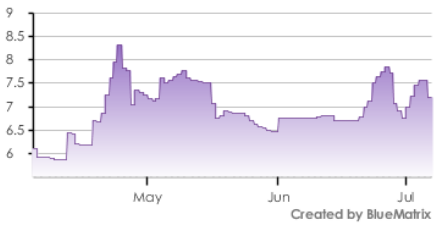
SHIELD THERAPEUTICS (LON:STX)

October 3, 2023

Healthcare

52-WEEK HIGH	**14.50p**
52-WEEK LOW	**5.80p**
PRICE	**11.36p**
MARKET CAP MLN	£78.43

Share Price



Major Shareholders

AOP Health (40%)

Shares in issue	713,036,342
Avg Three-month trading volume	1,778,377
Primary index	AIM

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Shield Therapeutics: Accrufer progressing nicely, new finance put in place

Commercialisation going well, guidance refined

Shield Therapeutics' Q2 results and commentary suggest the US commercialisation of Accrufer (ferric maltol), which is conducted in collaboration with Viatris, continues to go well. However, the company has trimmed back its prescription volume guidance by c15-20% and highlighted that a high level of heavily discounted prescriptions - which had been thought might have started to reduce by now - is continuing to depress the average net realised price per prescription.

The commentary on Q3 performance confirms an upward trend in sales trajectory, with an inflexion point now clear after the joint marketing operation became effective in Q2. Shield has issued new guidance for prescription volume this year of 100-130K (from 125-160K previously) and made broadly similar changes to those of 2024 and 2025. The 2023 figure would suggest a Q4 sales volume of between 45-75k prescriptions (i.e. 60-160% sequential Q-on-Q growth). We view this as a refinement and note that even after this, the wide Q4 range highlights the fact that projections are still highly uncertain at this relatively early point in the commercialisation phase.

The results were accompanied by US$6.1mln equity fundraising as well as a US$20mln debt facility, both now completed, which should provide further growth capital and allow it to recruit a market access team to address an issue that is currently depressing the net realised price per prescription.

The cash position at the end of June was US$13,6mln (c£10.7mln). The funds raised in the placing and open offer were used to redeem the US $5.7mln convertible debt held by AOP Health. The pro forma cash position at the end of September can be estimated at cUS$9m. With the new debt facility providing an additional US$20m of headroom, Shield believes it has sufficient resources to fund operations until it reaches projected cash flow breakeven in 2025 (previously end of 2024).

Investment proposition

We continue view Shield's investment case very positively. The US is the key market for Accrufer and Shield is now operating with an appropriately sized sales force to the market opportunity. The US is the central element in the investment case, although the drug is under development elsewhere (by various partners) and marketed in Europe by Norgine, although it has underperformed expectations there.

Assuming an estimated US$9mln/£7mln pro forma net cash, Shield's enterprise value (market cap less net cash) would be c£55mln/US$67mln, based on an estimated c799mln shares in issue post funding. A valuation metric based on EV/sales should in our view be adjusted to reflect Viatris' 45% interest in US Accrufer sales. On this basis, Shield's EV/sales would be 1.6x based on possible 2024 sales of ~US$65m. We consider this to be low for a high-growth company and to highlight an attractive investment case. An indicative valuation for the stock would probably be in the region of 50p/share in our view.

Year end Dec 31	2021	2022
Revenue (£mln)	2	5
Gross Profit £ mln	0.5	2.0

Greg Madison, chief executive, was previously CEO of Melt Pharmaceuticals and Keryx Biopharmaceuticals (2015-2018), during which time he launched Aurixia for hyperphosphataemia and iron deficiency anaemia.

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

2024-25 expectations reset based on volume and price

Shield's Q2 results were broadly in line with expectations given the July trading update, but the modified guidance has led to an adjustment to market expectations for 2024-25 based on both volume and net realised price.

Revenue in the H1 2023 was $4.3mln (+66%), of which US$3.7mln was from Accrufer sales in the US (the balance of US$0.6mln being royalties from Norgine in respect of Feraccru sales in Europe). Sales volumes in Europe were up by 19% sequentially vs H2 2022, but continue to underperform relative to the US.

We would tentatively estimate US Accrufer sales for 2023 to be in the region of $14-15m (115K prescriptions at $120-130/Rx) so total revenues (including royalties from Norgine) are likely to be US$15-16m. However, this should rise quickly in 2024 as both volumes and - it is to be hoped - net realised price both rise. Assuming a baseline prescription volume of 350K and the average net realised price per prescription of say $160 (e.g. a 70:30 split of reimbursed: discounted prescriptions) could deliver revenues in the region of US$60mln.

Prescription volume guidance refined

Shield has refined its estimate for US prescriptions volume this year to 100-130K (from 125-160K previously), which would require Q4 sales volumes of 45-75k (i.e. 60-160% sequential Q-on-Q growth). Even after this, the still wide Q4 range highlights the fact that projections are highly uncertain at this relatively early point in the commercialisation phase.

Longer term, Shield now projects prescription volumes for 2024 and 2025 of greater than 350K and 500K respectively, compared with previous ranges of 370-420K and 550-600K. This new guidance for 2024-25 may, however, represent Shield being more cautious and potentially allow room for upgrade in the future. Shield has also revised its longer term, 2025 revenue forecast to at least US $120mln (previously $150mln)

Shares issue and new funding

Shield has completed a US$6.1mln (£5.0mln) equity fundraising of up to 62.4m shares at 8p/share and a retail offer of up to c.£1.1mlm on the same terms, which could potentially result in the issue of an additional 14.3m shares. The placing price was a 17.9% discount to the mid-market price of 9.75p on 27 September.

Most of the proceeds have been used to redeem the convertible note held by AOP Health (£5.7mln, including accrued interest). AOP, which is also Shield's largest shareholder, also intends to exercise all of its warrants (c.5.1m), which should generate funds of £350k. We estimate if the retail offer is fully taken up, these three transactions will result in Shield having c799m shares in issue and pro forma cash of US$9mln.

US$20mln loan facility

Shield has separately agreed a $20m term loan facility with SWK Holdings (a specialist US debt provider to pharmaceutical companies), secured over its IP rights. The loan has a five-year term (repayable in October 2028), with interest (SOFR +9.25%, so currently c.14.6%) payable quarterly in arrears. The principal repayments will be paid at $1m per quarter from Q4 2025, with a final balloon payment ($8m) repaid at term. The loan has an arrangement fee of 1.0% (ie. US$0.2mln) and a final payment fee of 6% (ie. up to $1.2m) as well as 6% warrant coverage and other customary terms (covenants etc). Shield considers the terms to be competitive in the current environment and selected SWK from ~10 providers.

Reimbursement and PA issue

The average net sales price for Accrufer in US was US$119 in H1 (vs. US$124 in H1 2022) and expectations were that this would be starting to rise by now. Shield has highlighted that the main reason for this is the high rate (c50%) of discounted prescriptions versus reimbursed ones. Around half the prescriptions are being reimbursed by commercial payers at a price of c.$250-260 per month (roughly half the Average Wholesale Price of c.$530 per month), with the balance of going through the Patient Access Program (PAP). These discounted prescriptions, which have only a US$25 co-pay, are effectively provided free of charge by Shield, depressing the average revenue/prescription. This is known as the gross-to-net (GTN) adjustment.

Shield has determined that the issue is being caused by physicians failing to seek prior authorisations (PAs) even when they could do so and the patient would be reimbursed. It intends to address this issue with a 12-person "market access" team dedicated to supporting physicians to navigate the system, rather than this being a subsidiary role of the salesforce. The requirement for prior authorisations is a well-known phenomenon in the US market and is particularly problematic in this case because of the presence of generic oral iron products. In addition, it intends to modify the PAP program, by requiring a PA submission to occur before the patient can access preferred cash price, with effect from early Q4.

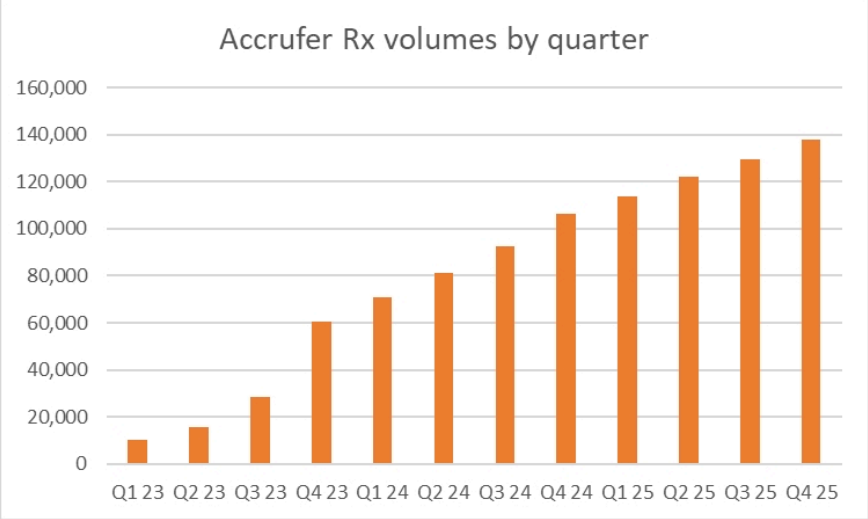
Point of inflection in growth curve

A particularly positive item is that the inflexion point in the growth trajectory anticipated as a result of the salesforce expansion can now clearly be seen, even though the full effect of an increase in promotional activity does not usually translate into new prescriptions for three to five months, so would not have been expected before late Q3 or Q4.

In particular, the sequential quarter-on-quarter prescription volume growth was an estimated 80% in Q3 (up from 53% in Q2). All the other key performance indicators (KPIs) are trending in a positive direction: eg the month-on-month growth in prescriptions has averaged 26% from May to August, with first-time prescription writers increasing by 157%; new prescriptions increased by 63% and there is a high proportion of repeat writers (73% in Q2). Shield and Viatris have also been able to expand the number of covered lives by securing agreements with Medicare in California and New York. This has added 23m payer lives.

Sales volume projections modified

We have revised and updated our Accrufer's sales model to reflect the mid-point of Shield's 2023 target for US prescriptions this year (115K) and the low end of its new guidance for 2024 and 2025 (now >350k and >500K). This is shown in the graphic.



Ironic marketing campaign

Shield is continuing to use a promotional campaign with ads based around the concept that Accrufer removes the “irony” associated with generic ferrous iron supplements whose GI side effects often make patients feel worse than the anaemia for which they are prescribed. Accrufer is differentiated from these products by its very tolerable side effect profile.

Financials

We do not publish detailed financial forecasts for Shield. However, we have indicated sales for 2023 should be in the region of US $16-17mln and US$60-65mln in 2024. Shield has indicated an expectation of sales of at least $120mln by 2025. We observe that the 2025 sales forecast would require an increase its average net realised price from the current US$120 to US$240. This could be achieved by reducing the proportion of discounted scripts as well as reducing the discount the reimbursed price represents to the AWP (although this would require renegotiation of contracts with payors).

We also anticipate a rise in the royalty from Norgine but from a low base. European sales (as Ferracru) are likely to remain a fraction on the US figure for Accrufer, despite the markets being of a broadly similar size. The development of Accrufer in China has been slow,

primarily for logistical reasons connected with the pandemic. However, there are potentially important milestones from ASK Pharm due on regulatory approval and launch in China.

We expect there to be an increase in selling, general and administrative (SG&A) and cost of sales going forward, The latter now includes a payment to Viatris equivalent to 45% of sales. Underlying SG&A expenses were US$17.2mln in H1. We would expect this figure to be around US$35m for 2023 and potentially increase by ~20% rise in 2024 to reflect the costs of the new market access team.

The cash position at the end of June was US$13,6mln (c£10.7mln). The funds raised in the placing and open offer will largely be used to redeem the US$5.7mln convertible debt held by AOP Pharma. The pro forma cash position at the end of September can be estimated at cUS$9m. With the new debt facility providing an additional US$20m of headroom, Shield believes it has sufficient resources to fund operations until it reaches projected cash flow breakeven in 2025 (previously end of 2024).

As a result of the share issue, there will be up to 799mln shares in issue. AOP has taken up shares to maintain its 40% shareholding and remains the largest shareholder.

Valuation observations

Shield's market capitalisation would be US$74mln (£61mln) based on an estimated c799mln shares in issue post funding. Thus with an estimated US$9mln/£7mln pro forma net cash, the enterprise value (market cap less net cash) would be US$67mln/£54mln.

Valuation metrics based on EV/sales are probably most useful at this point, but in this case should be adjusted to reflect Viatris' 45% interest in US Accrufer sales in our view. On this basis, Shield's EV/sales would be 1.6x based on possible 2024 sales of ~US$65m. We consider this to be low for a high-growth company and to highlight an attractive investment case.

An indicative valuation based on a discounted cash flow would probably be in the region of 45-50p/share in our view.

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