



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

**Preliminary Results for the Year Ended 31 December 2018**

**London, UK, 3 April 2019.** Shield Therapeutics plc (LSE:STX), a commercial stage, pharmaceutical company with an initial focus on addressing iron deficiency, announces its preliminary Group results for the year ended 31 December 2018.

**Operational Highlights**

- Positive results for pivotal Phase III AEGIS-CKD study of Feraccru<sup>®</sup> vs. placebo
- Approved label significantly broadened in Europe to all adults with Iron Deficiency with or without anaemia – a market of 40 million patients
- Exclusive licence agreement with Norgine B.V. to commercialise Feraccru<sup>®</sup> in Europe, Australia and New Zealand
  - £11 million upfront payment
  - up to €54.5 million milestone payments
  - up to 40% sales royalties
- Recruitment completed for AEGIS-H2H Phase IIIb study of oral Feraccru<sup>®</sup> vs. intravenous iron therapy
- US New Drug Application accepted for review by FDA; 27 July 2019 target ("PDUFA") date for review completion

**Financial Highlights**

- Revenues of £11.9 million (2017: £0.6 million)
- Loss for the year of £1.8 million (2017: £19.6 million)
- Net cash of £9.8 million (2017: £13.3 million)
- £11.0 million upfront received from Norgine licence agreement extends cash runway significantly

**Post-period Feraccru<sup>®</sup> Highlights**

- Positive results in AEGIS-H2H non-inferiority study triggering €2.5 million development milestone receivable from Norgine
- Positive results achieved in long-term follow-up of patients enrolled in AEGIS-CKD clinical study
- Norgine has now commenced promotion of Feraccru<sup>®</sup> in UK and Germany

**Commenting on the preliminary results, Carl Sterritt, CEO of Shield Therapeutics plc, said:** *"2018 was a year of transition and Shield is now well positioned to deliver further positive news through 2019. I expect Norgine to continue to develop the sales performance of Feraccru<sup>®</sup> in the UK and Germany, and we anticipate concluding further out-licence agreements to cover additional geographies. In the US I look forward to the 27 July 2019 PDUFA date, which has the potential to unlock the world's largest prescription pharmaceutical market to Feraccru<sup>®</sup>, which has continued to demonstrate its effectiveness over the last 12 months in two demanding clinical trials. In the meantime, we will continue to build upon these positive data, which have demonstrated Feraccru<sup>®</sup>'s non-inferiority to the leading IV iron therapy, its effectiveness in treating IDA in CKD patients, and the application of Feraccru<sup>®</sup> to patients with iron deficiency."*

**Analyst briefing & Investor briefing**

A briefing for analysts will take place at 9.30am on Wednesday 3 April 2019 at the offices of Walbrook PR, 4 Lombard Street, London, EC3V 9HD and a briefing for investors will take place on Monday 8 April 2019 at Copper Bar, Balls Brothers, 6 Adams Court, Old Broad Street, London, EC2N 1DX from 4.30pm for a 4.45pm start. If you would like to register for either event, please contact Walbrook PR on 020 7933 8780 or email [shield@walbrookpr.com](mailto:shield@walbrookpr.com)

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**About Shield Therapeutics plc**

Shield is a de-risked commercial stage, pharmaceutical company delivering innovative specialty pharmaceuticals to address patients' unmet medical needs. The Company's clear purpose is to help its 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<sup>®</sup>, for the treatment of iron deficiency in adults which has exclusive IP rights until the mid-2030s. Feraccru<sup>®</sup> is commercialised in the European Union by Norgine BV and the US Food and Drug Administration (FDA) is currently considering a New Drug Application (NDA), with a PDUFA (Prescription Drug User Fee Act) date of 27 July 2019. For more information please visit [www.shieldtherapeutics.com](http://www.shieldtherapeutics.com).

## Chairman's statement

### Operations and strategy

2018 was a challenging year for the Group but a great deal has been achieved and the year ended on a far stronger note than seemed likely in February 2018. The 2017 annual report set out how, in February 2018, the initial top-line analysis of the AEGIS-CKD pivotal Phase III study of Feraccru<sup>®</sup> suggested that the study had not met its primary endpoint but that the subsequent detailed analysis of the study showed that the initial results had been confounded by certain patient-specific events. After adjusting for appropriate patient inclusion criteria, the study did in fact meet its primary and secondary endpoints. However, the requirement to announce the initial analysis in February caused a major fall in the Company's share price which in turn necessitated significant adjustments to the Group's strategy, which have been implemented during 2018.

The main change to the Group's strategy was the decision that Shield should no longer build its own sales and marketing capabilities to promote Feraccru<sup>®</sup> but should instead out-license the product. As a consequence the UK and German sales and marketing operations, which had already been established by the time of the readout from the AEGIS-CKD study, were closed down and corporate and administrative operations substantially reduced. Consequently, employee numbers have reduced from 50 at the start of 2018 to 15 at 31 December 2018, and the underlying cost base reduced accordingly. However, given the positive results which emerged from the detailed analysis of the CKD study and the broadening of the approved label in Europe to include all Iron Deficiency, with or without anaemia, the Group has continued to invest in the Feraccru<sup>®</sup> R&D programme, in particular the AEGIS-H2H study, which compared Feraccru<sup>®</sup> with intravenous iron therapy.

Despite the hiatus caused by the initial AEGIS-CKD results, the Group has made real and valuable operational progress in 2018. First, as mentioned above, in March 2018 the European Commission approved a major broadening of the approved indications for which Feraccru<sup>®</sup> can be prescribed to include all Iron Deficiency, with or without anaemia. Secondly, in September 2018, Feraccru<sup>®</sup> was licensed to Norgine B.V. for commercialisation in Europe, Australia and New Zealand, providing validation of the commercial prospects for the product and, importantly for the Group, an upfront payment of £11 million which has extended the Group's cash runway significantly. Also in September recruitment for the AEGIS-H2H study was completed and in March 2019 we were delighted to announce that the study showed that Feraccru<sup>®</sup> is non-inferior to Ferinject<sup>®</sup>, the market-leading intravenous iron therapy. Finally, and potentially most significantly, the Group filed a New Drug Application (NDA) for Feraccru<sup>®</sup> in the US in late September 2018 and the FDA has since confirmed its acceptance of the filing and set 27 July 2019 as the date for completion of the review. This opens up the possibility of commercialisation of Feraccru<sup>®</sup> in the near future in the US, the world's largest pharmaceutical market.

### Board changes

As previously reported, Andrew Heath stepped down as Chair of the Board in June 2018 and I would like to thank Andrew for his contribution to Shield since 2015. In April 2018 and July 2018 respectively Rolf Hoffmann and Hans Peter Hasler joined the Board as Non-Executive Directors. They both have broad and deep experience of the pharmaceutical sector which has already proved invaluable and I welcome them both to the Board.

### People

I would like to thank everyone who has worked for and with Shield during 2018. The considerable progress that has been delivered since the early part of the year could not have been achieved without the commitment, perseverance and resilience of all our employees.

**James Karis**

**Chairman, Shield Therapeutics plc**

## Chief Executive Officer's statement and financial review

2018 has been a year of excellent operational progress for Shield and Feraccru<sup>®</sup>, despite the setback caused by the announcement of the initial top-line data from the AEGIS-CKD study which was covered extensively in the 2017 annual report. However, there was a very significant fall in share price at that time which necessitated major changes to the Group's strategy and resulted in a substantial refocusing of the Group, but I believe we are well on track to deliver meaningful value to investors.

### ***Legacy AEGIS-CKD study issues - now resolved***

The early part of the year was taken up with dealing with the results of the AEGIS-CKD study. The initial top-line data announced in February 2018 suggested that the study had not met its primary endpoint and this disappointed the market. However, during March 2018, the more detailed evaluation of the data revealed that there were a number of confounding factors which, when adjusted for as required by the study protocol, resulted in the study clearly meeting its primary endpoint and also achieving statistically significant positive results across a range of secondary parameters. Also in March 2018 the European Commission approved a major broadening of the indication for which Feraccru<sup>®</sup> can be marketed in Europe to include all Iron Deficiency in adults, with or without anaemia. Clearly this provides significant validation of the merits of Feraccru<sup>®</sup> and opens up a much larger patient population which can now be treated with Feraccru<sup>®</sup>.

The impact of the initial announcement led to the need to reduce cash burn and this resulted in the Board taking the decision that the Group should no longer aim to build its own sales and marketing operations in Europe but instead to out-license Feraccru<sup>®</sup>. We therefore immediately closed the sales and marketing operations which we had established in the UK and Germany and, over the next few months, reduced the size of the supporting organisation. From having 50 employees at the start of 2018, we now have only 15. I was saddened by the impact this will have had on the employees who we had to make redundant, and I thank them for the contributions they made to Shield, but it was absolutely necessary to secure the future of the business. I would also like to thank the remaining employees who continued to perform so professionally through this upheaval and period of significant change. We could not be where we now are without their commitment and hard work.

### ***Norgine out-license agreement***

We immediately started working on the process to out-license Feraccru<sup>®</sup> in Europe and found serious interest from a number of potential licensees. After a competitive process I am delighted that we were able to conclude, in September 2018, an exclusive licence agreement with Norgine B.V. to commercialise Feraccru<sup>®</sup> in Europe, Australia and New Zealand. Norgine is a leading European specialist pharmaceutical company with a presence in all major European markets and employs over 1,000 people. It has a well-established European infrastructure to develop, manufacture and commercialise products and has an excellent track record of commercial success with specialty pharmaceutical products. Under the terms of the agreement, Shield received an immediate £11 million upfront payment, and is eligible to receive up to €4.5 million in short term development milestones and up to €50 million in sales milestones upon the achievement of specified targets. Shield will also receive tiered royalties ranging from 25% to 40% of net sales of Feraccru<sup>®</sup>.

It is worth noting that, although Shield had stopped its own sales and marketing efforts in the UK and Germany by the end of March 2018, the upward sales momentum of Feraccru<sup>®</sup> in those markets continued throughout the year. This suggests that once doctors and patients have experienced Feraccru<sup>®</sup> they want to continue to use it and I expect, now that Norgine has started its own promotion of the product in those markets, that sales will grow significantly.

### ***FDA progress & China***

During the second and third quarters of 2018, we were working hard on preparing a New Drug Application (NDA) for Feraccru<sup>®</sup> in the US and we announced on 1 October 2018 that we had successfully submitted the application. Since then, the FDA has accepted the NDA filing for review and confirmed that it will complete its review by 27 July 2019. This is clearly a very exciting opportunity as the US market remains the largest pharmaceutical market in the world and there are substantial numbers of patients who suffer from inflammatory bowel disease and chronic

kidney disease, two of the leading causes of Iron Deficiency Anaemia. We have already started work on identifying potential sales and marketing partners for the US market.

During 2018 we also began discussions with a number of Chinese companies which are interested in acquiring sales and marketing rights to Feraccru® in China. I am optimistic that we should be able to conclude an agreement during 2019.

### ***Intellectual Property***

It is important to note that Shield retains ownership of, and control over, the intellectual property and further development of Feraccru®, and over the supply chain arrangements. We manage the supply chain and currently work with several suppliers to meet our requirements for the active ingredient and the formulation into finished product. These include a supplier on continental Europe which we believe will give protection to our supply chain in the event of a disorderly Brexit.

Feraccru® has a strong IP position including granted patents in Europe and the US over the composition of matter until 2035. This means that Feraccru® offers substantial long term value to Shield for the next 16 years. It is not unusual in the pharmaceutical industry for patents to be challenged and one of our patents was recently the subject of a challenge from Teva. The European Patent Office found in favour of Shield in respect of the opposition application on 14 March 2019. Teva has challenged a second patent but I am confident in the validity and strength of the patent and we will defend it vigorously.

### ***Further development studies***

We are continuing to invest in targeted development of Feraccru® where we believe it will increase its commercial value. The AEGIS-CKD study delivered compelling evidence of Feraccru®'s benefits in chronic kidney disease to go alongside the 2016 study results in inflammatory bowel disease. In January 2019 we announced positive results for the long-term phase of the AEGIS-CKD study. For the patients initially treated for 16 weeks with Feraccru®, haemoglobin levels were maintained over the 36-week follow-up period and the treatment continued to be well tolerated. Those subjects who were initially treated for 16 weeks with placebo and who switched to Feraccru® for the follow-up period demonstrated a similar rise in haemoglobin over their first 16 weeks of Feraccru® treatment when compared to those initially treated with Feraccru®, and subsequently maintained the improvement over the 36-week follow-up period. Much of our R&D effort during 2018 was spent on completing the recruitment to the AEGIS-H2H study which compared the performance of Feraccru® with the leading intravenous iron therapy. The recruitment was completed in September 2018. I was delighted in March 2019 that the study results demonstrated that Feraccru® is non-inferior to Ferinject®. This is a very significant outcome as it means that, in Feraccru®, there is now an oral alternative to IV iron therapy. Our plans for 2019 include starting a paediatric Phase III study which is likely to last two to three years. If successful, children and young adults suffering from Iron Deficiency will be able to benefit from Feraccru® along with adults for whom it is currently approved. We will also explore whether a once-daily formulation is feasible.

In 2018 we were not able to prioritise or invest in the rest of our development pipeline but we continue to believe that PT20 has the potential to be a significant product in the phosphate binder market. This market continues to grow and, within it, the new iron-based phosphate binders are growing particularly rapidly. PT20, which is iron-based, has characteristics which could give it competitive advantages over existing iron-based products. In 2019 we therefore intend to develop a new formulation of PT20, suitable for commercial use, and which will allow a Phase III study to be carried out. At this stage our intention is to out-license PT20 to a partner which could carry out the Phase III study and commercialise the product.

### **Outlook**

2018 was a year of transition and Shield is now well positioned to deliver further positive news through 2019. I expect Norgine to continue to develop the sales performance of Feraccru® in the UK and Germany, and we anticipate concluding further out-licence agreements to cover additional geographies. In the US I look forward to the 27 July 2019 PDUFA date, which has the potential to unlock the world's largest prescription pharmaceutical market to Feraccru®, which has continued to demonstrate its effectiveness over the last 12 months in two

demanding clinical trials. In the meantime, we will continue to build upon these positive data, which have demonstrated Feraccru®'s non-inferiority to the leading IV iron therapy, its effectiveness in treating IDA in CKD patients, and the application of Feraccru® to patients with iron deficiency.

### **Financial review**

The major financial events in 2018 have been the refocusing of the cost base to eliminate sales and marketing expenditure, reduction of administrative spend, and the licence agreement with Norgine, which resulted in an upfront receipt of £11 million.

### **Revenue**

Revenue of £11.9 million in 2018 (2017: £0.6 million) was dominated by the £11.0 million receipt from Norgine as the non-refundable upfront payment for the licence agreement. The remaining £0.9 million comprised (a) £0.6 million Shield sales in the UK and Germany prior to the signing of the licence agreement, (b) £0.1 million royalties from Norgine on its sales in the UK and Germany since the signing of the licence agreement, and (c) £0.2 million sales to AOP Orphan Pharmaceuticals.

### **Selling, general and administrative expenses**

Selling, general and administrative expenses reduced to £12.4 million in 2018 from £16.7 million in 2017. This reduction was largely due to the reduction of selling expenses from £9.1 million in 2017 to £3.5 million in 2018 as a consequence of the strategic decision in February 2018 to cease our own selling and marketing in Europe. General administrative expenses in 2018 were £6.6 million (2017: £5.2 million). The increase was created by redundancy payments and an increase in non-cash share-based payments from £0.6 million to £1.2 million. Depreciation and amortisation expenses were broadly flat at £2.3 million (2017: £2.4 million).

### **Research and development**

Research and development charged to the profit and loss account was £4.3 million in 2018 (2017: £4.7 million). This was incurred mainly on the AEGIS-CKD study. Development costs of £3.3 million (2017: £3.2 million) incurred on the AEGIS-H2H and PK studies, together with patents and trademarks were capitalised in line with the Group's accounting policy.

### **Tax**

The tax credit of £3.4 million (2017: £1.4 million) is comprised of £1.9 million of cash claimed and received during 2018 in respect of R&D tax credits for the 2017 financial year and an anticipated claim of £1.5 million in respect of the 2018 financial year.

### **Loss per share**

The basic loss per share for 2018 was £0.02 (2017: £0.17). Details of the loss per share calculations are provided in Note 8.

### **Balance sheet**

Net assets at 31 December 2018 were £40.4 million (2017: £41.2 million), including cash of £9.8 million (2017: £13.3 million) and intangible assets of £31.0 million (2017: £30.0 million).

### **Cash flow**

The loss for the year of £1.8 million, after adjustment for non-cash items (depreciation and amortisation, share-based payments, and the 2018 R&D tax credit accrual of £1.5 million), resulted in a cash inflow of £0.1 million, before working capital adjustments. Working capital movements amounted to an outflow of £0.3 million such that the net cash outflows from operations was £0.2 million. Investment in development, mainly the AEGIS-H2H clinical study, and intangible assets totalled £3.3 million resulting in an overall cash outflow for the year of £3.5 million.

### **Going concern**

At the year end the Group held £9.8 million of cash. Since the year end, the Group has achieved a successful Head to Head study, resulting in a milestone receivable of €2.5 million under the current European out-licensing agreement with Norgine.

The Directors have considered the funding requirements of the Group through the preparation of detailed cash flow forecasts for the period to December 2020. Under current business plans the current cash resources will extend to the third quarter of 2020. Based on this, additional funding is expected to be required by the third quarter of 2020 in order to support the Group's going concern status. The Directors are considering further commercialisation out-licensing opportunities for Feraccru<sup>®</sup>, in particular in the USA and China. These arrangements would be expected to include upfront payments which, if any one was achieved, would further extend the Group's cash runway (being the period for which the Group's cash resources are expected to last). The Directors also believe that other forms of finance, such as royalty finance underpinned by the existing European out-licensing agreement with Norgine, are likely to be available to the Group. However, there can be no guarantee that any of these opportunities will be successfully concluded.

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 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.

### **Financial outlook**

The Group expects Norgine to grow Feraccru<sup>®</sup> sales in the UK and Germany during 2019, and increased royalties will flow from that growth, but launches in the other major European markets are unlikely in 2019 as Norgine will need to negotiate pricing and reimbursement in those countries. Following the results of the AEGIS-H2H clinical study, a €2.5 million milestone is receivable from Norgine and further upfront receivables are possible in the event that the Group concludes any further out-licensing agreements. Costs in 2019 will be substantially lower than in 2018 as selling expenses have been removed and G&A expenditure will be reduced to around the levels previously seen in 2017. Total R&D expenditure (i.e. both the amount charged to the statement of profit and loss and any amounts capitalised) will be broadly in line with the amount charged to the statement of profit and loss in 2018. Overall, the Group's cash runway extends into the third quarter of 2020 without including potential upfronts from further out-licensing agreements.

**Carl Sterritt**

**CEO, Shield Therapeutics plc**

# Consolidated statement of profit and loss and other comprehensive income

for the year ended 31 December 2018

	Note	2018 £000	2017 £000
Revenue	5	11,881	637
Cost of sales		(311)	(155)
<b>Gross profit</b>		<b>11,570</b>	<b>482</b>
Operating costs – selling, general and administrative expenses	6	(12,438)	(16,722)
Operating loss before research and development expenditure		(868)	(16,240)
Research and development expenditure		(4,300)	(4,711)
<b>Operating loss</b>		<b>(5,168)</b>	<b>(20,951)</b>
Financial income		50	15
Financial expense		(35)	(58)
<b>Loss before tax</b>		<b>(5,153)</b>	<b>(20,994)</b>
Taxation	7	3,359	1,406
<b>Loss for the year</b>		<b>(1,794)</b>	<b>(19,588)</b>
<i>Attributable to:</i>			
Equity holders of the parent		(1,794)	(19,588)
<b>Other comprehensive income</b>			
<i>Items that are or may be reclassified subsequently to profit or loss:</i>			
Foreign currency translation differences – foreign operations		4	(41)
<b>Total comprehensive expenditure for the year</b>		<b>(1,790)</b>	<b>(19,629)</b>
<i>Attributable to:</i>			
Equity holders of the parent		(1,790)	(19,629)
<b>Total comprehensive expenditure for the year</b>		<b>(1,790)</b>	<b>(19,629)</b>
<b>Earnings per share</b>			
Basic and diluted loss per share	8	£(0.02)	£(0.17)



# Group balance sheet

at 31 December 2018

	Note	2018 £000	2017 £000
<b>Non-current assets</b>			
Intangible assets	9	30,957	29,961
Property, plant and equipment		8	13
		<b>30,965</b>	<b>29,974</b>
<b>Current assets</b>			
Inventories		109	125
Trade and other receivables		1,031	1,572
Current tax asset		1,500	-
Cash and cash equivalents		9,776	13,299
		<b>12,416</b>	<b>14,996</b>
<b>Total assets</b>		<b>43,381</b>	<b>44,970</b>
<b>Current liabilities</b>			
Trade and other payables		(2,548)	(3,501)
Other liabilities		(403)	(262)
		<b>(2,951)</b>	<b>(3,763)</b>
<b>Total liabilities</b>		<b>(2,951)</b>	<b>(3,763)</b>
<b>Net assets</b>		<b>40,430</b>	<b>41,207</b>
<b>Equity</b>			
Share capital	10	1,746	1,746
Share premium		88,338	88,338
Merger reserve		28,358	28,358
Currency translation reserve		36	32
Retained earnings		(78,048)	(77,267)
<b>Total equity</b>		<b>40,430</b>	<b>41,207</b>

# Group statement of changes in equity

for the year ended 31 December 2018

	Share capital £000	Share premium £000	Warrants reserve £000	Merger reserve £000	Currency translation reserve £000	Retained earnings £000	Total £000
<b>Balance at 1 January 2017</b>	1,622	77,963	2,760	28,358	73	(62,380)	48,396
Loss for the year	-	-	-	-	-	(19,588)	(19,588)
<i>Other comprehensive income:</i>							
Foreign currency translation differences	-	-	-	-	(41)	-	(41)
Total comprehensive expense for the year	-	-	-	-	(41)	(19,588)	(19,629)
<b>Transactions with owners, recorded directly in equity</b>							
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
<b>Balance at 31 December 2017</b>	1,746	88,338	-	28,358	32	(77,267)	41,207
Loss for the year	-	-	-	-	-	(1,794)	(1,794)
<i>Other comprehensive income:</i>							
Foreign currency translation differences	-	-	-	-	4	-	4
Total comprehensive expense for the period	-	-	-	-	4	(1,794)	(1,790)
<b>Transactions with owners, recorded directly in equity</b>							
Equity-settled share-based payment transactions	-	-	-	-	-	1,013	1,013
<b>Balance at 31 December 2018</b>	1,746	88,338	-	28,358	36	(78,048)	40,430

# Group statement of cash flows

for the year ended 31 December 2018

	2018 £000	2017 £000
<b>Cash flows from operating activities</b>		
Loss for the year	(1,794)	(19,588)
<i>Adjustments for:</i>		
Depreciation and amortisation	2,354	2,437
Equity-settled share-based payment expenses	1,013	560
Financial income	(50)	(15)
Financial expense	35	17
Unrealised foreign exchange losses	4	39
Income tax	(3,359)	(1,406)
	<b>(1,797)</b>	<b>(17,956)</b>
Decrease in inventories	16	293
Decrease/(increase) in trade and other receivables	541	(171)
Decrease in trade and other payables	(953)	(409)
Increase in other liabilities	141	101
Financial income	50	15
Financial expense	(35)	(17)
Income tax received	1,859	1,993
<b>Net cash flows from operating activities</b>	<b>(178)</b>	<b>(16,151)</b>
<b>Cash flows from investing activities</b>		
Acquisitions of intangible assets	(346)	(235)
Capitalised development expenditure	(2,999)	(3,173)
<b>Net cash flows from investing activities</b>	<b>(3,345)</b>	<b>(3,408)</b>
<b>Cash flows from financing activities</b>		
Proceeds of Warrants exercise	-	10,792
Proceeds of placing	-	1,500
Proceeds of subscription	-	144
Share issue costs	-	(556)
<b>Net cash flows from financing activities</b>	<b>-</b>	<b>11,880</b>
Net decrease in cash	(3,523)	(7,679)
Cash and cash equivalents at 1 January	13,299	20,978
<b>Cash and cash equivalents at 31 December</b>	<b>9,776</b>	<b>13,299</b>

# Notes

for the year ended 31 December 2018

## 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 2018 or 2017 but is derived from those accounts. Statutory accounts for 2017 have been delivered to the registrar of companies, and those for 2018 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 both years 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 2 April 2019.

## 2. Accounting policies

This financial information has 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

At the year end the Group held £9.8 million of cash. Since the year end, the Group has achieved a successful Head to Head study, resulting in a milestone receivable of €2.5 million under the current European out-licensing agreement with Norgine.

The Directors have considered the funding requirements of the Group through the preparation of detailed cash flow forecasts for the period to December 2020. Under current business plans the current cash resources will extend to the third quarter of 2020. Based on this, additional funding is expected to be required by the third quarter of 2020 in order to support the Group's going concern status. The Directors are considering further commercialisation out-licensing opportunities for Feraccru®, in particular in the USA and China. These arrangements would be expected to include upfront payments which, if any one was achieved, would further extend the Group's cash runway (being the period for which the Group's cash resources are expected to last). The Directors also believe that other forms of finance, such as royalty finance underpinned by the existing European out-licensing agreement with Norgine, are likely to be available to the Group. However, there can be no guarantee that any of these opportunities will be successfully concluded.

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 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.

### Basis of consolidation

The consolidated financial statements comprise the financial statements of the Group and its subsidiaries as at 31 December 2018.

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.

# Notes (continued)

for the year ended 31 December 2018

## 2. Accounting policies (continued)

### Foreign currency (continued)

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.

### Financial instruments

#### (i) Recognition and initial measurement

Trade receivables are initially recognised when they are originated. All other financial assets and financial liabilities are initially recognised when the company becomes a party to the contractual provisions of the instrument.

A financial asset (unless it is a trade receivable without a significant financing component) or financial liability is initially measured at fair value plus, for an item not at FVTPL, transaction costs that are directly attributable to its acquisition or issue. A trade receivable without a significant financing component is initially measured at the transaction price.

#### (ii) Classification and subsequent measurement

##### Financial assets

##### (a) Classification

On initial recognition, a financial asset is classified as measured at: amortised cost; FVOCI – debt investment; FVOCI – equity investment; or FVTPL.

Financial assets are not reclassified subsequent to their initial recognition unless the Company changes its business model for managing financial assets in which case all affected financial assets are reclassified on the first day of the first reporting period following the change in the business model.

A financial asset is measured at amortised cost if it meets both of the following conditions:

- it is held within a business model whose objective is to hold assets to collect contractual cash flows; and
- its contractual terms give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding.

On initial recognition of an equity investment that is not held for trading, the Company may irrevocably elect to present subsequent changes in the investment's fair value in OCI. This election is made on an investment-by-investment basis.

All financial assets not classified as measured at amortised cost or FVOCI as described above are measured at FVTPL.

Investments in subsidiaries are carried at cost less impairment.

##### Cash and cash equivalents

Cash and cash equivalents comprise cash balances and call deposits.

##### (b) Subsequent measurement and gains and losses

*Financial assets at FVTPL* - these assets (other than derivatives designated as hedging instruments) are subsequently measured at fair value. Net gains and losses, including any interest or dividend income, are recognised in profit or loss.

*Financial assets at amortised cost* - These assets are subsequently measured at amortised cost using the effective interest method. The amortised cost is reduced by impairment losses. Interest income, foreign exchange gains and losses and impairment are recognised in profit or loss. Any gain or loss on derecognition is recognised in profit or loss.

##### Financial liabilities and equity

Financial instruments issued by the Company are treated as equity only to the extent that they meet the following two conditions:

# Notes (continued)

for the year ended 31 December 2018

## 2. Accounting policies (continued)

### Financial instruments (continued)

- (a) 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
- (b) 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's 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 these financial statements for called up share capital and share premium account exclude amounts in relation to those shares.

Financial liabilities are classified as measured at amortised cost or FVTPL. A financial liability is classified as at FVTPL if it is classified as held-for-trading, it is a derivative or it is designated as such on initial recognition. Financial liabilities at FVTPL are measured at fair value and net gains and losses, including any interest expense, are recognised in profit or loss. Other financial liabilities are subsequently measured at amortised cost using the effective interest method. Interest expense and foreign exchange gains and losses are recognised in profit or loss. Any gain or loss on derecognition is also recognised in profit or loss.

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.

#### *Intra-group financial instruments*

Where the company enters into financial guarantee contracts to guarantee the indebtedness of other companies within its group, the company considers these to be insurance arrangements and accounts for them as such. In this respect, the company treats the guarantee contract as a contingent liability until such time as it becomes probable that the company will be required to make a payment under the guarantee.

#### (iii) Impairment

The company recognises loss allowances for expected credit losses (ECLs) on financial assets measured at amortised cost, debt investments measured at FVOCI and contract assets (as defined in IFRS 15).

The company measures loss allowances at an amount equal to lifetime ECL, except for other debt securities and bank balances for which credit risk (i.e. the risk of default occurring over the expected life of the financial instrument) has not increased significantly since initial recognition, which are measured as 12-month ECL.

Loss allowances for trade receivables and contract assets are always measured at an amount equal to lifetime ECL.

When determining whether the credit risk of a financial asset has increased significantly since initial recognition and when estimating ECL, the company considers reasonable and supportable information that is relevant and available without undue cost or effort. This includes both quantitative and qualitative information and analysis, based on the company's historical experience and informed credit assessment and including forward-looking information.

The company assumes that the credit risk on a financial asset has increased significantly if it is more than 30 days past due.

The company considers a financial asset to be in default when:

- the borrower is unlikely to pay its credit obligations to the company in full, without recourse by the company to actions such as realising security (if any is held); or
- the financial asset is more than 90 days past due.

Lifetime ECLs are the ECLs that result from all possible default events over the expected life of a financial instrument.

12-month ECLs are the portion of ECLs that result from default events that are possible within 12 months after the reporting date (or a shorter period if the expected life of the instrument is less than 12 months).

The maximum period considered when estimating ECLs is the maximum contractual period over which the company is exposed to credit risk.

# Notes (continued)

for the year ended 31 December 2018

## 2. Accounting policies (continued)

### Financial instruments (continued)

#### *Measurement of ECLs*

ECLs are a probability-weighted estimate of credit losses. Credit losses are measured as the present value of all cash shortfalls (i.e. the difference between the cash flows due to the entity in accordance with the contract and the cash flows that the company expects to receive). ECLs are discounted at the effective interest rate of the financial asset.

#### *Credit-impaired financial assets*

At each reporting date, the company assesses whether financial assets carried at amortised cost and debt securities at FVOCI are credit-impaired. A financial asset is 'credit-impaired' when one or more events that have a detrimental impact on the estimated future cash flows of the financial asset have occurred.

#### *Write-offs*

The gross carrying amount of a financial asset is written off (either partially or in full) to the extent that there is no realistic prospect of recovery.

### **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.

### **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. Costs relating to clinical trials, such as the Head to Head study, are only capitalised once Marketing Authorisation has been received and prior to this point are instead expensed as research and development expenditure.

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. Capitalisation ceases when the related project concludes.

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 once intangible assets are available for use, being also the point at which 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 – over the assumed five year life associated with the process

Intellectual property purchase costs – over the term of the patents

# Notes (continued)

for the year ended 31 December 2018

## 2. Accounting policies (continued)

### Intangible assets

#### *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.

### 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.

The Group has two revenue streams, being revenue associated with the sale of goods and revenue arising under milestone payments included in licensing agreements.

Revenue is recognised in the consolidated statement of profit and loss and other comprehensive income when control of goods passes 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 when related performance obligations are met, 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.

The Norgine contract is assessed to be a right to use licence, on the grounds that the Group's post-deal activity is not expected to significantly enhance the value of the asset to Norgine, and includes three types of performance obligation:

- Execution of the licence – revenue is recognised at a point in time upon signature of the agreement
- Event based milestones such as successful completion of clinical trials and achievement of sales thresholds – these comprise variable consideration and as such, revenue is only recognised when it is highly probable that no revenue will be reversed in the future. No revenue has been recognised in respect of these performance obligations in the year.
- Sales based royalties – these are attributable to the licence and revenue is recognised when the subsequent sale or usage occurs.

#### *Norgine licence agreement*

Revenue is recognised at a point in time. The Norgine contract has been assessed as containing a right to use licence as opposed to a right to access and therefore revenue is recognised at a point in time. If the licence were right to access, revenue would have been recognised over the life of the agreement. The contract also contains performance obligations with variable consideration. No amounts have been recognised in relation to these performance obligations in the year as management have judged that it is not highly probable that any revenue recognised would not be reversed in future periods since the outcome of the events is uncertain.

### Expenses

#### *Financial income and expense*

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

Interest income and interest payable are recognised in profit or loss as they accrue, using the effective interest method. Dividend income is recognised in the income statement 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 years.



# Notes (continued)

for the year ended 31 December 2018

## 2. Accounting policies (continued)

### Taxation (continued)

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.

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.

### 3. Critical accounting judgments and key sources of estimation uncertainty

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

The 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

Following the receipt of the £11.0 million upfront on signing the licence agreement with Norgine and the preparation of detailed cash flow forecasts, the Directors are of the opinion that the Group has sufficient working capital for its present requirements, that is for at least twelve months from the date of this report. The Directors therefore consider it appropriate to adopt the going concern basis of accounting in preparing the financial statements.

#### Valuation of intellectual property acquired with Phosphate Therapeutics Limited – £21.5 million

The valuation of intellectual property acquired with Phosphate Therapeutics Limited in 2016 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 value in use 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 the event that commercial returns are lower than current expectations this may lead to an impairment.

#### Valuation of intellectual property associated with Feraccru® – intangible assets £9.5 million; investments in company balance sheet £76.9 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. An agreement was reached during the year with a strategic commercial partner for the asset in Europe. An upfront payment of £11.0 million was received as part of the agreement, with the potential for significant additional milestone payments and royalties to follow. 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.

#### Development expenditure

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

#### 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 2018

## **4. 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:

From 1 January 2018 the Company adopted IFRS 15 Revenue from contracts with customers. The Company has also adopted IFRS 9 Financial instruments. No adjustments have been required as a consequence of these standards' adoption, as the impact is immaterial. There are no other new or amended standards which impact the Group in the year.

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.

IFRS 16 Leases.

The Group is continuing to assess the impact of IFRS 16 and expects from an initial assessment that the impact on the financial statements will not be material.

## Notes (continued)

for the year ended 31 December 2018

### 5. Segmental reporting

The following analysis by segment is presented in accordance with IFRS 8 on the basis of those segments whose operating results are regularly reviewed by the Chief Operating Decision Maker (considered to be the Board of Directors) to assess performance and make strategic decisions about the allocation of resources. Segmental results are calculated on an IFRS basis.

A brief description of the segments of the business is as follows:

- Feraccru® – development and 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.

	2018				2017			
	Feraccru £000	PT20 £000	Central and unallocated £000	Total £000	Feraccru £000	PT20 £000	Central and unallocated £000	Total £000
Revenue	<b>11,881</b>	-	-	<b>11,881</b>	637	-	-	637
Operating profit/(loss)	<b>2,009</b>	<b>(1,904)</b>	<b>(5,273)</b>	<b>(5,168)</b>	(16,718)	(2,047)	(2,186)	(20,951)
Financial income				<b>50</b>				15
Financial expense				<b>(35)</b>				(58)
Tax				<b>3,359</b>				1,406
Loss for the year				<b>(1,794)</b>				(19,588)

The revenue analysis in the table below is based on the country of registration of the fee-paying party. £11.1 million (2017: £Nil) of revenue is derived from milestone payments from commercial partners. The remainder of revenue is derived from the sale of goods. All revenue in 2017 related to the sale of goods.

	2018 £000	2017 £000
UK	<b>171</b>	70
Europe	<b>11,710</b>	567
	<b>11,881</b>	637

## Notes (continued)

for the year ended 31 December 2018

### 5. Segmental reporting (continued)

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

	2018 £000	2017 £000
Customer A	11,025	-
Customer B	516	497
Customer C	126	93
Other customers	214	47
	<b>11,881</b>	<b>637</b>

Year ended 31 December 2018	Feraccru® £000	PT20 £000	Central and unallocated £000	Total £000
Segment assets	12,643	21,627	9,111	43,381
Segment liabilities	(2,068)	(57)	(826)	(2,951)
<b>Total net assets</b>	<b>10,575</b>	<b>21,570</b>	<b>8,285</b>	<b>40,430</b>
Depreciation, amortisation and impairment	435	1,919	-	2,354
Capital expenditure	-	-	-	-
Capitalised development costs	2,999	-	-	2,999

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)
<b>Total net assets</b>	<b>6,053</b>	<b>23,435</b>	<b>11,719</b>	<b>41,207</b>
Depreciation, amortisation and impairment	421	2,016	-	2,437
Capital expenditure	-	-	-	-
Capitalised development costs	3,173	-	-	3,173

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

### 6. Operating costs – selling, general and administrative expenses

Operating costs are comprised of:

	2018 £000	2017 £000
Selling costs	3,495	9,133
General administrative expenses	6,589	5,152
Depreciation and amortisation	2,354	2,437
	<b>12,438</b>	<b>16,722</b>

### 7. Taxation

The Group's tax credit in the year ended The tax credit of £3.4 million (2017: £1.4 million) is comprised of £1.9 million of cash claimed and received during 2018 in respect of R&D tax credits for the 2017 financial year and an anticipated claim of £1.5 million in respect of the 2018 financial year.

## Notes (continued)

for the year ended 31 December 2018

### 8. Loss per share

	Year ended 31 December 2018			Year ended 31 December 2017		
	Loss	Weighted	Loss per	Loss	Weighted	Loss per
	£000	shares	share	£000	shares	share
Basic and diluted	(1,794)	116,426	(0.02)	(19,588)	112,358	(0.17)

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 3,104,186 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 3,104,186 additional Ordinary Shares (approximately 2.7% 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.

### 9. Intangible assets

Group	Patents and trademarks £000	Feraccru development costs £000	Phosphate Therapeutics licences £000	Total £000
<b>Cost</b>				
Balance at 1 January 2017	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
Additions – externally purchased	346	-	-	346
Additions – internally developed	-	2,999	-	2,999
<b>Balance at 31 December 2018</b>	<b>2,021</b>	<b>8,811</b>	<b>27,047</b>	<b>37,879</b>
<b>Accumulated amortisation</b>				
Balance at 1 January 2017	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
Charge for the period	71	427	1,851	2,349
<b>Balance at 31 December 2018</b>	<b>488</b>	<b>869</b>	<b>5,565</b>	<b>6,922</b>
<b>Net book values</b>				
<b>31 December 2018</b>	<b>1,533</b>	<b>7,942</b>	<b>21,482</b>	<b>30,957</b>
31 December 2017	1,258	5,370	23,333	29,961

## Notes (continued)

for the year ended 31 December 2018

### 9. 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 for each of the two CGUs .

#### Feraccru®

- The value in use has been calculated based on out-licensing income which expires in 2035, being the current patent life of the asset.
- Anticipated sales are based on a third party assessment provided to the Company.
- Two independent forecast revenue streams (one for Europe and one for the US) which are valued separately with different assumptions in certain cases but still form one CGU.
- A discount factor of 15% in Europe, reflecting the Marketing Authorisation already obtained for the drug and commercial progress to date and 20% in the US, reflecting the higher perceived risks of commercialisation pre-FDA approval.

#### Phosphate Therapeutics Limited

- The value in use has been calculated based on out-licensing income which expires 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 15%, reflecting the inherent uncertainty attached to obtaining Marketing Authorisation for the drug and an anticipated out-licensing business model.

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

	2018 £000	2017 £000
Feraccru®	9,475	6,628
Phosphate Therapeutics Limited	21,482	23,333
	<b>30,957</b>	<b>29,961</b>

Management has identified that if the discount rate was changed as follows this would result in the recoverable amount in respect of the assets reducing so as to equal their carrying amount.

	Feraccru® Europe	Feraccru® US	Phosphate Therapeutics Limited
Discount rate	58%	300%	25%

The Company had no intangible assets (2017: £Nil).

### 10. Share capital

	2018 Number 000	£000	2017 Number 000	£000
At 1 January 2017	116,426	1,746	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
<b>31 December 2018</b>	<b>116,426</b>	<b>1,746</b>	<b>116,426</b>	<b>1,746</b>

#### Fundraising

During the prior year the Company raised gross proceeds of £12.4 million through the combination of an exercise of Warrants, institutional placing and subscription for shares. Details of these transactions are provided below.

#### 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.

# Notes (continued)

for the year ended 31 December 2018

## 10. Share capital (continued)

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.

## 11. Post balance sheet events

No adjusting post balance sheet events have been noted.