

## SHIELD THERAPEUTICS PLC

### Investment Profile

- De-risked, growing business
- Commercial stage
- Large market opportunities
- Cash runway extended to 2021
- Strong IP protection

### Ticker (AIM listed) **STX**

Share Price	55.50p
Shares in issue	117.62m
Market Cap	£64.10m
12m Hi/Low	165.50/48.50p

(Source: The London Stock Exchange, January 2021)

### 12 Month Share Price



(Source; The London Stock Exchange, January 2021)

### Major Shareholders (as of January 2021)

Name	%
Inventages	47.62
MaRu AG	10.66
Blackrock Investment Mgt	4.31
Jupiter Asset Management	4.23
Directors	4.06

(Source; company website)

### Key Newsflow

- Jan:** Business and Trading Update
- Dec:** Investor presentation
- Dec:** Update re US Partnering discussion
- Oct:** Withdrawal of all oppositions by TEVA
- Sept:** Half-Year results
- Aug:** AEGIS -H2H study reanalysis
- June:** Appointment of Non-Exec Director
- June:** Feraccru®/Accrufer® publications
- May:** Preliminary Results

[www.shieldtherapeutics.com](http://www.shieldtherapeutics.com)

## Company Overview

**Shield Therapeutics PLC (AIM: STX)** is a de-risked, specialty pharmaceutical company focused on commercialising its lead product, **Feraccru®/Accrufer®** (ferric maltol), a novel, non-salt oral therapy for adults with iron deficiency with or without anaemia. Feraccru®/Accrufer® has been approved for use in the **United States, European Union, UK and Switzerland** and is patent-protected until the mid-2030s. Feraccru® is commercialised in the UK and European Union by Norgine B.V. and the Company is currently in the process of evaluating commercialisation options for the US market, including the potential launch of Accrufer® in the US by Shield. Shield also has an exclusive licence agreement with Beijing Aosaikang Pharmaceutical Co., Ltd., for the development and commercialisation of Feraccru® in China, Hong Kong, Macau and Taiwan.

## Iron deficiency and Feraccru®/Accrufer®

Iron deficiency is a highly prevalent ailment caused either by insufficient iron being absorbed through diet or bleeding. It is associated with many underlying diseases including inflammatory bowel disease, chronic kidney disease, women's health issues, oncology, cardiology and is prevalent in the elderly. Doctors will normally treat iron deficient patients first with oral iron salt products but, as these are poorly tolerated by patients, intravenous (IV) iron infusions are used as second line therapy.

The chemical structure of ferric maltol means that, unlike other oral iron therapies, the molecule does not break down until it reaches the duodenum and proximal jejunum where the body absorbs iron. This means that Feraccru®/Accrufer® is well tolerated and, because it delivers the iron to where it is needed, effective. Three Phase III clinical studies have demonstrated the product's tolerability and effectiveness, and also that it is a credible alternative to, and has some advantages over, intravenous iron therapy which is used in more serious cases of iron deficiency anaemia.

Feraccru®/Accrufer® is protected by a number of patents, including a patent covering the crystalline forms of ferric maltol which lasts until 2035.

## Paediatric study

The first stage of the paediatric study plan to compare the relative bioavailability of the liquid formulation required for children with the adult capsule was completed during Q4 2020. The study report from this stage will be completed by the end of Q1 2021 and Shield expect to be able to start the main paediatric study in 120 children around mid-2021. Successful completion of this study could lead to expansion of the available market and potentially further patent protection.

**Shield Therapeutics plc continued...**

**Commercialisation of Feraccru®/Accrufer®**

In Europe Feraccru® has been out-licensed to **Norgine** for commercialisation. Shield receives royalties ranging from 25% to 40% of Norgine’s net sales dependent on sales tiers, but bears the cost of manufacturing the product. At the end of 2020, Feraccru was marketed in **Germany, the UK and Scandinavia** with launches expected in other European markets during 2021/2022.

Feraccru has been out-licensed to **ASK Pharm** for development and commercialisation in **China, Taiwan, Hong Kong and Macau**. It is anticipated that one further Phase III study is needed before marketing approval is granted in China which could happen by 2023. On approval, Shield will receive an \$11.4m development milestone from ASK Pharm and is entitled to royalties on net sales of 10% or 15% depending on sales tiers, with ASK Pharm paying for the product manufacturing costs.

**Commercialisation in the US**

There are estimated to be **10 million oral and 2.3 million IV iron prescriptions annually** in the US and peak sales potential of Accrufer® in the US could be as much as \$300m-\$400m per annum. Shield is currently assessing whether to out-licence the product for commercialisation, or to launch the product itself. A licence agreement would generate an upfront receipt and subsequent royalties on net sales whereas a Shield launch might require launch finance of \$30m-\$40m but, with an estimated 90% gross margin, long term profit potential is substantial. Either route should generate substantial shareholder value.

**Investment Case**

- Shield’s market valuation at time of writing is fully underpinned by the European and Chinese licence agreements
- The **US** is the world’s **largest and most profitable pharmaceutical market** and offers substantial upside to Shield’s current share price
- The iron deficiency market is poorly served – other oral products are poorly tolerated and not very effective whereas IV iron infusions require hospital visits which are costly, inconvenient, and not ideal in the COVID environment



**EXPERIENCED MANAGEMENT TEAM**

Shield has an experienced management team with extensive expertise in the healthcare space. **Tim Watts** became **CEO** in April 2020 after serving as CFO since August 2018. Tim has extensive biotech and Pharmaceutical experience, having previously been CFO of Oxford BioMedica PLC and Archimedes Pharma Ltd, preceded by 22 years at AstraZeneca.

**Meet Shield Therapeutics**

You can view the latest Company presentation and register to receive notification of future presentations by signing up with **Investor Meet Company here:**

<https://www.investormeetcompany.com/shield-therapeutics-plc/register-investor>

To receive RNS announcements, the latest Company Investment Summaries and invitations to all future events hosted by Shield Therapeutics plc please email [Shield@walbrookpr.com](mailto:Shield@walbrookpr.com)

**FORECASTS (Source: Consensus forecasts compiled by Walbrook PR)**

	DEC '19 (Actual)	DEC '20 (Est.)	DEC '21 (Est.)	Dec '22 (Est.)
<b>Sales (£m)</b>	0.7	10.2	5.8	12.2
<b>EBITDA (£m)</b>	(6.2)	1.8	(3.0)	2.2
<b>PBT (£m)</b>	(7.8)	0.0	(4.8)	0.6
<b>EPS (p)</b>	(8.0)	0.8	(3.6)	0.8

**FDA, EMA & Swiss approved**

