shield therapeutics

Shield Therapeutics PLC (AIM: STX)

Company Summary

WALBROOK INVESTOR RELATIONS

February 2023

Investment Profile

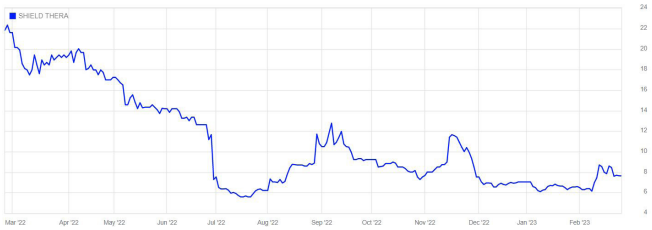
- Disruptive Innovator in the Oral Iron Market
- Collaborative sales agreement (Viatris) for Accrufer® in the US
- New funding of $36.7mln (gross) via a combined equity & debt fundraising
- Cash resources sufficient to support operations through cash flow break-even by end of 2024

Share Information

Ticker	STX
Share Price	7.70p
Shares in issue	215.85m
Market Cap	£45.10m

(Source: The London Stock Exchange, February 2023)

12-Month Share Price



(Source: The London Stock Exchange, February 2023)

Major Shareholders (as of February 2023)

Name	%
AOP Orphan International AG	27.0
Inventages	9.56
Jupiter Asset Management	6.34
Hargreaves Lansdown (EO)	5.80
Jarvis Investment Management (EO)	5.29
Premier Fund Manager	5.12
Interactive Investor (EO)	3.53
AJ Bell, stockbrokers (EO)	3.14

Key Newsflow

Feb '23: Full Year Trading Update
Jan '23: Partial AOP loan conversion
Jan '23: Result of GM & Open Offer
Dec '22: Successful completion of US$18.5m Equity Fundraise
Sept '22: Collaborative Sales Agreement signed with Viatris
Aug '22: Republic of Korea update

Company Overview

Shield Therapeutics PLC (AIM: STX) is a commercial stage specialty pharmaceutical company with a focus on addressing iron deficiency with its lead product **Accrufer®/Feraccru®** (ferric maltol) - a novel, non-salt oral therapy for adults with iron deficiency with or without anaemia.

Accrufer®/Feraccru® has a novel mechanism of absorption compared to other oral iron therapies and has been shown to be an efficacious and well-tolerated therapy in a range of clinical trials. It has been developed to overcome the side effect profile of salt-based oral iron therapies and provides an alternative treatment to IV administered iron.

FDA, EMA & Swiss approved

Shield launched Accrufer® in the US in mid-2021 and recently signed an exclusive, multi-year collaborative sales agreement with Viatris to expand commercial footprint. Feraccru® is commercialised in the UK and European Union by Norgine B.V., who also have the marketing rights in Australia and New Zealand.

Shield also has an exclusive license agreement with Beijing Aosaikang Pharmaceutical Co., Ltd., for the development and commercialization of Accrufer® / Feraccru® in China, Hong Kong, Macau and Taiwan, with Korea Pharma Co., Ltd. in the Republic of Korea, and with KYE Pharmaceuticals Inc. in Canada. Accrufer®/Feraccru® has patent coverage until the **mid-2030s**.

Signed Collaborative Sales Agreement with Viatris in the US

The oral iron market in the United States is an estimated US$2.3 billion market opportunity, and Accrufer® is the **first and only FDA approved oral iron** to treat iron deficiency, with or without anaemia.

In December 2022, Shield entered an **exclusive, multi-year agreement with Viatris Inc.** (NASDAQ: VTRS), a global healthcare company, to co-commercialise **Accrufer® (ferric maltol)** in the United States. This is a transformational deal for the Company and provides a path to sustainable profitability from the end of 2024E onwards.

This collaboration expands the commercial footprint and resources for Accrufer®, and will result in a 100-person sales team which will promote Accrufer® to over 12,000 Health Care Professionals that write the majority of oral iron prescriptions. This more than trebles the size of sales force promoting Accrufer.

Key Terms of Agreement include:

- **Upfront payment:** US$5M one-time payment
- **Milestone Payments:** Sales milestones payment up to a total of US$30M
- **Revenue Split and Marketing Costs:** Shield and Viatris will share revenues & marketing expenses

Key benefits include:

- Significant expansion of commercial resources with 100% dedication to Accrufer promotion in the US
- Ability to utilize Viatris expertise in digital marketing, payer access and distribution

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For more information email: Shield@walbrookpr.com
Tel: 020 7933 8780; web: www.walbrookpr.com

Commercialisation of Feraccru®/Accrufer® Outside US

Feraccru® is commercialised in **Europe** by the company's license partner **Norgine BV**. Shield has reported that the net sales in Europe by Norgine increased c.10% in 2022 - **Germany** now accounts for c.72% of the total net sales, followed by the **UK** with c.18%. Norgine has also begun expanding its call reach into Women's Health practitioners in Germany at the end of 2022.

In **Canada**, out-licensing agreement signed with KYE Pharmaceuticals in 2022 to bring Accrufer to Canada upon completion of the respective clinical and regulatory processes (expected in H2:2023).

Ongoing enrolment in Pivotal Trial in **China**, with Beijing Aosaikang Pharmaceutical Co., Ltd has completed its PK study, an essential regulatory requirement, and continue to enrol patients in the Phase 3 registrational trial. Shield is now working with Aosaikang Pharma to progress enrolment and advance the program.

Korea Pharma Co. Ltd reached agreement with the Korean Food and Drug Administration that a single pharmacokinetic study will be required to support a New Drug Application. Korea Pharma recruited the first subject in this study in January 2023. Approval is expected by the end of 2024.

Main Commercial Priorities

- Increase awareness
- Grow prescriptions
- Expand payor coverage

Trading Update Highlights

- Unaudited Revenue of £8.5 million (FY21: £1.5 million)
- Cash resources sufficient to support operations through to cash flow break-even by end of 2024
- 2022 has been a landmark year for Accrufer, marked by consistent improvements across all key performance indicators – increase product adoption, sales growth, physician awareness, expand payor coverage and positive clinical experience
- Completion of Viatris collaborative sales agreement has set Accrufer® up for strong 2023 growth in prescriptions and product sales

Experienced Management Team

The skilled Senior Executive Team and Board of Directors provide strong leadership for the Company's future growth.

Greg Madison 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.

Hans-Peter Rudolf joined Shield as **CFO** in March 2021 with extensive international experience, particularly in the US.

Growth Drivers

- Significant revenue potential
- Operating in large and growing markets, esp. in the US, ready for innovative disruption
- Positioned for growth and profitability
- Global partnerships continue to progress
- FDA Approved Potential Best in Class Solution
- Addressing an unmet need

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.

https://bit.ly/3XWsMCM

Please also find a link to the most recent interview conducted with Shield's CEO, Greg Madison, where he speaks to Proactive after releasing a full year trading update for 2022 that showed significant growth in revenues.

https://bit.ly/3IQiyPM

Visit the Company's new corporate website here: https://www.shieldtherapeutics.com/

Forecasts (Consensus forecasts compiled by Factset)

	DEC'21(Actual)	DEC'22 (Est.)	DEC'23 (Est.)	DEC'24 (Est.)
Sales (£m)	1.5	8.5	24.8	82.0
EBITDA (£m)	(17.8)	(17.3)	(21.3)	8.6
PBT (£m)	(19.8)	(18.5)	(23.1)	6.1