have been noted.