



**SHIELD**  
THERAPEUTICS

Improving Lives Together

## Investor Presentation

February 2019

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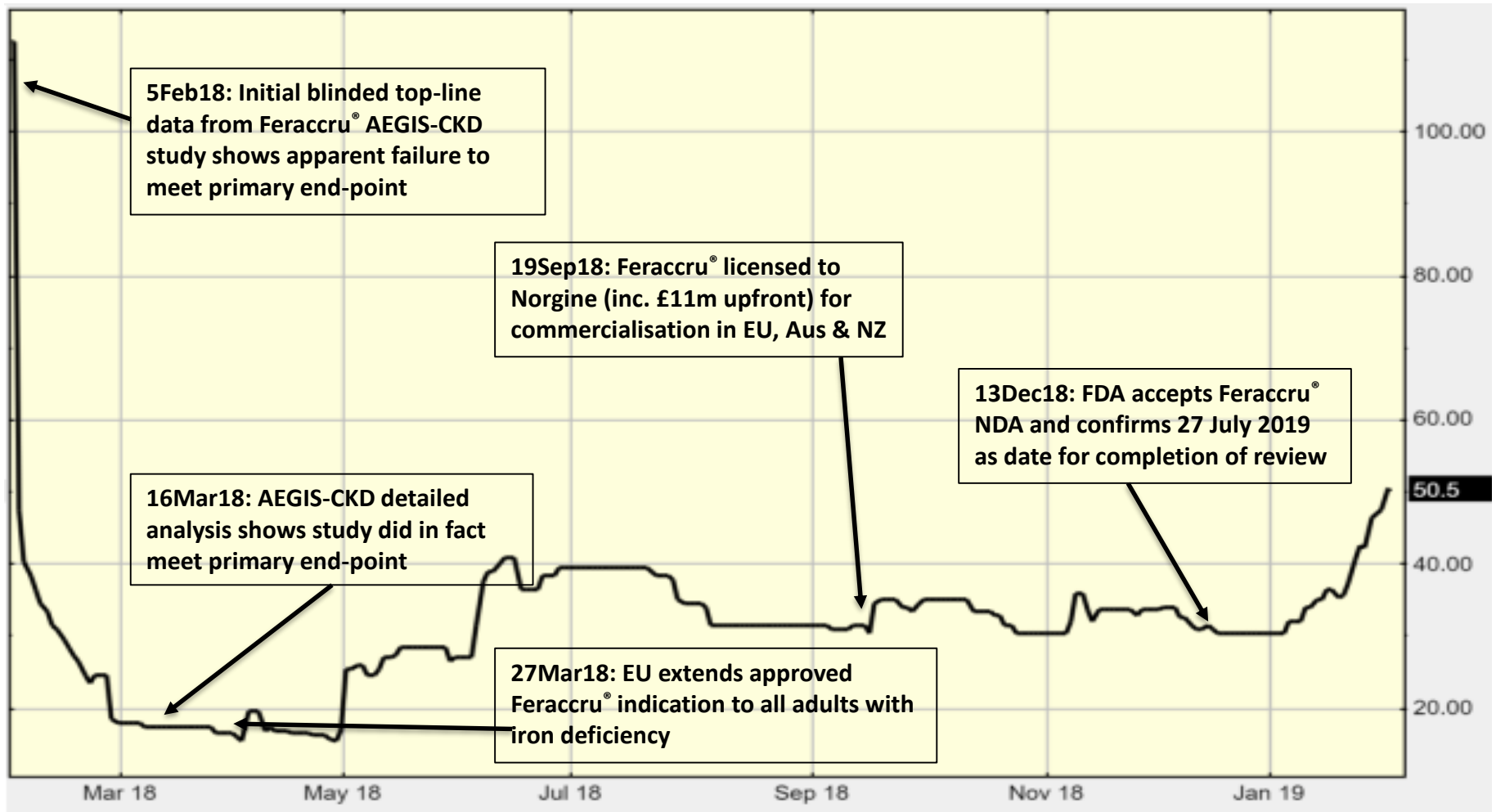
# Introduction to Shield Therapeutics

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- AIM-listed biotech company (STX.L)
  - Market capitalisation ~£59m (@31Jan19)
- Primary focus is on developing and commercialising Feraccru<sup>®</sup>
  - A novel oral treatment for iron deficiency
  - Out-licensed to Norgine in EU, Australia, New Zealand
  - US NDA: PDUFA date 27 July 2019
  - Additional late stage asset, PT20, requires one phase 3 study to submit a MAA in Europe and NDA in the USA
- Semi-virtual UK-based company – conduct of clinical trials as well as manufacturing and commercialisation are out-sourced
  - 15 employees
  - Highly experienced management team
- £11m up-front licence payment for EU territory from Norgine in September 2018 means company is comfortably funded into 2020



## A brief history of last 12 months...



**Investment proposition – the recovery of the business from the consequences of the initial and ultimately incorrect AEGIS-CKD study results have not yet been fully reflected in the share price**



# Iron deficiency and Feraccru<sup>®</sup>

# Iron deficiency (ID)

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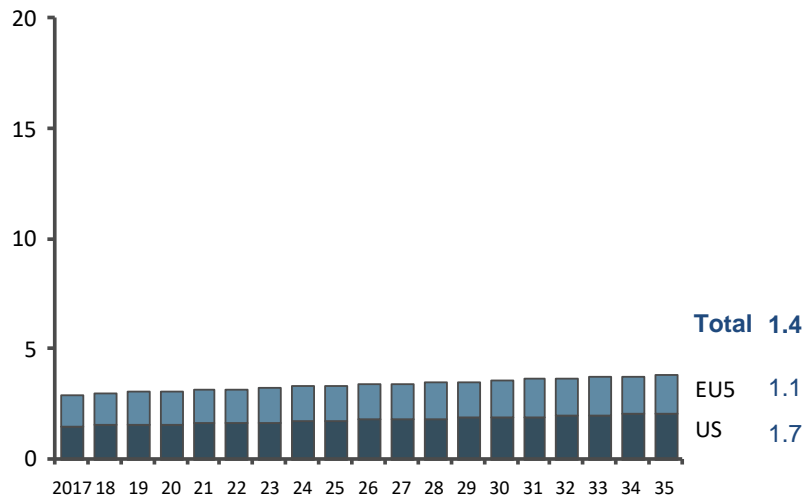
- Iron deficiency is the most common form of anaemia
- Iron required for multiple vital functions
  - Key component of haemoglobin, carrying oxygen from lungs to tissue
  - Transport mechanism for electrons within cells
  - Facilitating oxygen enzyme reactions
- Iron deficiency occurs when a body either:
  - Does not absorb enough iron to supply its needs or,
  - Loses iron through blood loss
- ID can be caused by malnutrition, bleeding and a number of chronic diseases, in particular:
  - Inflammatory bowel disease (IBD) and
  - Chronic kidney disease (CKD)

# IBD and CKD are prevalent diseases

**c.15 million patients are estimated to have diagnosed IBD or CKD in 2017. This is expected to grow to c.19 million by 2035**

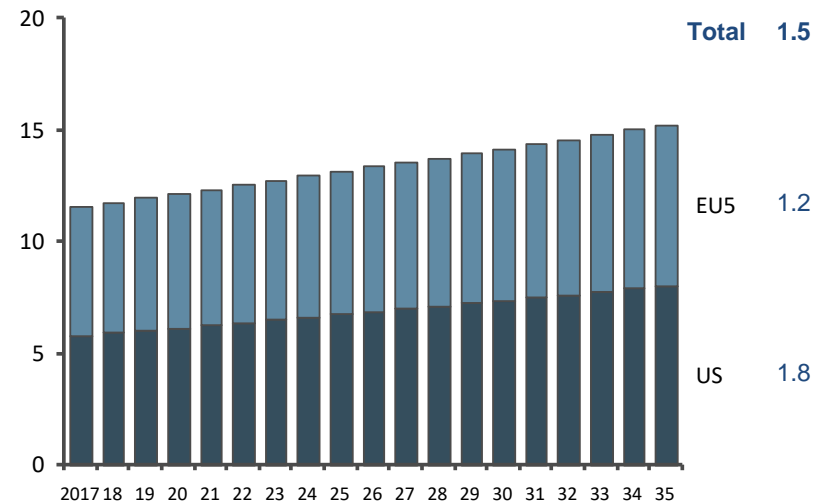
**IBD diagnosed prevalence in US, EU5 (2017-35F)** Millions of patients

**CAGR % (2017-35F)**



**CKD diagnosed prevalence in US, EU5 (2017-35F)** Millions of patients

**CAGR % (2017-35F)**



- Growth in prevalence driven by population growth and underlying proportion of people developing the primary diseases:
  - IBD rate estimated to be growing at c.1% p.a. in developed nations driven by improved awareness amongst other factors
  - CKD rate estimated to be growing at c.1% p.a. in developed nations due to higher levels of obesity & diabetes plus growth in population >50 yrs old as kidney function declines with age

# Iron replacement therapy can be oral or intravenous (IV)

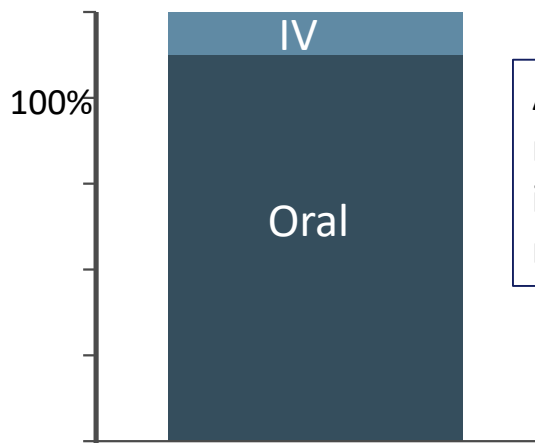
## Oral

- Historically salt-based iron compounds
- Inexpensive and convenient
- Poor absorption = slower to restore iron-levels
- Not well tolerated = poor compliance

## Intravenous

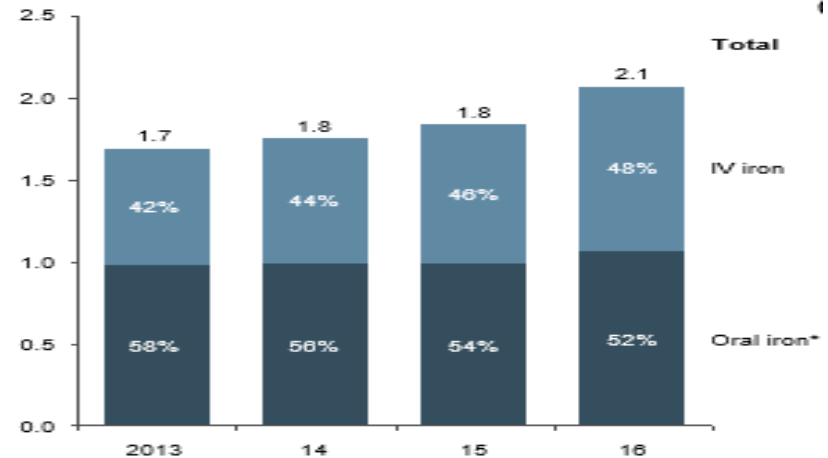
- Used in more severe patients or patients intolerant of oral therapies
- Requires intravenous infusion in hospital or clinic setting due to safety risk
- Resource heavy, inconvenient and expensive

## Iron market by volume:



Although oral iron has majority of volume, IV iron has close to 50% of market by value

Global market for Rx iron products (2013-16)  
Billions of GBP

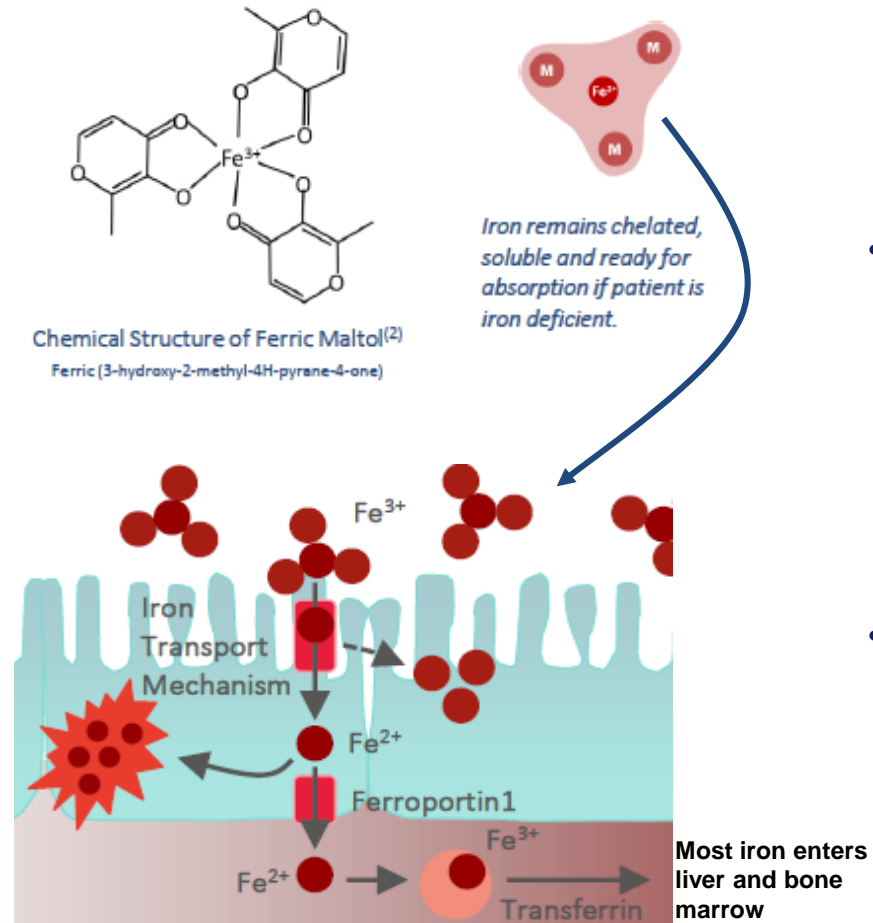


**The tolerability of oral iron and the cost and inconvenience of IV iron together create a major unmet need and commercial opportunity**



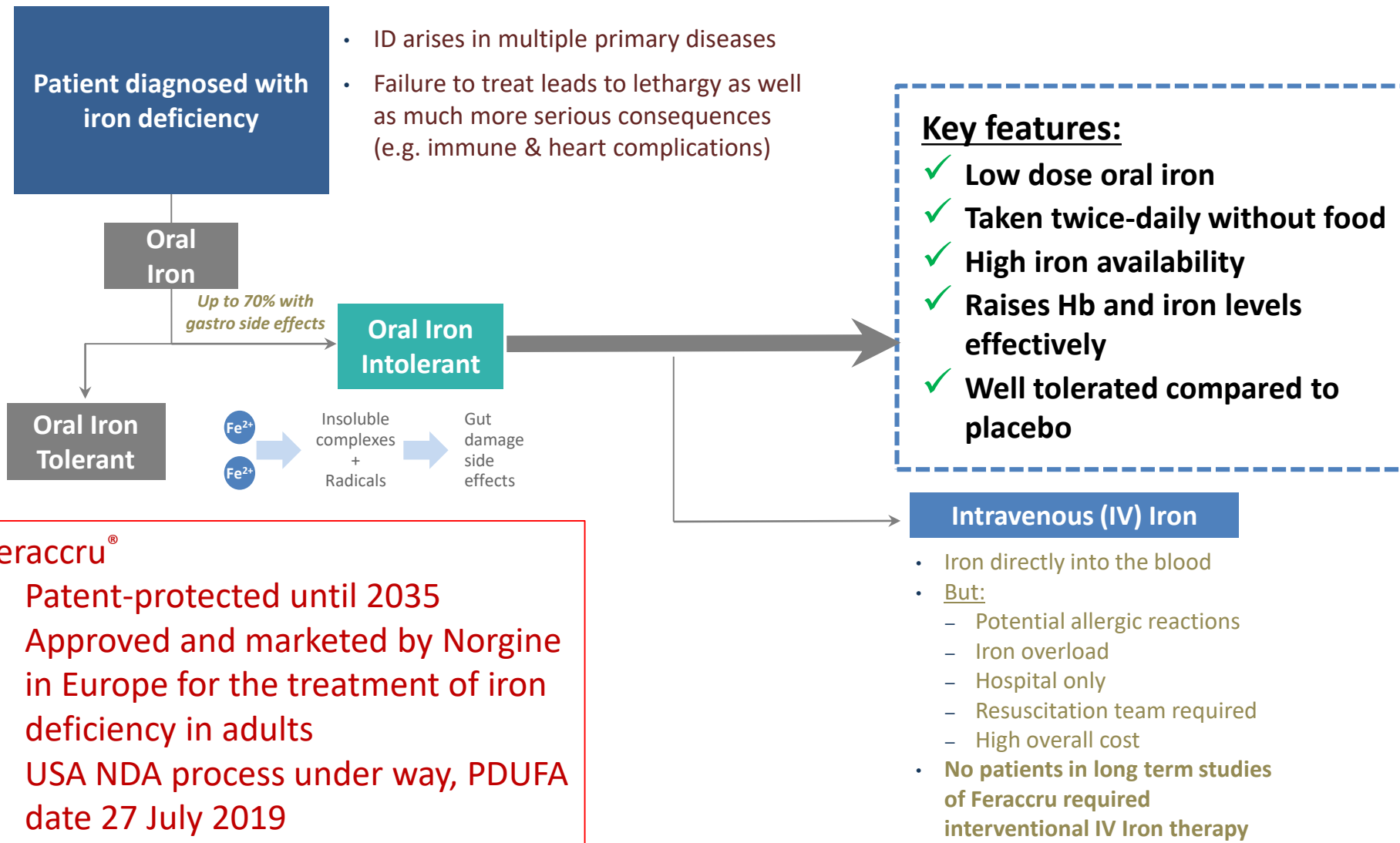
# Feraccru is a novel oral formulation

## Feraccru<sup>®</sup> mechanism of action:



- Feraccru<sup>®</sup> is a low dose oral formulation of a non-salt complex of Fe<sup>3+</sup>, which is stable in the GI tract
  - Other oral irons are salts and require the Fe to dissociate to be absorbed
  - This causes formation of insoluble products in the GI tract, causing intolerance in patients
- The Fe<sup>3+</sup> in Feraccru<sup>®</sup> remains in complex with maltol until absorbed and the iron is delivered to the bloodstream where it binds to transferrin
  - Maltol gets metabolised and excreted in urine
  - Unabsorbed Feraccru<sup>®</sup> passes through the digestive system in the benign complex and is excreted in faeces
- Feraccru<sup>®</sup> is a well tolerated oral iron replacement therapy
  - Potential for use as a first line treatment for patients with iron deficiency or as an alternative to IV iron in patients failing existing oral iron salts

# Feraccru<sup>®</sup> in the treatment algorithm

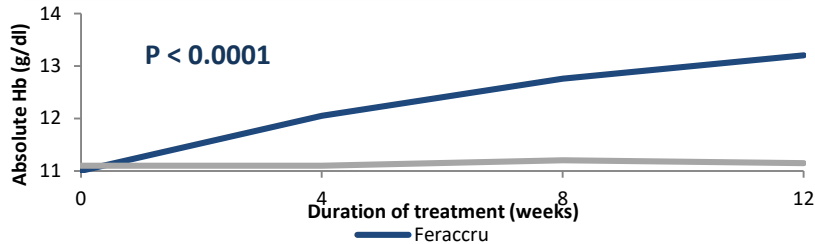




# Feraccru<sup>®</sup> clinical studies

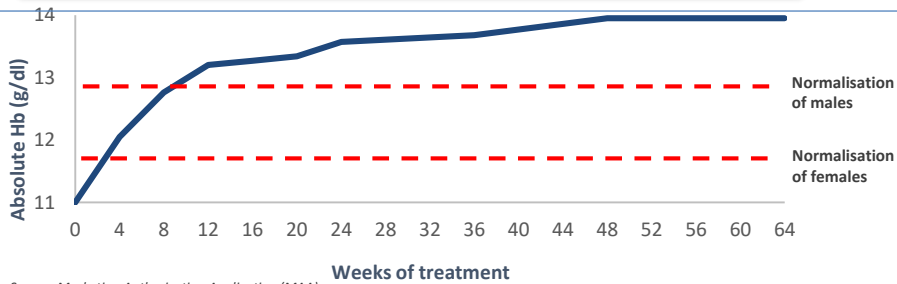
# Feraccru's efficacy and safety are key differentiators: AEGIS-IBD

## Feraccru provides rapid and effective results...



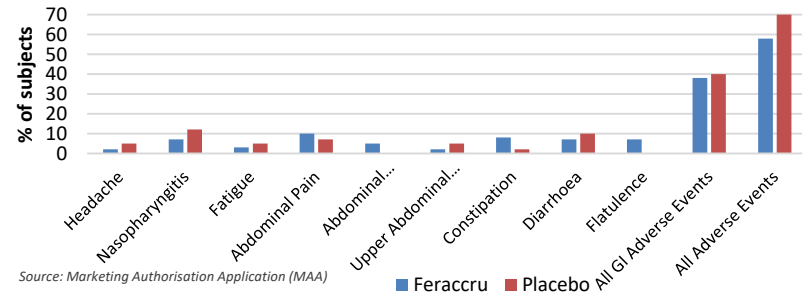
Source: Marketing Authorisation Application (MAA)

## ...works over the long term



Source: Marketing Authorisation Application (MAA)

## ...and is well-tolerated



Source: Marketing Authorisation Application (MAA)

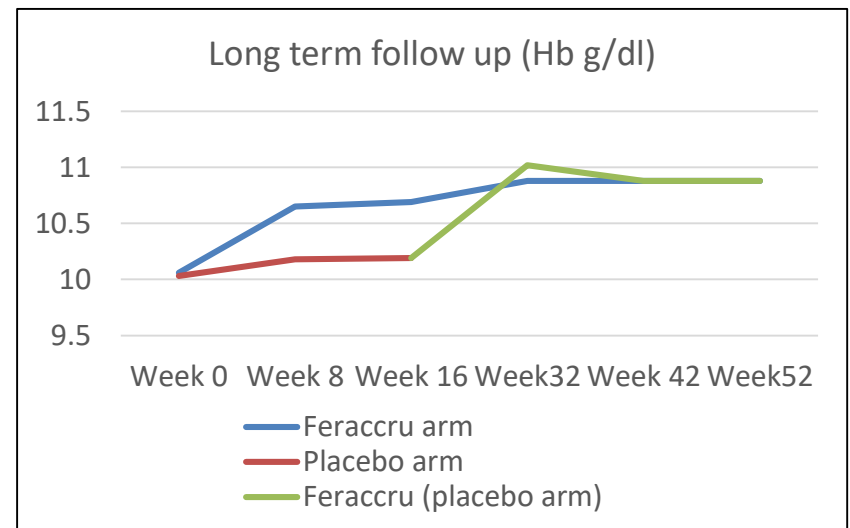
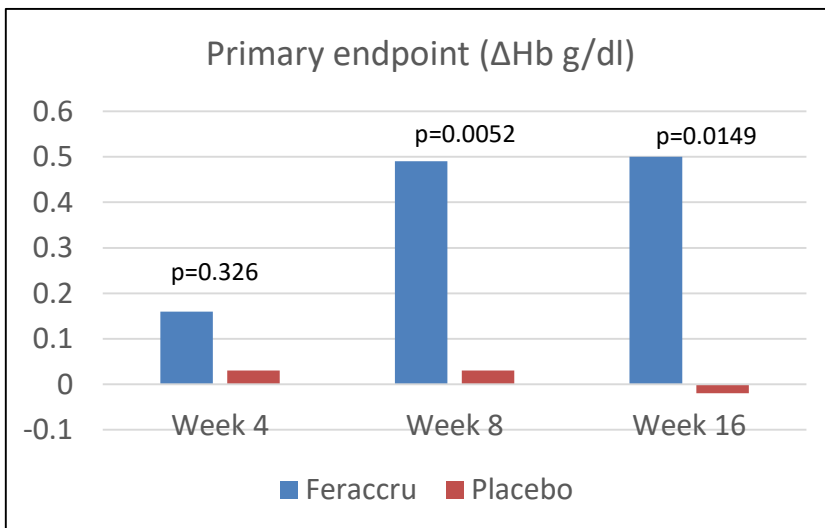
- Study of 128 IBD patients with IDA
- Patients were intolerant of or unwilling to take oral iron salts
- A clinically relevant haemoglobin (Hb) increase is considered to be 1g/dL
- Feraccru<sup>®</sup> delivered highly relevant and rapid 2.3g/dL rise inside 12 weeks with 1g/dL in only 4 weeks

- Normalised mean Hb by week 12
- Long term compliance levels of 97%
- With chronic therapy patients' anaemia did not recur and iron indices continued to improve
- Ongoing Feraccru<sup>®</sup> therapy may prevent need for IV iron

- Majority of adverse events were related to IBD status
- Low incidence of other adverse events
- Neither short or long-term Feraccru<sup>®</sup> therapy led to iron overload

## AEGIS-CKD Study Analysis <sup>(1)</sup> <sup>(2)</sup>

- Study met primary endpoint (change in Hb from baseline at 16 wks)
- Statistically significant change in Hb is observed across all analyses (ITT, mITT and PP) and in all sensitivity analyses at both wk 8 and 16
- Change in ferritin, TSAT and serum iron from baseline statistically significant at weeks 4, 8 and 16 demonstrating early effect
- Hb levels increased and maintained over 52 weeks



ITT: intention-to-treat; MI: multiple imputations

(1) SAP v1.1  
(2) 169 patients





## **Europe commercialisation Norgine licence headlines**

# Norgine licence headlines

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- Exclusive licence to commercialise Feraccru<sup>®</sup> in Europe\*, Australia and New Zealand (announced September 2018)
  - £11 million upfront licence payment
  - Up to €54.5million in development and sales milestones
  - Royalties ranging from 25% to 40% as sales increase
- *Why Norgine?* It is a well-resourced, European-focused specialty pharma business with a proven commercial track record for whom Feraccru<sup>®</sup> will be a central product in its future growth
  - Commercial operations now active in the UK and Germany, with >80 field-based staff promoting and supporting Feraccru<sup>®</sup>
- Shield globally responsible for
  - Manufacture and supply of Feraccru<sup>®</sup>
  - All aspects of current and future development
  - All aspects of intellectual property
- Shield also retains full commercial rights to Feraccru<sup>®</sup> in all unlicensed countries including the USA

\* Excluding countries covered by AOP (Scandinavia) and EWO (Switzerland)



**USA**

# USA

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- September 2018 - NDA for Feraccru<sup>®</sup> submitted
- December 2018 - FDA accepted Feraccru<sup>®</sup> NDA for review
- December 2018 – PDUFA date (completion of review) confirmed as 27 July 2019
- Shield now considering commercialisation options for Feraccru<sup>®</sup> in the USA, most likely to out-license



# Financial headlines



# Financial position

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- Revenues of £11.9m\* in 2018
  - £11m upfront payment from Norgine to licence Feraccru® in the EU
  - £0.9m of Feraccru® revenue (sales + royalties) despite the product being commercially unsupported since February 2018
  - Feraccru® demonstrated quarter on quarter growth of 'in market' sales through 2018
- Cash balance of £9.8m\* at year end
- Cash runway extends into 2020

\* Unaudited results



# Newsflow and investment highlights

## Anticipated 2019 newsflow

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Indicative timing	Event
Q1 2019	AEGIS-H2H study results
27 July 2019	PDUFA date for US approval of Feraccru®
H2 2019	Start of Paediatric Phase III study
Ongoing/ad hoc	Potential further out-licensing agreements for Feraccru® in USA and other territories

# Key messages and investment highlights

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- Iron deficiency is a major market with significant unmet needs and an attractive commercial opportunity
- Feraccru®
  - Novel oral ferric iron therapy with broad approval in Europe & an excellent commercial partner in place and active
  - US Feraccru® NDA review completion by 27 July 2019 with potential approval in the world's largest and most attractive pharma market
  - Further licensing opportunities being actively pursued for Feraccru® in geographies inc. USA, China etc...
- Cash runway extending into 2020
- Valuation upside
  - Investment proposition: the recovery from the consequences of the initial AEGIS-CKD study results and the underlying strength of the business are not yet reflected in the share price
    - Current market capitalisation - £59m (@50.5p as of 1Feb19)
    - Consensus analyst valuation<sup>1</sup> - £80m - £90m (70p-80p) based on the EU opportunity alone
    - US NDA approval for Feraccru®, positive H2H study data, additional out-licensing agreements

<sup>1</sup> Peel Hunt & Liberum



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# Management team

Name	Role	Biography
Carl Sterritt	CEO & Founder	Started Shield Therapeutics in 2008 and identified the Feraccru opportunity in 2010. Previously held senior management roles at United Therapeutics and Encysive Pharmaceuticals, working on innovative therapies for the treatment of pulmonary arterial hypertension; founding the Group after Encysive was acquired by Pfizer Inc
Tim Watts	Chief Financial Officer	Tim joined the company as Interim Chief Financial Officer in August 2018 and has over 25 years' experience in the pharmaceutical and biotech sectors. A chartered accountant, he was Group Financial Controller of AstraZeneca plc (2002-2006), CFO of Archimedes Pharma (2007-2011) and CFO of Oxford Biomedica plc (2012-2017)
Mark Sampson	Chief Medical Officer	Having joined in 2015, Mark has more than 25 years of pharmaceutical development and commercialisation experience at companies such as SmithKline Beecham, Amgen and Gilead. Before entering into the pharmaceutical industry Mark qualified and practised as a surgeon in the NHS
Jackie Mitchell	VP, Regulatory Affairs and Quality	With over 20 years' experience in regulatory affairs Jackie has led the group's regulatory activities since 2012. She has led several major regulatory projects, including successful MAA and NDA submissions, including MAAs for the Feraccru, Kaletra and Humira.
David Childs	Director, Product Supply & Commercial Alliances	David joined in 2011 as Director of Manufacturing. During his tenure at GSK, David gained over 18 years' of experience in chemical and pharmaceutical development and worked closely with several outsourcing partners.
Lucy Bailey	General Counsel & Company Secretary	Lucy has worked with Shield since 2015 and was a key member of the team working on the admission of Shield Therapeutics to the AIM market in 2016. She is admitted as a Solicitor of the Senior Courts of England and Wales and has worked previously at both a boutique and an international US law firm based in Singapore