

SHIELD THERAPEUTICS PLC

Investment Profile

- De-risked, growing business
- Commercial stage
- Large market opportunities
- Experienced management team
- Strong IP protection

| Ticker (AIM listed) | STX |
|---------------------|--------------|
| Share price | 93.75 |
| Shares in issue | 117.09m |
| Market Cap | £114.12m |
| 12m Hi / Low | 100.0p/23.0p |

[Source; Company website]

12 Month Price



[Source; The London Stock Exchange]

Major Shareholders

| Name | % |
|----------------------------|------|
| W. Health L.P | 48.1 |
| MaRu AG | 10.8 |
| Carl Sterritt | 8.7 |
| Richard Griffiths & family | 6.3 |
| Christian Schweiger | 4.9 |
| Universities | 4.4 |
| Superannuation Scheme | |

[Source; Company website]

Key Newsflow

- April '19 – Swiss broader label
- April '19 – Final Results
- Mar '19 – Positive decision on Feraccru's process patent
- Mar '19 – Positive results for Feraccru In AEGIS-H2H study
- Jan '19 – Positive results of AEGIS-CKD study

Next financial & operational updates

- June '19 - AGM
- Jul '19 – FDA decision on Feraccru

Company Overview

Shield Therapeutics PLC (AIM: STX) is a de-risked, commercial stage, pharmaceutical company delivering innovative specialty pharmaceuticals that address patients' unmet medical needs, with an initial focus on iron deficiency with or without anaemia (ID/IDA) with its approved product **Feraccru®**.

Lead product- Feraccru®



Feraccru® is a novel oral treatment for ID/IDA that offers a compelling alternative to IV Iron, for those patients intolerant of salt-based oral iron therapies. ID/IDA is a common, poorly treated complication of a wide range of primary diseases, such as IBD, CKD, CHF and women's health. In a range of pivotal trials Feraccru® has been proven to be a well absorbed and well tolerated treatment which can be taken without the need for hospital-based administration. In a recently-completed clinical study, Feraccru® has demonstrated that it is comparable to IV iron therapy at correcting IDA.

Following receipt of marketing authorisation in early 2016, Feraccru® is commercially available in Europe via its commercial partner, Norgine, for use in adult patients with ID/IDA. In September 2018, a New Drug Application was submitted in the US and is being reviewed by the FDA, with a PDUFA date of 27 July 2019. Shield is seeking a commercial partner for this market also.

The Directors believe that Feraccru® has an achievable global peak annual sales opportunity in excess of \$500m.

In addition to its lead asset, Shield is working on a pipeline of products, with the Company currently developing a formulation for **PT20**, its second, late stage asset, which is in preparation for Phase III trials.

PT20 is a novel iron-based phosphate binder being developed for the treatment of abnormally high serum phosphates levels, a complication of advanced kidney disease. It is exclusively licensed from the UK's Medical Research Council. Other products which are at the pre-clinical stage consist of PT30 and PT40, with the latter being developed to be the first generic version of iron sucrose.

Strategy

With a small and highly experienced team, Shield Therapeutics focuses its own resources on the strategic development and management of its intellectual property, using recognised vendors for manufacturing, conducting clinical trials and commercialising products.

www.shieldtherapeutics.com

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COMMERCIAL & LICENCE AGREEMENT – NORGINE B.V.

In September 2018, Shield entered into an exclusive licence and commercialisation agreement with **Norgine** for Feraccru[®], covering the major markets of Europe, as well as Australia and New Zealand.

The agreement saw Shield retain full ownership of global IP and manufacturing rights for Feraccru[®], receive an £11m upfront licence payment, up to EUR54.5m of milestone payments and royalties ranging from 25% to 40% of net sales of Feraccru[®]. The first milestone has already been achieved by Shield and paid by Norgine.

The agreement is aimed at accelerating the commercialisation of Feraccru[®] in Europe as it will utilise Norgine's much larger established infrastructure and commercial expertise, meaning many more patients should benefit from Feraccru[®].

Positive results in AEGIS H2H trial

In March 2019, Shield received positive results from its AEGIS H2H non-inferiority study, showing that Feraccru[®] is non-inferior to Ferinject[®], the market-leading intravenously delivered iron replacement therapy, in treating IDA.

The positive results of this study have validated Feraccru[®] as a simple and effective alternative to hospital-based IV iron injections for people who are intolerant of regular salt-based prescription iron tablets and triggered a €2.5m milestone payment from Norgine who will now begin reimbursement discussions across the rest of the EU, further accelerating and de-risking the commercialisation of Feraccru[®].

With multiple positive clinical trial results, Feraccru[®] is now well placed to gain a share of the €1.7bn in annual global IV iron sales. GfK estimates there are approx. 1.4 to 1.5m patients in Europe and the US just with IBD who have IDA. Feraccru[®] finally offers a real alternative to patients intolerant of the current standard of care – salt-based oral irons – and can address a large, growing, global market.



EXPERIENCED MANAGEMENT TEAM

Shield has an experienced management team with extensive expertise in the healthcare space. **Carl Sterritt, CEO and founder** (pictured) has over 20 years of management and executive level experience in large and small pharma companies, having previously held management roles at United Therapeutics and Encysive Pharmaceuticals. He is supported by a skilled management team.

James Karis was appointed as **Non-Executive Chairman** in January 2019, bringing extensive experience in corporate strategy particularly with respect to the US market. The Board provides a strong platform for future growth.

The team is well equipped to advance discussions with commercialisation partners to ensure Shield is well positioned to exploit the large market opportunity.

FORECASTS (Source: Consensus forecasts compiled by Walbrook PR)

| | DEC '18 (Actual) | DEC '19 (Est.) | DEC '20 (Est.) |
|--------------------|---------------------|-------------------|-------------------|
| Sales (£m) | 11.9 | 2.5 | 2.4 |
| EBITDA (£m) | (1.2) | (5.7) | (5.9) |
| PBT (£m) | (2.7) | (7.8) | (7.4) |
| EPS (p) | (1.1) | (4.3) | (4.7) |

INVESTMENT CASE

- EMA and Swiss approved, revenue generating lead product sold by strong commercial partners
- Recent positive results for Feraccru[®] from an active comparator study
- FDA approval possible in 2019 for Feraccru[®]
- Long patent life remaining for Feraccru[®]
- Portfolio of aligned products

MEET SHIELD THERAPEUTICS

Carl Sterritt, CEO and Tim Watts, CFO, will be presenting at various times during the year to investors

Please contact Walbrook to register your interest

Last updated: May 2019