Shield Therapeutics plc

Interim report 2016

Improving lives together

As a unified team we are constantly driven by and committed to our goals, seeking to deliver them with transparency and respect. Being consistent to this vision, while enjoying the journey, has brought us to where we are today and underpins our unwavering confidence in our ability to create a truly outstanding organisation that we are all proud to be part of and that will deliver value to all of our key stakeholders.

Carl Sterritt
Chief Executive Officer and co-founder

Read more in the Chief Executive Officer's statement from page 4

Providing solutions to unmet medical needs. **Delivering more value** to our shareholders. Offering our employees **opportunity, ambition and development.**

Shield Therapeutics is a specialty pharmaceutical company focused on the development and commercialisation of late-stage, hospital-focused pharmaceuticals which address areas of unmet medical need.

Stay up to date at our investor relations website:

www.shieldtherapeutics.com

Highlights

Shield Therapeutics is a well-funded, high potential, commercial stage specialty-pharma company.

Our lead product, Feraccru®, a novel oral treatment for iron deficiency anaemia in patients for whom intravenous iron or blood transfusions have been the only option to date, is now commercially available following receipt of marketing authorisation in early 2016. Our second asset, PT20, is a treatment for hyperphosphatemia that has successfully completed a first pivotal trial. In addition, the Group has earlier stage assets that it intends to develop or out-license over time.

Pipeline

Shield has a rare opportunity to build an integrated, highly profitable specialty pharma business, with an additional pipeline of three prescription pharmaceutical assets (PT20, PT30, PT40) with commercial synergies. Our most advanced pipeline asset, PT20, has completed its first pivotal study with one further pivotal Phase 3 study planned in order to seek regulatory approval in major markets.

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The period covering the first half of 2016 and particularly since the Company's IPO in February has been one of foundation building, implementation of the first stages of Feraccru®'s commercial launch and resource growth for Shield Therapeutics; as well as receipt of our first commercial revenues. During this time the Company has successfully achieved attractive pricing agreements in the UK and Germany, and has been accelerating our commercial activities for Feraccru® in the UK, whilst laying the foundations for launch in Germany in October 2016.

Operational and commercial

- Achievement of first revenues of £240k from sales of Feraccru, Shield Therapeutics' first prescription medicine which was approved in February 2016
- Initial stages of Feraccru's European commercial launch progressing in line with expectations:
  - UK commercial activities accelerating, post-June 2016 launch, as per plan
  - >10 members of Shield Therapeutics' team interacting with UK customers on a daily basis
  - Access to formularies and approvals by clinical commissioning groups in the UK being achieved to cover an increasing number of prescribers
  - Feraccru pricing of £47.60 per 28-day treatment pack agreed with the UK NHS
  - Higher pricing of €64.00 per 28-day treatment pack agreed and published in Germany, with sales operations to commence in October 2016
- Key composition of matter patent granted, significantly increasing the level and duration of exclusive intellectual property protection afforded to Feraccru from 2023 to at least 2034
- AEGIS-H2H and AEGIS-CKD Phase 3 studies of Feraccru progressing on track
- Discussions progressing well with potential licensing partners in a selection of non-core markets
- PT20 and PT40 activities continue in-line with plan

Financial[1]

- Successful completion of an Initial Public Offering (IPO) on AIM raising £32.5 million (gross) and further potential gross proceeds of £17.5 million, subject to the full exercise of Warrants
- First reported UK revenues of £240k
- Net loss for period of £8.9 million on an IFRS basis. Adjusted net loss for period of £5.1 million[1]
- Period end cash balance of £28.4 million

1. Adjusted net loss excludes IFRS financing costs in respect of pre-IPO structure, one-off costs and share based payments

What sets us apart

Near term revenue potential

The Group received MA approval in Europe for Feraccru® in February 2016 and undertook our first commercial launch of Feraccru® in the UK with our own commercial team in May 2016. Roll-out across Europe directly or via commercial partners will continue through 2016 and 2017.

Late-stage assets that have either been approved or have delivered proof of concept

In addition to Feraccru®'s MA approval, the Phase 2b pivotal study with respect to PT20 has been successfully completed. In addition, further Phase 3 trials have commenced with Feraccru® in a second indication, CKD. Consequently, the Group has multiple complimentary late-stage assets.

Large market opportunities with unmet needs

Feraccru® addresses a large and structurally growing market with significant potential in the near term. GfK estimates there are approximately 1.4 to 1.5 million patients in Europe and the US with IBD who have the potential to be treated for IDA of which a significant proportion are currently ineffectively treated. GfK also estimates that there are over 3.4 million patients in the EU and US with IDA and CKD.

Experienced management team with extensive expertise

The Company has an experienced Board with extensive expertise in the pharmaceutical and biotechnology industry. Two of the Directors are members of the executive management team and have been heavily involved in the development of the Group and key to driving its success to date. Carl Sterritt has been CEO since he co-founded the Group in 2008 and Richard CM Jones has been CFO since 2011.

The Board is supported by an experienced, skilled management team which provides a strong platform for future growth and gives strategic direction to the development and commercialisation of the Group's products. The team grew significantly during 2015 in preparation for commercial launch of Feraccru®.

Opportunity to create operational leverage across the product portfolio

Initially Feraccru® and subsequently PT20 will be commercialised using a mix of our own commercial operations in major markets and best in class local commercial partners in other non-core markets. Our assets are naturally targeted to specialist prescribers based in hospitals and private clinics, providing the potential for significant operational leverage, which could be further enhanced with selective small scale bolt-on acquisitions or in-licensing of allied products.

Strong intellectual property protection

The Group's assets are supported by a suite of strong intellectual property rights including key patents in major markets and with MA approval. Feraccru® benefits from data and marketing exclusivity in the EU for up to 10 years. The Group routinely pursues new patent applications. Filing five new patent applications for Feraccru® since its acquisition in 2010. The new patents, as granted, will provide significant additional patent protection up to 2035 in relation to Feraccru®.

Attractive financial profile

The proceeds of the recent IPO in February 2016, together with the future opportunity of receiving further funds as a result of the exercise of the Warrants (see page 12) provides a strong financial platform for the growth of the Group. The Directors expect the Company to generate near term revenues with inherently high gross margins following the recent launch of Feraccru®. Whilst development activity will continue for the foreseeable future, the Directors believe that the level of R&D spend should be relatively modest bearing in mind the potential revenues from Feraccru® and PT20.

Our values:

- **Patient centric:** The patients our therapies treat are at the heart of why we do it
- **Ethical:** Always professional with the highest of standards
- **Product focused:** We have a great track record of identifying value and are always looking for more
- **Freedom to operate:** It is "our" Company and we avoid hierarchy, we challenge to succeed
- **Relationships:** Strong and human... everyone is valuable
- **Continuously develop:** We only want people who are committed, effective and determined to succeed

Chief Executive Officer's statement

Carl Sterritt
Chief Executive Officer
and co-founder

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The period under review has been a transformational time for Shield Therapeutics.

Following the significant achievement of our successful IPO onto the AIM market of the London Stock Exchange in February 2016 to raise £32.5 million of growth capital and receiving the pan-European Marketing Authorisation Approval of our first product, Feraccru®, the period has since been characterised by the growth of Shield Therapeutics and operational implementation of our commercial plans, focused on the launch of Feraccru® in the key first two markets of the UK and Germany. The immediate impact of this has been to deliver our first product-related revenues and by the end of 2016 approximately 60% of the IDA in IBD EU-5 commercial opportunity for Feraccru® should be available to us.

Feraccru®

Feraccru® launch

Tellingly, without requiring Health Technology Assessments, Feraccru® has achieved attractive price points in both the UK and Germany, with a published price of £47.60 and €64.00 per 28-day treatment pack, respectively. Such achievements in two strategically important – and often referenced – markets give a clear indication of the value that Feraccru® can deliver to integrated healthcare systems and we expect they will support our pricing and reimbursement activities across a broader basket of countries throughout the pan-European launch of Feraccru®.

Feraccru® is estimated to have an achievable peak annual sales opportunity in excess of £500 million in more than 4 million patients in Europe and the USA that make up its two core markets of IDA in IBD and IDA in chronic kidney disease ("CKD")[2]. The Company believes the overall market has more than 33 million patients suffering with IDA who could be effectively treated with Feraccru®[3].

Following the pricing agreement with the NHS and Department of Health in the UK, our field-based team of Key Account Managers and Medical Science Liaisons has been focused on three core activities: (i) introducing commercially available Feraccru® to the initial target prescriber base of UK gastroenterologists; (ii) educating Clinical Commissioning Groups (CCGs) on the health economic benefits of Feraccru®; and (iii) critically, with the agreement and support of prescribers, submitting applications to and achieving access for Feraccru® from hospital formularies. Steady progress is being made across this triumvirate of key stakeholders in an IDA patient's journey in the UK, as with their support and approvals we will deliver commercial success for Feraccru®. Widening the audience of potential patients and prescribers as quickly as possible is an important target and this has been aided by the fact that, at the time of Feraccru®'s UK launch, the British Society of Gastroenterology ("BSG") was holding its main annual scientific and commercial meeting. We ensured maximum coverage at this key event for the UK's leading gastroenterologists.

2. GfK report from 2015 as included in IPO Admission Document

3. IPO Admission Document

We are pleased to report our first commercial revenues from Feraccru® in this interim results statement. These first revenues represent stock sold to our two UK wholesalers in preparation for the commencement of commercial prescribing of Feraccru® as our in-house team of Key Account Managers and Medical Science Liaisons commenced work. We look forward to updating the market on Feraccru®'s in-market demand in early 2017.

Whilst we have employed our own sales team of Key Account Managers in the UK we have chosen to utilise a slightly different field-based model via a Contract Commercial Organisation in Germany to minimise time to commercial launch. As such, in Germany, we are employing our own central team of commercial and medical professionals, and have initially contracted the resources of the highly regarded inVentiv Health to provide our field-based team of eight Key Account Managers initially and a National Sales Manager. This has significantly streamlined the otherwise complicated logistics of identifying and recruiting our own field-based sales team in this, our first overseas market, whilst giving us the ability to have a lower risk "try before we buy" period with each Key Account Manager. Product training is scheduled for early October, after which the team will be out in the market actively implementing our commercial strategy in Germany.

As with the UK launch, we have an early, pan-German opportunity to raise awareness of Feraccru® at Deutsche Gesellschaft für Gastroenterologie, Verdauungs und Stoffwechselkrankheiten ("DGVS"), the annual scientific congress of the German gastroenterology society, which is taking place just as Feraccru® becomes commercially available in Germany. The commercial launch and prescriber/payor approval process in Germany is more streamlined than in the UK and we also have the advantage of starting our commercial operations with a broader prescriber experience of Feraccru® due to the clinical trials we have run and are running in multiple key institutions in Germany. As a result of this existing experience with Feraccru®, it is hoped that these key institutions will transition into important commercial customers.

Over the period, we have also made significant progress in refining our launch strategies in the other member countries of the EU-5. In France, we have taken the commercial decision to include data from the AEGIS H2H clinical study in our Pricing and Reimbursement submission, as specialist research conducted post Feraccru®'s marketing authorisation approval has provided a strong signal that this will facilitate optimum pricing in this market. This has become even more relevant following the recently announced news on Shield receiving the composition of matter patent grant for Feraccru® that will see protection extended through at least 2034, versus the previously estimated 2023 before approval-related term extensions. Similar specialist research is ongoing in Spain and Italy and is currently expected to result in the same decisions on the timing of Pricing and Reimbursement submissions.

Feraccru® Intellectual Property Rights

2016 has seen very significant intellectual property progress on a number of fronts that protect, facilitate and enhance Feraccru®'s exclusive commercial opportunity. In particular, since Admission:

i. The European approval of Feraccru® has provided the product with 10 years of data and marketing exclusivity in the countries covered by the approval, giving protection to February 2026.

ii. The approval in Europe has also allowed Shield to apply for a supplementary protection certificate to be applied to one of the core patents protecting Feraccru®. We have requested that this be issued against the core manufacturing patent that protects Feraccru® and, upon issuance, this will extend that patent out to August 2028 in a number of core markets.

iii. In addition to this increased coverage, our patent protecting Feraccru®'s use in achlorhydric patients was granted in the USA in February, having already been granted in other major territories. This patent covers an important feature of Feraccru®'s mode of action by demonstrating a unique ability as an oral iron to remain in solution and be available for absorption, even if a patient's gastrointestinal pH has been artificially increased. In many patients with diseases concomitant to their IDA, the use of pH raising pharmacotherapies like the proton pump inhibitors omeprazole or lansoprazole is very common and in such patients ferrous-based oral iron therapies simply precipitate out of solution and are unabsorbable. In such patients, prior to the availability of Feraccru®, parenteral iron therapy was the only realistic option.

iv. However, the most significant progress we have made with Feraccru®'s IPR is the granting of UK Patent GB2531742, entitled 'Polymorphs of Ferric Maltol', a composition of matter patent that significantly expands Feraccru®'s intellectual property portfolio by protecting the active substance of Feraccru® through to at least 2034, as announced on 7 September 2016. We are delighted that such a highly regarded body as the UKIPO has granted Shield a composition of matter patent to the active substance in Feraccru® and in doing so has significantly added to the breadth of the IP for Feraccru® as well as providing a lengthy extension to that protection. Allowance at the UKIPO is an indicator of the protection that we are anticipating in other territories when the national phase is entered in April 2017. We will now seek protection across a broad range of geographies and such composition of matter protection should enable Shield to prevent third parties from manufacturing or selling the product for any use until at least 2034.

Chief Executive Officer's statement continued

> The period covering the first half of 2016 and particularly since the Company's IPO in February has been one of foundation building, implementation of the first stages of Feraccru®'s commercial launch and resource growth for Shield Therapeutics; as well as receipt of our first commercial revenues.

Feraccru® continued

Feraccru® clinical development progress

Shield's two ongoing Phase 3 clinical trials are moving forward as planned, with AEGIS H2H recruiting in Europe and preparing to commence recruitment in the USA – an important expansion as positive data from this study will now allow an earlier filing of the NDA for Feraccru® with the US FDA. Meanwhile AEGIS CKD set-up is approaching finalisation and we remain expectant of first patients being enrolled during Q4-16. Together with existing data on Feraccru®, these studies are designed to further increase the product's commercial opportunity by achieving a broader label in Europe and giving access to the USA.

Other products in development

PT20

As previously advised, an end of Phase 2 meeting with the FDA is due to take place in Q4-16. The outcome of such a meeting is expected to allow us to finalise what additional clinical and non-clinical work is required for us to be able to submit an NDA. Our search for a commercial/co-development partner for PT20 has begun with meaningful discussions with potential development partners not expected to occur until after the FDA meeting. Work on the development of a suitable formulation of the drug product for use in a second pivotal study is also ongoing.

PT40

Following receipt of guidance from FDA on how to most efficiently develop PT40 through to submitting the supplemental New Drug Application (sNDA) that would be required, activities have commenced to identify both a suitable scale-up contract manufacturer and commercial partners who would license this technology from Shield.

Financial review

We are delighted to report our first Group revenues of £240k for the period, which relate entirely to sales of Feraccru® into the UK distribution channel. Operating loss for the period was £5.6 million after R&D costs of £0.8 million, which excludes £0.9 million of R&D that was capitalised following a review of our R&D capitalisation policy in respect of Feraccru® post-marketing approval.

Our accounts for the period were again impacted by various IFRS adjustments in respect of our pre-IPO corporate structure. Phosphate Therapeutics Ltd ("PTL") has been consolidated into the results from the IPO. Reported net loss was £8.9 million. On an adjusted basis net loss, after taking account of these non-cash IFRS adjustments, one-off costs of £170k and non-cash share based payments of £143k was £5.1 million and adjusted loss per share was £0.05 per share.

Net cash at the period end was £28.4 million after taking account of the non-cash IFRS adjustments, the positive impact of the net IPO funds raised and funds raised immediately prior to the IPO from pre-existing share options. Net assets of £54.3 million include the £27 million acquisition of PTL capitalised under intangible assets.

Referendum vote to leave the EU

Shield does not anticipate any direct regulatory or commercial impact from Brexit and there has been no immediate impact on the Company's operations following the UK's referendum vote to leave the European Union. Considering foreign exchange rates, in the short term we are both naturally hedged to Euro costs due to investments made into the Company prior to the IPO and have had no significant expenditure in the USA in the period. Going forward, we actively update our currency plans and keep a conservative outlook on FX movements and, in addition, where appropriate, we maintain healthy cash reserves to protect the Company against large fluctuations in individual currencies.

Corporate development and licensing

Since Feraccru®'s European approval we have had an encouraging level of inbound interest from potential partners in a wide range of non-core territories. We remain confident in our ability to convert this interest into licensing agreements in the near term and thereby expand the commercial opportunity for Feraccru®. Thinking more strategically, to supplement the organic growth that Feraccru®'s commercialisation will finance, we are actively considering a narrow selection of both portfolio and infrastructure enhancing opportunities in the specialty pharmaceuticals arena, as we recognise that such expansion has the potential to accelerate our growth and diversify our opportunities.

Summary and outlook

Shield has now transformed itself from wholly development-focused into a commercially-focused and customer-facing organisation that is selling its innovative and value-added lead product, whilst continuing its development to enable the commercial opportunity to be maximised throughout the lengthy period of intellectual property protection that is available to and has recently been extended for Feraccru®.

Looking forward we are excited that, over the course of the next few months, increasing numbers of patients will have the chance to benefit from Feraccru therapy, as it is launched in Germany and commercial progress continues to be made in the UK. With detailed out-licensing discussions ongoing in a number of non-core territories, we look forward to being in a position to report positive news in this regard in the near term. Finally, we also look forward to agreeing development plans for PT20 with FDA and then identifying suitable co-development and licensing partners for this attractive product, so it can be moved into the final stage of development prior to MAA and NDA filings.

Carl Sterritt
Chief Executive Officer

Consolidated statement of profit and loss and other comprehensive income

for the six months ended 30 June 2016

	Note	**Six months ended 30 June 2016 (unaudited) £000**	Six months ended 30 June 2015 (unaudited) £000	Year ended 31 December 2015 (audited) £000
Revenue		**240**	–	–
Cost of sales		**(54)**	–	–
Gross profit		**186**	–	–
Operating costs (selling, marketing, general and administrative expenses)		**(5,004)**	(574)	(1,371)
Other operating income		**40**	120	221
Operating loss before research and development expenditure		**(4,778)**	(454)	(1,150)
Research and development expenditure	9	**(787)**	(1,215)	(5,284)
Operating loss		**(5,565)**	(1,669)	(6,434)
Financial income		**27**	–	–
Net foreign exchange gains		**151**	1,890	1,941
Foreign exchange losses on financial instruments	2	**(1,059)**	–	–
Net loss on financial instruments designated as fair value through profit or loss	2	**(2,398)**	(28,949)	(18,123)
Financial expense		**(7)**	(1,299)	(1,872)
Loss before tax		**(8,851)**	(30,027)	(24,488)
Taxation		**–**	–	–
Loss for the period		**(8,851)**	(30,027)	(24,488)
Attributable to:				
Equity holders of the parent		**(8,851)**	(29,611)	(23,627)
Non-controlling interests		**–**	(416)	(861)
Other comprehensive income				
Items that are or may be reclassified subsequently to profit or loss:				
Foreign currency translation differences – foreign operations		**(30)**	(295)	(257)
Total comprehensive income for the period		**(8,881)**	(30,322)	(24,745)
Attributable to:				
Equity holders of the parent		**(8,881)**	(29,906)	(23,884)
Non-controlling interests		**–**	(416)	(861)
Earnings per share				
Basic and diluted loss per share	8	**£(0.09)**	£(0.93)	£(0.57)
Non-GAAP measure				
Adjusted loss per share	8	**£(0.05)**	£(0.03)	£(0.13)

Consolidated balance sheet

at 30 June 2016

	Note	30 June 2016 (unaudited) £000	30 June 2015 (unaudited) £000	31 December 2015 (audited) £000
Non-current assets				
Intangible assets	9	**27,527**	494	513
Property, plant and equipment	10	**23**	20	17
		27,550	514	530
Current assets				
Inventories		**246**	–	–
Trade and other receivables		**1,182**	140	1,605
Cash and cash equivalents	2	**28,455**	3,663	725
		29,883	3,803	2,330
Total assets		**57,433**	4,317	2,860
Current liabilities				
Trade and other payables		**(2,978)**	(1,023)	(3,502)
Interest bearing loans and borrowings	2	**–**	(12,107)	–
Other liabilities		**(181)**	(41)	(73)
		(3,159)	(13,171)	(3,575)
Non-current liabilities				
Interest bearing loans and borrowings	2	**–**	(891)	–
Other financial liabilities	2	**–**	(38,728)	(17,928)
		–	(39,619)	(17,928)
Total liabilities		**(3,159)**	(52,790)	(21,503)
Net assets/(liabilities)		**54,274**	(48,473)	(18,643)
Equity				
Share capital	12	**1,622**	365	690
Share premium		**77,963**	2,393	–
Warrants reserve		**2,760**	–	–
Merger reserve		**28,358**	–	28,358
Currency translation reserve		**(69)**	(77)	(39)
Retained earnings		**(56,360)**	(52,484)	(47,652)
Equity attributable to owners of the parent		**54,274**	(49,803)	(18,643)
Non-controlling interest		**–**	1,330	–
Total equity		**54,274**	(48,473)	(18,643)

Consolidated statement of changes in equity

for the six months ended 30 June 2016

	Issued capital £000	Share premium £000	Warrants reserve £000	Merger reserve £000	Currency translation reserve £000	Retained earnings £000	Non-controlling interest £000	Total £000
Balance at 1 January 2015	365	2,393	–	–	218	(23,006)	1,746	(18,284)
Loss for the period	–	–	–	–	–	(23,627)	(861)	(24,488)
Other comprehensive income	–	–	–	–	(257)	–	–	(257)
Total comprehensive income for the period	–	–	–	–	(257)	(23,627)	(861)	(24,745)
Group reorganisation	325	(2,393)	–	28,358	–	(1,901)	(885)	23,504
Equity-settled share based payment transactions	–	–	–	–	–	882	–	882
Balance at 31 December 2015	690	–	–	28,358	(39)	(47,652)	–	(18,643)
Loss for the period	–	–	–	–	–	(8,851)	–	(8,851)
Other comprehensive income	–	–	–	–	(30)	–	–	(30)
Total comprehensive income for the period	–	–	–	–	(30)	(8,851)	–	(8,881)
Share issue – IPO	325	26,487	2,760	–	–	–	–	29,572
Share options exercised	309	25,011	–	–	–	–	–	25,320
Phosphate Therapeutics Ltd acquisition	298	26,465	–	–	–	–	–	26,763
Equity-settled share based payment transactions	–	–	–	–	–	143	–	143
Balance at 30 June 2016	**1,622**	**77,963**	**2,760**	**28,358**	**(69)**	**(56,360)**	**–**	**54,274**

Consolidated statement of cash flows

for the six months ended 30 June 2016

	Six months ended 30 June 2016 (unaudited) £000	Six months ended 30 June 2015 (unaudited) £000	Year ended 31 December 2015 (audited) £000
Cash flows from operating activities			
Loss for the period	**(8,851)**	(30,027)	(24,488)
Adjustments for:			
Depreciation and amortisation	**1,372**	27	50
Loss on derivative financial instruments	**2,398**	28,949	18,123
Equity-settled share based payment expenses	**143**	133	882
Financial (income)/expense	**(155)**	1,299	1,872
Unrealised foreign exchange losses/(gains)	**1,105**	(1,923)	(1,927)
	(3,988)	(1,542)	(5,488)
(Increase)/decrease in inventories	**(246)**	–	–
Decrease/(increase) in trade and other receivables	**427**	(61)	(1,526)
(Decrease)/increase:			
Trade and other payables	**(988)**	329	2,808
Other liabilities	**108**	(9)	23
Net cash flow from operating activities	**(4,687)**	(1,283)	(4,183)
Cash flows from investing activities			
Acquisitions of intangible assets	**(378)**	(84)	(123)
Capitalised development expenditure	**(879)**	–	–
Acquisition of property, plant and equipment	**(10)**	(10)	(9)
Cash acquired with Phosphate Therapeutics Ltd	**177**	–	–
Net cash flow from investing activities	**(1,090)**	(94)	(132)
Cash flows from financing activities			
Proceeds of IPO (Note 2)	**32,500**	–	–
IPO costs (Note 2)	**(2,427)**	–	–
Other costs	**(501)**	–	–
Share options exercised (Note 3)	**3,935**	–	–
Issuance of convertible bonds	**–**	1,062	1,062
Issuance of preference shares	**–**	3,501	3,501
Net cash flow from financing activities	**33,507**	4,563	4,563
Net increase in cash	**27,730**	3,186	248
Cash and cash equivalents at 1 January	**725**	477	477
Cash and cash equivalents at period end	**28,455**	3,663	725

Notes

for the six months ended 30 June 2016

1. General information

Shield Therapeutics plc (the "Company") was incorporated in England and Wales as a public limited company on 3 September 2015. The Company was admitted to the London Stock Exchange's AIM market on 26 February 2016. The Company's Ordinary Shares and Warrants commenced trading on 26 February 2016.

The Company is domiciled in England and the registered office of the Company is at Northern Design Centre, Baltic Business Quarter, Gateshead Quays NE8 3DF.

This interim report, which is not audited, has been prepared in accordance with the measurement and recognition criteria of EU Adopted International Financial Reporting Standards. It does not include all the information required for full annual financial statements and should be read in conjunction with the financial statements of the Company and its subsidiaries (the "Group") as at and for the year ended 31 December 2015. This financial information does not constitute statutory financial statements as defined in Section 435 of the Companies Act 2006. It does not comply with IAS 34 Interim financial reporting, as is permissible under the rules of AIM.

The interim report was approved by the board of directors on 19 September 2016.

2. AIM listing

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

As part of the listing process Warrants with a subscription price of £1.50 were issued to participants in the placing, providing an opportunity for the Company to raise up to £17.5 million by 30 June 2017 when the Warrants expire. The Warrants trade under the ticker STXW.

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

3. Acquisition of Phosphate Therapeutics Limited

On 26 February 2016 Shield Therapeutics plc acquired 100% of the share capital of Phosphate Therapeutics Limited in consideration for 19,887,791 shares in the Company with a fair value of £27 million. As this does not meet the definition of a business combination this has been accounted for as an asset acquisition of the intellectual property of Phosphate Therapeutics Limited.

4. Selected relevant accounting policies

The accounting policies set out below have, unless otherwise stated, been applied consistently to all periods presented in this financial information. The financial information is 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 information is presented in GBP and all values are rounded to the nearest thousand (£000), except as otherwise indicated.

Basis of consolidation

The consolidated interim financial information comprises the financial information of the Group and its subsidiaries as at 30 June 2016.

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.

Losses within a subsidiary are attributed to the non-controlling interest even if that results in a deficit balance. A change in the ownership interest of a subsidiary, without a loss of control, is accounted for as an equity transaction.

Group reorganisations in the prior period are accounted for as a continuation of the existing Shield Group. Accordingly, the consolidated financial information of Shield Therapeutics plc has been prepared as a continuation of the existing Group. Shield Holdings AG in effect remains the accounting parent entity. The consolidated financial information reflects any difference in share capital between Shield Therapeutics plc and Shield Holdings AG as an adjustment to equity.

4. Selected relevant accounting policies continued

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

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

Exchange differences arising from this translation of foreign operations are reported as an item of other comprehensive income and accumulated in the translation reserve or non-controlling interest, as the case may be.

Intangible assets

Research and development

Expenditure on research activities is recognised as an expense in the statement of profit and loss.

During the period the Group met the criteria to capitalise development expenditure for the first time due to the progression of certain projects beyond the research phase. Consequently the policy on research and development costs has been expanded to include the capitalisation criteria for and composition of development costs. No previously reported balances have been restated as a consequence of this change.

Expenditure on development activities directly attributable to an intangible asset is capitalised when the following conditions are met:

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

The Group considers that Marketing Authorisation Approval "MAA" regulatory approval in the relevant jurisdiction confirms these criteria.

Internally developed intangible assets are recorded at cost and subsequently measured at cost less accumulated amortisation and accumulated impairment losses.

Capitalised directly attributable development costs include clinical trial costs, Chemistry, Manufacturing and Controls "CMC" costs and contractor costs. Internal salary costs have not been capitalised as they are not considered to directly relate to bringing the asset to its working condition and employee costs are not allocated by project.

Expenditure in relation to patent registration and renewal of current patents is capitalised and recorded as an intangible asset. Registration costs are continually incurred as the Group registers these patents in different countries. Patent assets are stated at cost less accumulated amortisation and accumulated impairment losses.

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

Patents	– over the term of the patents
CMC costs	– over five years
Intellectual property purchase costs	– over the term of the patents

Notes continued

for the six months ended 30 June 2016

4. Selected relevant accounting policies continued

Intangible assets continued

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.

Revenue

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

Revenue is recognised in the consolidated statement of profit and loss and other comprehensive income when the risks and rewards associated with the ownership of goods are transferred to the customer. This is deemed to occur when the customer collects and loads the product, resulting in the legal transfer of title.

Operating income

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

Expenses

Financing income and expenses

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 is recognised in profit or loss as it accrues, 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 period comprises current and deferred tax. Tax is recognised in the income statement except to the extent that it relates to items recognised directly in equity, in which case it is recognised in equity.

Current tax is the expected tax payable or receivable on the taxable income or loss for the year, using tax rates enacted or substantively enacted at the balance sheet date, and any adjustment to tax payable in respect of previous periods.

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

Share based payments

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

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

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.

4. Selected relevant accounting policies continued

Share based payments continued

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 investment in subsidiary undertakings, with a corresponding credit to equity in the parent entity accounts.

5. Critical accounting judgments and key sources of estimation uncertainty

In the application of the Group's accounting policies, which are described in Note 4, 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.

Share based payment transactions

The Group measures the cost of equity-settled transactions with employees by reference to the fair value of the equity instruments at the date at which they are granted. Estimating fair value for share based payment transactions requires determining the most appropriate valuation model, which is dependent on the terms and conditions of the grant. This estimate also requires the determination of the most appropriate inputs to the valuation model including the expected life of the share options and volatility and making assumptions about them.

Fair value of derivative instruments

Where the fair value of derivative instruments recorded in the statement of financial position cannot be derived from active markets, their fair value is determined using valuation techniques. The inputs to these models are taken from observable markets where possible. Where this is not feasible, a degree of judgment is required in establishing fair values. The judgments include considerations of inputs such as entity value and volatility.

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.

Development expenditure

Development expenditure is capitalised when the conditions referred to in Note 4 are met.

Valuation of intellectual property acquired with Phosphate Therapeutics Limited

The valuation of intellectual property acquired with Phosphate Therapeutics Limited during the period is based on cash flow forecasts for the underlying business and an assumed appropriate cost of capital and other inputs in order to arrive at a fair value for the asset. The realisation of its value is ultimately dependent on regulatory approval and successful commercialisation of the asset. In the event that commercial returns are lower than current expectations this may lead to an impairment.

Notes continued

for the six months ended 30 June 2016

6. New standards and interpretations

The Group has adopted the following new standards 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.

- Amendment to IFRS 11 Joint arrangements.
- Amendment to IAS 1 Presentation of financial statements.
- Amendment to IAS 16 Property, plant and equipment.
- Amendment to IAS 27 Separate financial statements.
- Amendment to IAS 38 Intangible assets.
- Amendment to IAS 41 Agriculture.
- Annual improvements to IFRSs – 2012-2014 cycle.

7. 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 whose revenue, expenses, assets, liabilities and cash flows are measured and reported on a basis consistent with the financial information. All revenue reported in the period relates to the UK market and originated in the UK. No additional numerical disclosures are necessary.

8. Loss per share

	Six months ended 30 June 2016			Year ended 31 December 2015		
	Loss £000	**Weighted shares 000**	**Loss per share £**	Loss £000	Weighted shares 000	Loss per share £
IFRS – basic and diluted	**(8,851)**	**94,107**	**(0.09)**	(23,627)	41,507	(0.57)
Adjusted – basic and diluted	**(5,081)**	**94,107**	**(0.05)**	(5,279)	41,507	(0.13)
Proforma adjusted – basic and diluted	**(5,081)**	**108,135**	**(0.05)**	n/a	n/a	n/a

The diluted loss per share is identical to the basic loss per share in both periods, as potential dilutive shares are not treated as dilutive since they would reduce the loss per share. Warrants issued as part of the IPO process would potentially provide an additional 11,666,658 shares (approximately 10.8% of the current share capital) if exercised between the period end and 30 June 2017 (8,012,815 on a weighted basis), which are considered to be non-dilutive as they would increase the loss per share.

The adjusted loss is calculated after adding back non-recurring items as illustrated in the table below.

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

The adjusted proforma loss per share is calculated using the number of Ordinary Shares in issue following the IPO.

8. Loss per share continued

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

	Six months ended 30 June 2016 (unaudited) £000	Year ended 31 December 2015 (audited) £000
Loss for the period	**(8,851)**	(23,627)
Interest on preference shares	**–**	1,761
FX movement on preference shares	**–**	(259)
Fair value remeasurement of preference share embedded derivative	**–**	15,610
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 share options	**2,398**	(59)
FX movement on share options	**1,059**	–
Non-recurring legal and professional fees	**170**	–
Share based payments charge	**143**	–
Adjusted loss	**(5,081)**	(5,279)

9. Intangible assets

	Patents and trademarks £000	Development costs £000	Phosphate Therapeutics licences £000	Total £000
Cost				
Balance at 1 January 2015	566	–	–	566
Additions – externally purchased	104	–	–	104
Effect of movements in foreign exchange	19	–	–	19
Balance at 31 December 2015	689	–	–	689
Additions – externally purchased	378	–	–	378
Additions – internally developed	–	879	–	879
Acquisition with Phosphate Therapeutics Limited	–	–	27,047	27,047
Effect of movements in foreign exchange	104	–	–	104
Balance at 30 June 2016	**1,171**	**879**	**27,047**	**29,097**
Amortisation				
Balance at 1 January 2015	(130)	–	–	(130)
Charge for the period	(46)	–	–	(46)
Balance at 31 December 2015	(176)	–	–	(176)
Charge for the period	(42)	(84)	(1,242)	(1,368)
Effect of movements in foreign exchange	(26)	–	–	(26)
Balance at 30 June 2016	**(244)**	**(84)**	**(1,242)**	**(1,570)**
Net book amount				
At 30 June 2016	**927**	**795**	**25,805**	**27,527**
At 31 December 2015	513	–	–	513

£27 million of additions during the period to 30 June 2016 relate to the acquisition of intellectual property with Phosphate Therapeutics Limited (see Note 3).

£1.7 million was spent on development expenditure during the period, with £0.9 million capitalised above and £0.8 million charged to the profit and loss account.

Notes continued

for the six months ended 30 June 2016

10. Tangible assets

	Total £000
Cost	
At 1 January 2015	12
Additions	9
At 31 December 2015	21
Additions	10
At 30 June 2016	**31**
Amortisation	
At 1 January 2015	–
Charge for the period	(4)
At 31 December 2015	(4)
Charge for the period	(4)
At 30 June 2016	**(8)**
Net book amount	
At 30 June 2016	**23**
At 31 December 2015	17

11. Related party transactions – Phosphate Therapeutics Limited

During the period the Company acquired the share capital of Phosphate Therapeutics Limited, as described in Note 3.

Phosphate Therapeutics Limited is considered to be a related party of the Company by virtue of its linked key management personnel.

12. Called up share capital

	Number	£000
At 31 December 2015 (audited)	69.0m	690
2 for 3 share consolidation	(23.0)m	–
Issuance of shares pursuant to listing	21.7m	325
Exercise of share options	20.5m	309
Acquisition of Phosphate Therapeutics Limited intellectual property	19.9m	298
At 30 June 2016 (unaudited)	**108.1m**	**1,622**

Details of the reasons for the movements in share capital are provided in Notes 2 and 3.

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