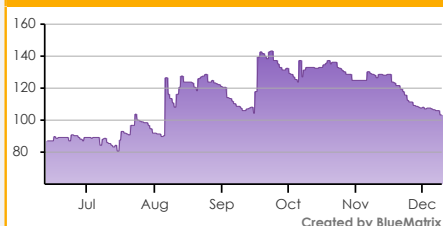


11 December 2020

Healthcare

52-WEEK HIGH	190.25p
52-WEEK LOW	39.10p
PRICE	76.00p
MARKET CAP (M)	£89

Share Price



Major Shareholders

W Health	47.7%
MaRu	10.7%
Carl Sterritt	6.96%
Shares in issue	117,347,035
Avg Three-month trading volume	133,390
Primary Index	AIM
Next Key Announcement	Confirmation of commercial strategy

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Shield Therapeutics: US commercial update and cash reach extension

Shield Therapeutics PLC (STX) has updated on its commercialisation plan for the US market for its oral treatment Feraccru, (Accrufer in the US) to treat iron deficiency. While the company has engaged with a range of potential commercial partners for Accrufer, it is unlikely to conclude a deal in 2020 as planned, although STX remains confident that there is still room for negotiating on advantageous terms.

STX has moved to provide financial headroom to the end of 2021 via debt financing, initially obtaining c. £4m from two key shareholders. Its strategic options now include an independent launch in the US facilitated by a lean infrastructure. With a successful market strategy, this could enable STX to recoup substantially greater medium-to-long term returns on Accrufer, in an iron replacement market worth up to US\$1bn, than via a profit share or on a royalty basis.

The company is confident that Accrufer's prospects remain attractive given that it is well-tolerated, has comparable efficacy to standard-of-care, and particularly given that it can be administered safely in a home setting.

While STX has not yet concluded a licensing deal for lead product Accrufer in the US iron deficiency market, the company reports that this is based largely on 'adverse business events', possibly related to COVID-19 related market conditions of the counter-parties' existing products.

The attractions of an oral treatment include its ease of administration and comparable long term efficacy to intravenous (IV) iron and good tolerability, which position it as a real alternative to standard-of-care. The commercial strategy includes the option for a self-funded launch of Accrufer via a lean marketing model. The benefits of adopting e-marketing and promotion as opposed to in-person selling, including lower costs and the potential to operate equally if not more efficiently, have been heightened during the lockdown.

Shield estimates that there are around 10 million iron deficiency anaemia patients and up to 30 million in the iron deficiency pool, forming a US iron replacement market worth up to US\$1bn and still growing. The characteristics of Accrufer position it to take a substantial share of this market (peak sales target of several hundred million dollars per annum).

New advances in treating severe anaemia in Chronic Kidney Disease (CKD) patients including the imminent approval decision on Roxadustat (Fibrogen/AstraZeneca) by the US Food and Drug Administration (FDA) can be a catalyst for the adoption of Accrufer in this indication. The former is a first in class oral treatment, with IV iron replacement therapy integral to treatment regimes. Since at-home care of CKD is one of the goals outlined in the recent executive order, "Advancing American Kidney Health", Accrufer appears to be an attractive companion product in this regard, particularly given the additional burden on CKD dialysis patients of accessing a transfusion clinic and IV administration. Fibrogen estimates that around five million of the 37 million CKD patients in the US have anaemia.

Tim Watts joined the company as interim chief financial officer in August 2018 and was appointed **chief executive officer** in April 2020. He brings with him more than 25 years' experience in the pharmaceutical and biotech sectors.

Hans Peter Hasler: Non-executive chairman, he previously held senior exec roles at Biogen, Elan Pharma and Wyeth. Current non-exec roles at HBM Healthcare Investments and Minerva Neuroscience.

If Accrufer gains good commercial traction, Shield may derive higher medium-to-long term returns via an independent strategy than via partners

STX will conduct more research into the feasibility of launching Accrufer itself, and at the same time continues licensing discussions. Options also include executing a hybrid strategy via sub-licensing or co-promotion partners in specific indications. The company's initial cost estimates are for US\$30-40m to cover its own launch costs, and to run a paediatric study until the group starts generating cash. The intention is to focus on debt financing to minimise dilution; initially, a loan facility has been arranged through substantial shareholders, demonstrating their commitment to the strategy, to take the cash runway to the end of 2021 with commitments from shareholders AOP International (10.7%) and Dr Christian Schweiger (3.5%) for an aggregate convertible loan of £4m gross at 10% per annum interest.

If STX commercialises Accrufer in the US it will likely incur higher near term expenses than via partnering although these could be minimised by using e-detailing and online marketing techniques. It is also likely to receive a much higher proportion of net product sales to recoup returns on its investment provided it achieves commercial traction. Conversely, partnering would likely provide cash inflow from upfront and milestone payments, although, at 15-20% royalties on sales, for example, longer-term returns on product sales would be shared with a partner.

Conclusions: While the market expectation was for a US deal or deals in 2020, the company has acted to broaden its options and maximise returns under the circumstances and remains confident about the commercial prospects of Accrufer. Judging by industry metrics, if Accrufer gains good commercial traction, Shield may derive higher medium-to-long term returns via an independent strategy. In the interim, it seeks to fund ongoing operations via debt funding to minimise dilution, while reviewing the overall commercial strategy and extending its search for partners.

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