Shield Therapeutics PLC (AIM: STX)

Company Summary

Investment Profile

- De-risked, growing business
- Commercial stage
- Large addressable market
- Strong IP protection
- Listed on the OTCQX Best Market in the US under the ticker 'SHIEF'

Share Information

| Ticker | STX |
|-----------------|------------|
| Share Price | 42.50p |
| Shares in issue | 215.85m |
| Market Cap | £97.13m |
| 12m Hi/Low | 148.68/31p |

(Source: The London Stock Exchange, July 2021)

12-Month Share Price



(Source: The London Stock Exchange, July 2021)

Major Shareholders (as of January 2021)

| AOP Orphan International AG Hargreaves Lansdown Jupiter Asset Management | % |
|--|-------|
| Hargreaves Lansdown | 25.94 |
| | 13.13 |
| Jupiter Asset Management | 7.80 |
| | 5.61 |
| Interactive Investor | 5.25 |
| Directors | 3.21 |
| Sterling Investments | 3.11 |
| AJ Bell | 3.03 |

Key Newsflow

July: US launch of Accrufer®

June: Investor Presentation / AGM **May:** Appointment of new CEO

April: Prelim Results

March: Appointment of new CFO / TGA approved Feraccru

in Australia

Feb: Completion of £25m fundraise

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, Australia and Switzerland and is commercialised in the UK and European Union by Norgine B.V. The Company launched Accrufer® in the US on 1 July 2021 and 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.

July 2021

Visit Shield Therapeutics PLC's website: www.shieldtherapeutics.com

Iron deficiency and Feraccru®/Accrufer®

Iron deficiency is a highly prevalent ailment caused either by insufficient iron being absorbed through diet, or as a consequence of 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.

US launch of Accrufer®

There are estimated to be **10 million oral and 2.3 million IV iron prescriptions annually i**n the US and peak sales potential of Accrufer® in the US could be as much as \$300m-\$400m per annum. Since launching on July 1, stocks of Accrufer® have been distributed through wholesaler channels and are available to doctors and other prescribers in all parts of the US.

The Wholesaler Acquisition Cost (headline price of a pharmaceutical product in the US) for Accrufer® has been set at \$500 per pack (which contains 30 days' supply at two capsules per day).





Commercialisation of Feraccru®/Accrufer® outside US

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.

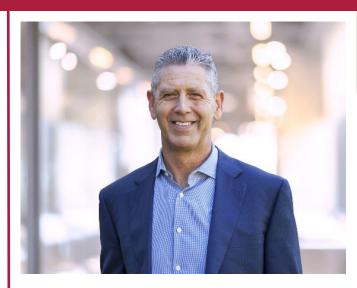
Paediatric study

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. 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.

Investment Case

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- 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
- Feraccru®/Accrufer® patent-protected until the mid-2030s
- £27.8m net proceeds raised in March 2021 to launch Accrufer® in the US, with current cash runway extended to at least the end of 2022



EXPERIENCED MANAGEMENT TEAM

Greg Madison (above) joined Shield as **CEO** in June 2021 bringing with him an excellent commercialisation track record and a deep knowledge and previous experience in the US iron deficiency marketplace. Prior to joining Shield, Greg held several CEO positions at a number of pharmaceutical companies.

Hans-Peter Rudolf joined Shield as CFO in March 2021 with extensive international experience, particularly in the US. Hans-Peter is a US Certified Public Accountant.

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://bit.ly/3wFZ47p

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

> FDA, EMA & Swiss approved



Forecasts (Consensus forecasts compiled by Factset)

| | DEC'19 | DEC'20 | DEC'21 (Est.) | DEC'22 (Est.) | DEC'23 (Est.) |
|-------------|--------|--------|---------------|---------------|---------------|
| Sales (£m) | 0.7 | 10.4 | 5.5 | 31.1 | 75.4 |
| EBITDA (£m) | (6.2) | 0.6 | (20.5) | 5.1 | 32.2 |
| PBT (£m) | (7.8) | (2.0) | (22.4) | (7.0) | 30.3 |
| EPS (p) | (8.0) | (2.0) | (11.2) | (3.0) | 12.6 |