



## Shield Therapeutics plc

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

### Maiden Preliminary Results for the Year Ended 31 December 2015

**London, UK, 14 June 2016.** Shield Therapeutics plc (LSE:STX), a specialty pharmaceutical Company focused on secondary care, today announces its maiden preliminary Group results for the year ended 31 December 2015.

#### Highlights (including post period end)

##### Operational

- Pan-European Marketing Authorisation Approval of Feraccru for the treatment of Iron Deficiency Anaemia ("IDA") in Inflammatory Bowel Disease ("IBD") received in February 2016
- Subsequent launch of Feraccru utilising the Company's own in-house commercial team commenced in the UK during May 2016
- Feraccru to be priced in the UK at £47.60 per pack (£1.70 per day equivalent) as agreed with the Department of Health
- Two additional Phase 3 studies of Feraccru have commenced to support future expansion of the market opportunity for Feraccru
- Successful completion of Phase 2b pivotal trial for PT20 in dialysis-dependent Chronic Kidney Disease ("CKD") patients and drug substance manufacturing for second pivotal study
- Significant investment in Shield's operational team with headcount now at 45, increased from 14 at the year end

##### Financial<sup>1</sup>

- Successful completion of an Initial Public Offering (IPO) on AIM of the London Stock Exchange in February 2016 raising £32.5m (gross) and further potential gross proceeds of £17.5m, subject to the full exercise of Warrants
- Net loss for FY2015 of £24.5m on IFRS basis; EPS loss of £0.57 per share
- Adjusted net loss for FY2015, excluding the impact of the pre-IPO capital and equity structure, of £5.3m, loss per share of £0.13
- Year end net cash of £0.7m; net cash as at 31<sup>st</sup> May 2016 of £28.8m

**Commenting on the maiden preliminary results, Carl Sterritt, Chief Executive Officer of Shield Therapeutics plc, said:** *"The period through 2015 into 2016 has been a transformational time for Shield Therapeutics. During this time the Company has successfully achieved three key long-term strategic objectives with its IPO, the first approval and commencement of commercialisation of its lead product,*

---

<sup>1</sup>Note: the Company's FY2015 results reflect the structure of the group pre-IPO and are pre-acquisition of Phosphate Therapeutics Limited which completed post year end.

*Ferracru and finally the successful completion of the first pivotal trial of PT20. We look forward to the future with great excitement.”*

**Conference call for analysts**

A briefing for analysts will be held at 9.30am BST on 14 June 2016 at the offices of Consilium Strategic Communications, 41 Lothbury, London, EC2R 7HG. There will be a simultaneous live conference call with Q&A and the presentation will be available on Shield’s website at <http://www.shieldtherapeutics.com/>

Conference call details:

**Participant dial-in:** 0800 694 0257  
**International dial-in:** +44 (0) 1452 555566  
**Participant code:** 13815220

An audio replay file will be made available shortly afterwards via the Company website: <http://www.shieldtherapeutics.com/>

- Ends -

**For further information please contact:**

**Shield Therapeutics plc** +44 (0)191 511 8507  
Carl Sterritt, Chief Executive Officer  
Richard Jones, Chief Financial Officer

**NOMAD** +44 (0)20 3100 2222  
**Liberum Capital Limited**  
Christopher Britton/Steve Pearce

**Financial PR Advisor** +44 (0)203 709 5700  
**Consilium Strategic Communications** [shieldtherapeutics@consilium-comms.com](mailto:shieldtherapeutics@consilium-comms.com)  
Mary-Jane Elliott/Matthew Neal/Lindsey Neville/Hendrik Thys

**About Shield Therapeutics plc**

Shield Therapeutics is a specialty pharmaceutical company focused on the commercialisation and development of late-stage, hospital-focused pharmaceuticals which address areas of high unmet medical need. The Company has a marketed product, Feraccru®, for the treatment of iron deficiency anaemia (IDA). In addition, the Company has a late-stage pharmaceutical for the treatment of systemic phosphate accumulation (hyperphosphatemia), PT20. Shield, based in London and Newcastle, joined LSE’s AIM in 2016 under the ticker STX. For more information please visit [www.shieldtherapeutics.com](http://www.shieldtherapeutics.com).

**Chairman's statement**

By any measure the past 12 months have been very busy, hugely exciting and a period of remarkable achievement for Shield Therapeutics. Less than 6 years after starting operations Shield achieved a marketing authorisation for Feraccru, the first oral prescription pharmaceutical product approved across Europe for the treatment of iron deficiency anaemia in patients with inflammatory bowel disease. This approval has positioned the Company for transformational growth and the successful completion of the Group's IPO during February 2016 has provided Shield with the resources to deliver this transformation. The support of investors at IPO provided £32.5m (gross) of new growth capital. This money is already fuelling the rollout of Feraccru's commercialisation, in-turn rapidly advancing Shield towards becoming a successful, revenue-generating specialty pharmaceutical company. In addition to these two substantial achievements, during 2015 Shield also successfully completed the first of PT20's two pivotal trials that will be required for the Company to achieve a marketing authorisation. PT20 is being developed to treat the ever-increasing number of chronic kidney disease patients with hyperphosphataemia.

The pharmaceutical model which grew out of the US in the latter half of the twentieth century is changing rapidly. Evidence based medicine, along with a recognition of the true costs - and savings - of drug therapy has led to payors taking more control over the purchase of drugs. Feraccru is well positioned for this changing model as it is being targeted at patients who have failed existing oral iron therapies and therefore previously would only have had the option of intravenous iron infusions, which are costly and carry a small but significant risk of life-threatening anaphylactic reactions.

Providing Feraccru as an effective therapeutic option has the potential to prove a game-changer for both payors and prescribers as it will remove the large financial costs associated with the administration of intravenous irons, which are a significant burden to already fiscally over-stretched healthcare providers.

On behalf of the Company I would like to thank all of Shield Therapeutics' original investors, whose funding supported the company to this point of transformation, as well as our previous board members who served the Company and represented the shareholders so effectively from 2010 through 2015. I would also like to welcome our two new Board members, James Karis and Peter Llewellyn-Davies, who joined Shield Therapeutics as the Company listed. Of course none of these achievements would have been possible without the outstanding team that make up Shield Therapeutics' staff and management and I thank them for their dedication, innovation and professionalism over the history of the Company and in particular the past 12 months. Finally I would like to both thank and welcome all of our new shareholders who have joined the Company's register through the IPO. We have exciting times ahead of us.

**Dr Andrew Heath, Non-Executive Chairman**

## Chief Executive's Overview

### Introduction

The period through 2015 into 2016 has been a transformational time for Shield Therapeutics. During this period, the Company has successfully achieved three key long-term strategic objectives with its Initial Public Offering (IPO), the first approval and commencement of commercialisation of our lead product, Ferracru, and the successful completion of the first pivotal trial of PT20.

### IPO

Shield successfully completed an IPO in February 2016, raising £32.5 million (gross) of growth capital from a high quality group of new and existing investors and gained admission to the London Stock Exchange's Alternative Investment Market (AIM). The IPO was a transformational event for the Company, providing the capital to deliver an in-house strategy for the commercialisation of Ferracru in the major European pharmaceutical markets. Shield's Board and management team believes that utilising its own commercial teams in these markets will enable the Company to build more effective relationships with prescribers, payors and patient associations, creating a key differentiator in the commercialisation of Ferracru, which in turn should lead to greater value creation. In support of the Company's own commercialisation activities, Shield is also actively pursuing licensing opportunities for Ferracru in smaller markets. With a pipeline of innovative and value-added specialty pharmaceuticals, the Company's talented, ambitious team has been energised by the resources the IPO has provided.

### Feracru<sup>2</sup>

Feracru is the Company's most advanced product and is a novel therapy for the treatment of Iron Deficiency Anaemia that received marketing authorisation across Europe in February 2016. Ferracru is the first oral iron therapy to be approved for the treatment of iron deficiency anaemia (IDA) in patients with inflammatory bowel disease (IBD). This novel secondary care product is estimated to have an achievable global peak annual sales opportunity in excess of £500 million. As outlined at the time of Shield's IPO, the Company plans to use the new funds to commercialise Ferracru via a phased roll-out across Europe in 2016 and 2017, as well as fund the additional clinical trials required to expand the product's geographic and indication reach.

The initial market for Ferracru is the approximately 1 million IBD patients in Europe who have IDA and require pharmaceutical therapy. Beyond that, as Shield gathers additional clinical evidence and broader regulatory approval to (i) treat patients with IDA related to CKD in Europe and (ii) patients with IDA related to IBD or CKD in the USA, this market opportunity will increase to more than 4 million IDA patients. This commercial activity is supported by a strong body of data that is already published or has been accepted for publication in recognised and peer-reviewed scientific journals. These data provide the compelling clinical evidence needed to successfully commercialise a specialty care focussed medicine.

In the longer term, Shield will seek an even wider label for Ferracru to enable Iron Deficiency Anaemia to be targeted across a wide range of underlying causes, giving access to a treatable population of more than 33 million patients.

---

<sup>2</sup> GfK report from 2015 as included in IPO Admission Document

## **PT20**

The Company's novel iron-based phosphate binder is initially being developed for the treatment of hyperphosphatemia related to chronic kidney disease ("CKD"). PT20 was invented in the UK by leading Cambridge-based scientists and the product is exclusively licensed from the Medical Research Council (MRC). Patients with late-stage renal disease suffer from hyperphosphatemia, which enhances the risk of vascular calcification, leading to increased morbidity and mortality. Low phosphate diets and regular dialysis sessions are unable to prevent gradual phosphate accumulation alone, therefore, oral phosphate binders are routinely used to reduce absorption of phosphate and thereby reduce blood phosphate levels.

PT20 is a phase 3 asset and recently met all primary and secondary endpoints of the first pivotal study (the PEACH study) it was taken through. It is expected that PT20 will undergo one further pivotal study before a marketing authorisation application can be filed in major pharmaceutical markets.

The Company believes there is a large and attractive market for PT20 as current treatments have limited therapeutic benefit due to issues such as low specificity, high pill loading, gastrointestinal side effects, calcium loading or significant toxicity concerns.

### **Team expansion and launch of commercial operations**

Shield's highly capable and deeply experienced management team was in place prior to the IPO and the approval of Feraccru. Since the IPO, to meet the demands of Feraccru's commercialisation and an opportunity-enhancing clinical development programme for Feraccru, the Company has grown significantly, increasing headcount from 14 employees at the time of the IPO to 45 currently. As part of this growth, the UK and Eire General Manager has recruited and trained a group of highly experienced hospital-focused Key Account Managers (KAMs) to form the UK commercial team and these KAMs are now active with customers in the field. The Medical team has expanded with the appointment of additional field-based Medical Science Liaisons based in the UK. Shield is also moving forward with the recruitment of a General Manager in Germany and has significantly enhanced its central infrastructure to facilitate the effective operations of the various in-country commercial teams and to support the regulatory commitments that come with the approval of a prescription pharmaceutical.

### **Operational advances since IPO**

Looking forward, the Company's attention is on making Shield Therapeutics a profitable and multi-product business. The core focus for the remainder of 2016 and into 2017 is the effective commercialisation of Feraccru across Europe by both Shield's own commercial team and with the use of licensing partners in non-core markets, with respect to which progress continues to be made. As such, the Company's Manufacturing and Supply Chain experts are working hard to ensure Feraccru is always readily available for doctors to prescribe and Shield's Commercial and Medical teams are ensuring Feraccru is effectively reimbursed and is included in local, national and pan-European treatment guidelines at the earliest opportunity.

Shield has made great strides since the IPO having (i) agreed an attractive reimbursement level for Feraccru of £47.60 per pack, equivalent to £1.70 per day, with the Department for Health in the UK and (ii) in Germany Shield has the agreement of the G-BA (*Gemeinsamer Bundesausschuss*) to set our own price for Feraccru. Through 2016, Feraccru will become commercially available in these critical markets as well as some other smaller European markets where the Company's commercial partners can also set a price point. Positive data from the ongoing AEGIS Head to Head study (AEGIS H2H) should further

facilitate reimbursement discussions and the effective launch of Feraccru in the additional large markets of Europe during 2017.

Shield's clinical development activities also continue to move forward. As well as advancing the development of a paediatric indication for Feraccru, as agreed with the European Medicines Agency as part of Feraccru's Marketing Authorisation, the Company has two Phase 3 clinical studies ongoing. These are designed to further increase the product's already highly significant commercial opportunity by achieving a broader label in Europe and giving access to the USA, the world's largest and most profitable pharmaceutical market:

- AEGIS-H2H is looking at the comparison of Feraccru versus Ferinject, the leading IV iron product, in 240 subjects with IDA associated with IBD over both a 12-week and 52-week treatment course. There are approximately 1 million IBD patients with treatment-requiring IDA in Europe and a successful study should better facilitate Feraccru's prescription in the 250,000 of these who are currently treated with IV iron therapies. It was initially envisaged that the study would recruit subjects across a total of approximately 40 expert gastro-intestinal centres in a handful of Western European countries. Approximately two-thirds of those centres are now in a position to recruit and this has taken a little longer than we hoped. Therefore we anticipate initial data will be available during the first half of 2017, slightly behind our previous timetable. However slower than planned start-up phase has created an opportunity for Shield, as following recent interactions with the FDA on an updated strategy for getting Feraccru approved in the USA, we are now considering the addition of a number of US-based centres.
- AEGIS-CKD is looking at Feraccru's potential to correct and maintain haemoglobin levels versus placebo in 170 patients with IDA associated with pre-dialysis chronic kidney disease over 16-week and 52-week time points. This study is Feraccru's first in this patient population and also the first study we have conducted for Feraccru in the USA. With Dr Geoff Block from Denver as the Principal Investigator, it is being conducted in approximately 40 expert nephrology centres. We anticipate that positive data from this study will facilitate a New Drug Application being made to the US FDA as well as a label expansion request in Europe, eventually enabling Feraccru's access to a pool of approximately 2.5 million pre-dialysis CKD patients with IDA in the US and Europe.

With respect to PT20, we have now manufactured the PT20 Drug Substance in preparation for development of a suitable formulation that we will use in the second and final pivotal study Shield is planning for PT20. In addition, the Company has commenced the search for co-development partners for PT20 as the preferred and de-risked way of funding this asset's advancement.

In respect of PT40, guidance has been received from the FDA indicating a clear route to regulatory approval.

Looking more broadly, with a focus on the key objectives of (i) the commercialisation of Feraccru in Europe and (ii) broadening the geographic and indication opportunities for Feraccru and (iii) the further development of PT20, the Company has set itself on a path of significant organic growth. Shield was created via acquisition of a valuable late-stage asset in Feraccru and the in-licensing of PT20 behaving therefore, from inception, as a specialty pharmaceutical company overwhelmingly focused on maximising commercialisation opportunities, rather than a classic biotech company focused on R&D. The Company is ambitious and recognises the potential benefits of portfolio and infrastructure expansion, thus when

appropriate Shield will likely consider additional opportunities that could add value by more rapidly building a presence and revenues in key geographies or providing a broader, de-risked product portfolio.

### **Summary and outlook**

In summary, over the past year, Shield has been transforming itself from a wholly development-focused and private company into a listed and increasingly commercially-focused, customer-facing organisation set up to sell its innovative and value-added specialty pharmaceuticals, such as Feraccru, that solve clear unmet medical needs. Shield is now well positioned to become a fast growing, independent, international specialty pharmaceutical company and, due to the strength of its products and team, and with great thanks to all of our supportive shareholders, I look forward to the future with great excitement.

### **Carl Sterritt, CEO**

### **Financial review**

The financial results for the Group to 31<sup>st</sup> December 2015 reflect a transitional stage of restructuring and development for Shield, which was completed with the IPO in February 2016. These results do not include the financial results for Phosphate Therapeutics Ltd, which was acquired by the Group at the time of the IPO itself, nor do they reflect the significant change to the capital structure that completed with the IPO including the £32.5m (gross) raised as part of the IPO onto the AIM market of the London Stock Exchange and the £3.6m raised via an institutional exercise of pre-existing options prior to IPO.

The 2015 (and 2014) results include a number of non-cash items charged to the P&L under IFRS reflecting a complex private debt and equity capital structure pre-IPO including P&L charges relating to changes in the fair value of embedded derivatives relating to investor options. Consequently, Proforma financial information for 2015 has been included to illustrate how the accounts may have been presented if the acquisition of Phosphate Therapeutics and the IPO were assumed to have occurred at the start of the year, which the Directors believe is more representative of the underlying operational financial results.

### **Financial performance**

During 2015 the Group continued to operate primarily as a development company with the focus of expenditure being R&D associated with the development and regulatory approval of Feraccru. However, 2015 also saw the commencement of commercial activity in preparation for the launch of Feraccru in 2016. These costs were funded out of shareholder investments raised privately and drawn down in various tranches within the Group during 2015 and in prior periods.

### **Other operating income**

Income in the year of £0.2m (2014: £0.2m) represents the recharge of management team costs to manage the strategic development of assets owned by Phosphate Therapeutics Ltd via an arms-length operating agreement. This agreement terminated in February 2016 at the time of the IPO.

### **Research and development costs**

Research and development expenditure of £5.3m (2014: £2.7m) include the following:

- **Commercial spend**

Total commercial spend in 2015 was £0.5m (2014: £nil) and related to the investment in the central

commercial and medical affairs teams and associated infrastructure in anticipation of the launch of Feraccru in 2016.

- **Development spend**

Total Development spend was £2.4m (2014: £1.7m) and included the balance of spend on Feraccru's phase 3 programme, initial costs relating to the Feraccru Phase 3b head to head study in the EU, costs associated with the regulatory filing for MAA approval and scale up of manufacturing activity.

- **Central costs**

Central costs were £2.4m (2014: £1.0m) and included £0.9m (2014:£0.2m) of non-cash share based charge in respect of historic options granted under a pre-existing EMI option scheme. All options were exercised and all then existing share option schemes closed prior to the IPO in February 2016. The balance of expenditure relate to non-R&D related personnel and associated support costs including expenses and bonus in respect of 2015.

### **Admin expenses**

Admin expenses were £1.4m (2014: £1.0m) and included establishment and legal and professional fees and one-off costs relating to the restructuring and IPO enabling work charged to P&L

### **Financial income**

Financial Income of £1.9m (2014: £0.2m) relates primarily to unrealised foreign exchange gains on the embedded derivative related to the pre-IPO capital structure. The underlying foreign exchange gain was £0.3m (2014: loss of £0.3m)

### **Financial expense**

Total net charge in 2015 was £20.0m (2014: £10.2m). This relates primarily to:

- (1) A non-cash IFRS P&L charge in respect of mark to market movements in the embedded derivative associated with the Group's private capital structure. All such charges ended at the time of the IPO
- (2) Interest charges in respect of preference shares, again in respect of the private company capital structure and, again, ending at IPO

### **Loss after tax**

Total net loss for 2015 was £24.5m (2014: £13.4m), equating to a loss per share of £0.57 (2014: £0.40). During the year, as part of the corporate re-organisation, a minority shareholding in a key subsidiary of the Group was eliminated. The actual allocation of losses to the minority was £0.9m (2014:0.5m) during the year.

Adjusting for the impact of IFRS charges in respect of the capital structure, underlying loss after tax attributable to the equity shareholders was £5.3 m (2014: £3.2m), equating to a loss per share of 13p (2014: 10p)

### **Statement of financial position**

At 31<sup>st</sup> December 2015, total Group net cash was £0.7m (2014 £0.5m). This excluded significant post balance sheet events including:

- Exercise of pre-existing institutional options pre-IPO to raise c. £3.6m

- Subscription and placing to raise £32.5m (gross), or £30.1m (net)

As at 31<sup>st</sup> May 2016, following the IPO transaction, total net cash was £28.8m including currencies translated into GBP equivalent.

Net liabilities at 31<sup>st</sup> December 2015 were £19.8m. This negative position was extinguished post year end due to the positive impact of the change to the capital structure combined with the IPO.

#### **Intangible assets**

At 31<sup>st</sup> December 2015 intangible assets were £0.5m (2014: £0.4m). The Group did not capitalise any R&D expenditure during the year in respect of the development of Feraccru as these costs were prior to the MAA approval. The balance represents the cost of acquiring, maintaining and expanding the patent portfolio for Feraccru net of amortisation during the year.

#### **Cashflow**

Net cash outflow from operating activities was £4.2m. This was funded by existing cash balances together with £4.6m raised through follow on financing from previously committed private venture capital and other funding into the Group during the year.

#### **Post year-end events**

##### **Acquisition of Phosphate Therapeutics Limited**

After the year end, effective on 26<sup>th</sup> February 2016, as part of the re-organisation of the Group, Shield acquired Phosphate Therapeutics Limited via the issue of 19,887,791 Shield shares representing £27m. This brought the assets PT20, PT30 and PT40 within the Group at IPO.

##### **IPO**

On 26<sup>th</sup> February 2016, Shield completed an IPO onto AIM raising £32.5m (gross) with the issuance of 21.67m shares at a price of £1.50.

The IPO also included the issuance of warrants to participants in the placing. These warrants are listed (under ticker STXW) and provide an opportunity for the Group to raise up to £17.5m by 30<sup>th</sup> June 2017 when the warrants expire. Warrants have a subscription price of £1.50 per share. Any additional funding generated from warrant exercise will be utilised to support further development of the Group's assets into the medium term.

##### **Proforma information**

In order to provide a better view of the underlying position of the Group, total losses for 2015 on a proforma underlying basis have been calculated using the following assumptions:

- PTL acquired on 1<sup>st</sup> January 2015
- Post IPO capital structure in place from 1<sup>st</sup> January 2015
- All IPO and restructuring related costs excluded as one-off items

On this basis, the total non-statutory proforma underlying loss after tax for the Group for 2015 would have been £7.8m (2014: £6.9m). On the same basis, basic loss per share would have been 6.9 pence per share (2014: 6.3p)

On an underlying non-statutory proforma combined basis, taking into account the assets of Phosphate Therapeutics Limited, the subscription and placing associated with the IPO and the changes to the capital structure, total net assets at 31<sup>st</sup> December 2015 would have been £32.1m

### **Summary and outlook**

The IPO in February was transformational for the Group which had previously relied on tranche funding from private financing rounds. The funds raised give Shield a robust balance sheet and the working capital required to build the commercial infrastructure to launch Feraccru across key markets in Europe and to continue a focused R&D programme in support of the expansion of Feraccru's market opportunity.

**Richard Jones, CFO**

**Consolidated Statement of Profit and loss and Other Comprehensive Income**  
**For the year ended 31 December**

	<i>Note</i>	2015 £000	2014 £000
Other operating income		221	244
Research and development expenditure		(5,284)	(2,668)
Administrative expenses		(1,371)	(967)
		<hr/>	<hr/>
<b>Operating loss</b>		(6,434)	(3,391)
Financial income		1,941	206
Net loss on financial instruments designated as fair value through profit or loss		(18,123)	(8,585)
Financial expense		(1,872)	(1,660)
		<hr/>	<hr/>
<b>Loss before tax</b>		(24,488)	(13,430)
Taxation	4	-	-
		<hr/>	<hr/>
<b>Loss for the period</b>		(24,488)	(13,430)
		<hr/>	<hr/>
<b>Attributable to:</b>			
Equity holders of the parent		(23,627)	(12,905)
Non-controlling interests		(861)	(525)
		<hr/>	<hr/>
<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		(257)	248
		<hr/>	<hr/>
<b>Total comprehensive income for the year</b>		(24,745)	(13,182)
		<hr/>	<hr/>
<b>Attributable to:</b>			
Equity holders of the parent		(23,884)	(12,657)
Non-controlling interests		(861)	(525)
		<hr/>	<hr/>
Total comprehensive income for the year		<u>(24,745)</u>	<u>(13,182)</u>
		<hr/>	<hr/>
Earnings per share			
Basic and diluted loss per share	3	£0.57	£0.40
		<hr/>	<hr/>
<b>Non-GAAP measure</b>			
Adjusted loss per share	3	£0.13	£0.10
		<hr/>	<hr/>

## Balance sheets

at 31 December 2015

	Note	Group 2015 £000	Group 2014 £000
<b>Non-current assets</b>			
Intangible assets		513	436
Property, plant and equipment		17	12
Investments		-	-
		<hr/>	<hr/>
		530	448
<b>Current assets</b>			
Other receivables		1,605	79
Cash and cash equivalents		725	477
		<hr/>	<hr/>
		2,330	556
		<hr/>	<hr/>
<b>Total assets</b>		<b>2,860</b>	<b>1,004</b>
		<hr/> <hr/>	<hr/> <hr/>
<b>Current liabilities</b>			
Trade and other payables		(3,502)	(694)
Interest bearing loans and borrowings	5	-	(8,258)
Other liabilities		(73)	(50)
		<hr/>	<hr/>
		(3,575)	(9,002)
		<hr/>	<hr/>
<b>Non-current liabilities</b>			
Interest bearing loans and borrowings	5	-	(197)
Other financial liabilities	6	(17,928)	(10,089)
		<hr/>	<hr/>
		(17,928)	(10,286)
		<hr/>	<hr/>
<b>Total liabilities</b>		<b>(21,503)</b>	<b>(19,288)</b>
		<hr/>	<hr/>
<b>Net liabilities</b>		<b>(18,643)</b>	<b>(18,284)</b>
		<hr/> <hr/>	<hr/> <hr/>
<b>Equity</b>			
Share capital		690	365
Share premium		-	2,393
Merger reserve		28,358	-
Currency translation reserve		(39)	218
Retained earnings		(47,652)	(23,006)
		<hr/>	<hr/>
<b>Equity attributable to owners of the parent</b>		<b>(18,643)</b>	<b>(20,030)</b>
Non-controlling interest		-	1,746
		<hr/>	<hr/>
<b>Total equity</b>		<b>(18,643)</b>	<b>(18,284)</b>
		<hr/> <hr/>	<hr/> <hr/>

These financial statements were approved by the board of directors on 13 June 2016 and were signed on its behalf by:

**R Jones**

Director

Company registered number: 1688482

## Consolidated statement of changes in equity

	Issued capital £000	Share premium £000	Merger reserve £000	Currency translation reserve £000	Retained earnings £000	Non- controlling interest £000	Total £000
<b>Balance at 1 January 2014</b>	365	2,393	-	(30)	(10,792)	747	(7,317)
Loss for the year	-	-	-	-	(12,905)	(525)	(13,430)
Other comprehensive income	-	-	-	248	-	-	248
Additional investment of non- controlling interest shareholder	-	-	-	-	-	1,968	1,968
Increase in non-controlling interest*	-	-	-	-	444	(444)	-
Equity-settled share based payment transactions	-	-	-	-	247	-	247
<b>Balance at 31 December 2014</b>	365	2,393	-	218	(23,006)	1,746	(18,284)
Balances at 1 January 2014	365	2,393	-	218	(23,006)	1,746	(18,284)
Loss for the period	-	-	-	-	(23,627)	(861)	(24,488)
Other comprehensive income	-	-	-	(257)	-	-	(257)
Group reorganisation**	325	(2,393)	28,358	-	(1,901)	(885)	23,504
Equity-settled share based payment transactions	-	-	-	-	882	-	882
<b>Balance at 31 December 2015</b>	690	-	28,358	(39)	(47,652)	-	(18,643)

\* Increase in non-controlling interest relates to the additional investment of £1,968,000 of non-controlling interest shareholder, resulting in the non-controlling interest ownership increasing from 8.60% to 16.47% in 2014.

\*\* Included in the reserves account in 2015 is a merger reserve balance amounting to £28.4 million arising from the group reorganisation activity. Please see note 9 for details.

**Consolidated statement of cash flows**  
**for the year ended 31 December**

	2015 £000	2014 £000
<b>Cash flows from operating activities</b>		
Loss for the period	(24,488)	(13,430)
<i>Adjustments for :</i>		
Depreciation and amortisation	50	36
Loss on derivative financial instruments	18,123	8,585
Equity-settled share based payment expenses	882	247
Financial expense	1,872	1,660
Unrealised foreign exchange (gains)/loss	(1,927)	(250)
	<hr/>	<hr/>
Decrease/(increase) in trade and other receivables	(5,488)	(3,152)
Increase/(decrease):		
Trade and other payables	2,808	(225)
Other liabilities	23	14
	<hr/>	<hr/>
<b>Net cash flow from operating activities</b>	<b>(4,183)</b>	<b>(3,341)</b>
	<hr/>	<hr/>
<b>Cash flows from investing activities</b>		
Acquisitions of intangible assets	(123)	(80)
Acquisition of property, plant and equipment	(9)	(12)
	<hr/>	<hr/>
<b>Net cash from investing activities</b>	<b>(132)</b>	<b>(92)</b>
	<hr/>	<hr/>
<b>Cash flows from financing activities</b>		
Investment of non-controlling interest shareholder	-	1,968
Issuance of convertible bonds	1,062	392
Issuance of preference shares	3,501	-
	<hr/>	<hr/>
<b>Net cash flow from financing activities</b>	<b>4,563</b>	<b>2,360</b>
	<hr/>	<hr/>
Net increase/(decrease) in cash	248	(1,073)
Cash and cash equivalents at 1 January	477	1,550
	<hr/>	<hr/>
<b>Cash and cash equivalents at period end</b>	<b>725</b>	<b>477</b>
	<hr/> <hr/>	<hr/> <hr/>

Shield Therapeutics plc was incorporated on 3 September 2015. The only cash transaction in the company during the period from 3 September 2015 to 31 December 2015 was the £2 investment in ordinary shares of Shield Holdings, AG.

## Notes

### *(forming part of the financial statements)*

#### 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 Group's statutory accounts for the years ended 31 December 2015. Statutory accounts for 2014 have been delivered to the Registrar of Companies, and those for 2015 will be delivered in due course. The auditor has reported on those accounts; their reports were (i) unqualified, (ii) did not include a reference to any matters to which the auditor drew attention by way of emphasis without qualifying their report (iii) did not contain a statement under s498 (2) or (3) of the Companies Act 2006.

These results were approved by the Board of Directors on 13 June 2016.

#### 2 Segmental reporting

The Board regularly reviews the Group's performance and balance sheet position for its operations and receives financial information for the group as a whole. As a consequence the Group has one reportable segment, which is Clinical Development. Segmental profit is measured at operating loss level, as shown on the face of the Income Statement. As there is only one reportable segment whose losses, expenses, assets, liabilities and cash flows are measured and reported on a basis consistent with the financial statements, no additional numerical disclosures are necessary.

#### 3 Loss per share

Basic EPS is calculated by dividing the profit 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 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.

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

	2015 £000	2014 £000
Loss for the period as used for calculated basic EPS	(23,627)	(12,905)
Interest on preference shares	1,761	1,654
FX movement of preference shares	(259)	(489)
Fair value remeasurement of preference share embedded derivative	15,610	8,585
Interest on convertible bonds	139	-
FX movement on convertible bonds	10	-
Fair value remeasurement of convertible bond embedded derivative	1,146	-
Fair value remeasurement of Troy options	(59)	-
	<hr/>	<hr/>
Loss attributable to ordinary equity holders of the parent adjusted for the effect of one off items as used for calculating Adjusted EPS.	(5,279)	(3,155)
	<hr/> <hr/>	<hr/> <hr/>
Weighted average number of ordinary shares for basic and Adjusted EPS	41,507	31,893
	<hr/> <hr/>	<hr/> <hr/>

## Notes (continued)

### 4 Taxation

#### Recognised in the income statement:

	2015 £000	2014 £000
<b>Current income tax:</b>		
Current income tax expense	-	-
Foreign income taxes	-	-
Tax expense/(credit) relating to prior year	-	-
<b>Deferred tax:</b>		
Relating to origination and reversal of temporary differences	-	-
Effect of changes in the tax rate	-	-
Total tax expense	-	-

#### Reconciliation of total tax expense:

	2015 £000	2014 £000
Loss excluding taxation	(24,488)	(13,430)
Standard rate of corporation tax in the UK	20.25%	21.5%
Tax using the UK corporation tax rate	(4,959)	(2,888)
Expenses not deductible for tax purposes	-	37
Effect of tax rates in foreign jurisdictions	3,153	1,856
Unrelieved tax losses	1,806	1,093
Utilised tax losses	-	(98)
Total tax expense	-	-

#### Factors affecting the future tax charge

Reductions in the UK corporation tax rate from 23% to 21% (effective from 1 April 2014) and 20% (effective from 1 April 2015) were substantively enacted on 2 July 2013. Further reductions to 19% (effective from 1 April 2017) and to 18% (effective 1 April 2020) were substantively enacted on 26 October 2015. This will reduce the Company's future current tax charge accordingly. The deferred tax assets and liabilities at 31 December 2015 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.

	2015 £000	2014 £000
Unutilised Swiss tax losses to carry forward	13,610	11,628
Potential deferred tax asset thereon	1,100	957
Unutilised UK tax losses to carry forward	15,440	3,254
Potential deferred tax asset thereon	2,780	651

## Notes (continued)

### 5 Interest bearing loans and borrowings

	2015 £000	2014 £000
<b>Non current liabilities</b>		
Convertible bonds	-	197
<b>Current liabilities</b>		
Shares classified as debt	-	8,258

#### Terms and debt repayment schedule

	Currency	Face value 2015 £000	Carrying Amount 2015 £000	Face value 2014 £000	Carrying amount 2014 £000
Convertible bonds	Euro	-	-	500	197
Shares classified as debt	Euro	-	-	9,300	8,258

#### Preference shares

At 31 December 2014, there were 22,703,716 preference shares in issue. Each share was convertible at the option of the preference shareholder into one ordinary share of the Company at either a qualified IPO event or merger or on the request of the preference shareholder. The preference shares could be redeemed for cash for the Preferred Amount on either a Deemed Liquidity Event or by the 31st December 2016 if a Deemed Liquidity Event had not occurred by that date.

The Preferred Amount was made up of the Liquidation Preference Amount (which was 1.5 times the amount of funding raised) plus the dividend amount. The preference shares carried a dividend of 10% per annum, compounded annually. The preference shares ranked ahead of the ordinary shares in the event of liquidation.

The preference share financial liability was extinguished as part of the reorganisation transaction on 1 October 2015. See note 9.

#### Convertible Loan

The Group issued a convertible loan for the face value of EUR 2,000,000 in 4 equal tranches on:

- 24 December 2014
- 16 February 2015
- 13 March 2015
- 15 April 2015

The Convertible Loan accrued interest at a rate of 10% per annum and was not compounding.

The outstanding loan amount plus accrued interest was payable on either a Deemed Liquidity Event or at Maturity Date (24 December 2019). In addition, the Group had the ability to repay the Convertible Loan at any time.

The Convertible Loan could be converted into newly issued A Shares at either a Deemed Liquidity Event or on maturity, at the request of the Convertible Loan note holder.

All €2 million convertible bonds were converted by the bond holder on 16 September 2015 for 1.4 million shares of ITH.

## Notes (continued)

### 6 Other financial liabilities

	31 December 2015 £000	31 December 2014 £000
Troy Option Instrument	(17,928)	-
Preference Share Derivatives	-	(9,895)
Convertible Loan Conversion Option	-	(194)

The Troy Option Instrument is a derivative. As part of the Group re-organisation, on 1 October 2015 Shield Therapeutics plc issued this new option instrument to a shareholder in exchange for the cancellation of all the options held by that shareholder and the subscription rights attached to the preference shares held. The instrument has been treated as an embedded derivative and is carried at fair value through profit and loss. The fair value of the option instrument to subscribe for additional ordinary shares of Shield Therapeutics plc has been calculated using a Black-Scholes-Merton model for a European option.

The Preference Share Derivatives were classified as embedded derivatives. They were separated from the host Preference Share financial instrument. The fair value of the conversion option of the outstanding Preference Shares and the option to subscribe for additional Preference Shares was calculated using a Black-Scholes-Merton model for a European option. This embedded derivative was extinguished as part of the group reorganisation transaction (see note 9).

The Convertible Loan Conversion Option was classified as an embedded derivative. It was separated from the host Convertible Loan financial instrument. The fair value of the conversion option on the outstanding convertible notes was calculated using Black-Scholes-Merton model for an American option. This embedded derivative was exercised in the year.

The valuation requires management to make certain assumptions about the model inputs, including forecasted cash flows and volatility. In particular, based on the company valuation, strikes have been determined and observable inputs like market interest rates and volatility index for similar listed companies has been used. The ranges of estimates within the calculation can be reasonably assessed and are used in the management's estimate of fair value.

### 7 Group structure and acquisition details

The Group's equity interest was as follows:

During the year ended 31 December 2015:

<i>Group company</i>	<i>Ownership</i>	<i>Country of incorporation</i>
Shield Holdings, AG	100%	Switzerland
Iron Therapeutics Holdings AG	100%	Switzerland
Iron Therapeutics (Switzerland) AG*	100%	Switzerland
Shield TX (UK) Ltd. *, **	100%	United Kingdom
Iron Therapeutics (US) Corp.*	100%	United States of America

\* Shield Therapeutics plc holds an indirect ownership through Iron Therapeutics Holdings, AG.

\*\*Iron Therapeutics (UK) Limited company name was changed to Shield TX (UK) Limited on 17 March 2016.

## Notes (continued)

### 7 Group structure and acquisition details (continued)

During the year ended 31 December 2014:

<i>Group company</i>	<i>Ownership</i>	<i>Country of incorporation</i>
Iron Therapeutics Holdings AG	83.53%	Switzerland
Iron Therapeutics (Switzerland) AG*	83.53%	Switzerland
Shield TX (UK) Ltd. *, **	83.53%	United Kingdom
Iron Therapeutics (US) Corp.*	83.53%	United States of America

\* Shield Therapeutics plc holds an indirect ownership through Iron Therapeutics Holdings, AG.

\*\* Iron Therapeutics (UK) Limited company name was changed to Shield TX (UK) Limited on 17 March 2016.

At 31 December 2014 Shield Therapeutics plc held investments in four entities which were classified as subsidiaries. Iron Therapeutics Holdings AG had a minority shareholder who owned less than 20% of the group. The other subsidiary entities were then held 100% by ITH. Therefore Shield Therapeutics plc had control over ITH and the rest of the entities in the group. At 31 December Shield Therapeutics plc owned 100% of all entities in the group.

#### *Non-Controlling Interests*

The following table summarises the information relating to Iron Therapeutics Holdings AG which was a subsidiary of the Group with a material Non-Controlling Interest, before intra-group eliminations.

<b>£000</b>	31 December 2015	31 December 2014
<b>NCI percentage</b>	-	16.47%
Non-current assets	-	501
Current assets	-	1,585
Non-current liabilities	-	(7,514)
Current liabilities	-	(137)
<b>Net assets (100%)</b>	-	(5,565)
<i>Carrying amount of NCI</i>	-	1,746
Revenue	-	-
Loss	(6,670)	(3,393)
OCI	-	256
<b>Total comprehensive income</b>	(1,411)	(3,137)
Cash flows from operating activities	(2,563)	(1,818)
Cash flows from investing activities	(123)	(87)
Cash flows from financing activities	2,288	2,165
<b>Net increase in cash and cash equivalents</b>	(398)	260

## **Notes** *(continued)*

### **8 Subsequent events**

Shield Therapeutics plc applied for admission to AIM on 26 February 2016 with a placing price of £1.50 per share for the additional 21.7 million new shares to be issued pursuant to the Placing.

Immediately succeeding the listing, Shield Therapeutics plc acquired intellectual property assets from the shareholders of Phosphate Therapeutics Limited for a consideration of 19,887,791 shares with a value of £27,047,396.

### **9 Group reorganisation**

Shield Therapeutics plc was incorporated on 3 September 2015 as part of the group reorganisation activities. Following the group reorganisation activities, Shield Holdings AG acquired the remaining non-controlling interests held by minority shareholders in Iron Therapeutics Holdings, AG through the issuance of its own share capital. Subsequent to the acquisition of the non-controlling interest, Shield Therapeutics plc acquired whole ownership interest in Shield Holdings, AG in consideration of Shield Therapeutics plc's ordinary shares. Following these reorganisation activities, the shareholders of Shield Holdings, AG, holds direct ownership in Shield Therapeutics plc.

Shares of Shield Therapeutics plc issued in relation to this group re-organisation activities amounted to 69.0 million shares with a par value of £0.01 per share. The fair value of Shield Holdings, AG on the date of acquisition amounted to £136.0 million. The total merger reserve recognised in the parent company financial statements amounted to £117.3 million. The merger reserve recognised in the consolidated financial statements amounted to £28.4 million after consolidation adjustments.