Pharmaceuticals & Biotechnology

Source: Refinitiv

Market data

EPIC/TKR	**STX/SHIEF**
Price (p)	**41/0.64**
12m high (p)	140/1.50
12m low (p)	33/0.57
Shares (m)	215.9
Mkt cap (£m)	88.5
EV (£m)	65.9
Free float*	43%
Primary country of listing	UK
Market	AIM/OTCQX

**As defined by AIM Rule 26*

Description

Shield Therapeutics is a de-risked pharmaceutical company with a lead product, Feraccru/Accrufer, approved in Europe and the US for the treatment of iron deficiency in adults. Outside the US, the strategy is to use distribution and commercialisation partners in return for royalties and sales milestones. In the US, Shield has just launched Accrufer itself.

Company information

CEO	Greg Madison
CFO	Hans-Peter Rudolf
Chairman	Hans Peter Hasler

+44 191 511 8500
www.shieldtherapeutics.com

Key shareholders

Directors	3.2%
Inventages	25.9%
AOP Orphan AG	13.1%
Hargreaves Lansdown	8.0%
Jupiter AM	5.6%
Interactive Investor	5.4%

Diary

23 Sep	Hardman LS forum
Feb'22	Final results

Analyst

Martin Hall 020 3693 7075
mh@hardmanandco.com

SHIELD THERAPEUTICS

Focused on US market penetration

Shield Therapeutics (Shield) is a commercial-stage pharmaceutical company delivering specialty products that address patients' unmet medical needs, with an initial focus on treating iron deficiency (ID). Accrufer® has just been launched in the US by Shield, where the initial aim is to greatly improve market awareness of its differentiating characteristics as an oral ID drug. In other territories, Feraccru® is being commercialised through licensing and partnerships. The US market has enormous potential, but, even on conservative forecasts with respect to market penetration, Shield is forecast to become profitable and cash-generative in 2023.

- **Strategy:** Outside the US, Shield's strategy is to out-license commercialisation rights to partners with appropriate expertise in target markets, which has been successfully achieved in Europe and China. In the US, Shield has decided to sell Accrufer itself, thus retaining a greater share of profits for shareholders.

- **Accrufer launch:** Accrufer was launched in the US on 1 July, with the strapline "Discover the legend of tolerable oral iron". New market research has indicated that Shield needs to raise awareness of Acrrufer's clinical profile and positioning with the key prescribers responsible for 60% of oral iron Rx.

- **Valuation:** DCF-modelling each of the three main income streams – the US, Europe and China – generates an NPV, which, summed together, gives an EV for the group of $852m/£608m, or 281p per share. The current share price clearly applies a hefty discount for the execution risk associated with Accrufer.

- **Risks:** While there remains regulatory risk in China and Korea, Feraccru/ Accrufer has been de-risked by regulatory approvals in Europe and the US. There is execution risk associated with Shield's go-it-alone strategy in the US, with a 12-month goal to increase awareness and establish payor coverage.

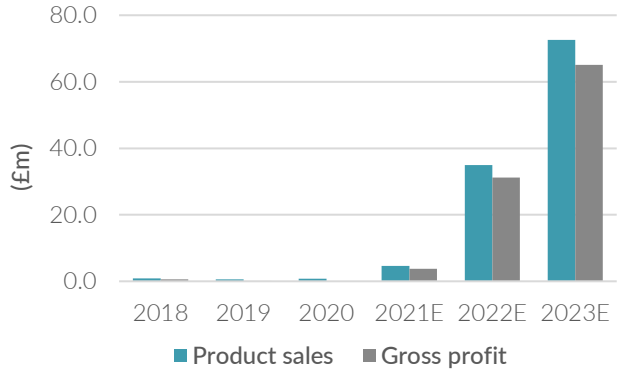
- **Investment summary:** The Shield-led launch of Accrufer was always the best option, in our opinion. Now that the period of commercial uncertainty in the US is over, the near-term target is to raise awareness, promote patient access programmes and establish payor coverage. The market seems overly worried about the "apparent" slow start, but any news on sales traction and/or the signing-up of payors should act as a catalyst to narrow the valuation disconnect.

Financial summary and valuation

Year-end Dec (£m)	2018	2019	2020	2021E	2022E	2023E
Product sales	0.86	0.62	0.70	4.60	34.90	72.60
R&D	-4.30	-2.50	-2.58	-3.30	-2.70	-2.70
Other income	11.03	0.10	9.66	0.00	0.00	12.55
EBITDA	-2.47	-6.41	0.55	-22.28	-1.68	42.27
Underlying EBIT	-3.26	-9.04	-2.15	-24.99	-4.38	39.57
Underlying PBT	-3.26	-9.07	-2.15	-24.59	-4.19	39.87
Statutory PBT	-5.16	-9.07	-1.89	-24.59	-4.19	39.87
Underlying EPS (p)	0.09	-7.52	-1.32	-12.28	-2.13	15.43
Statutory EPS (p)	-1.55	-7.52	-1.58	-12.28	-2.13	15.43
Net (debt)/cash	9.63	4.12	2.91	7.79	5.44	43.18
Equity issues	0.00	0.03	0.01	29.20	0.00	0.00
EV/sales	-	-	-	13.3	1.8	0.9

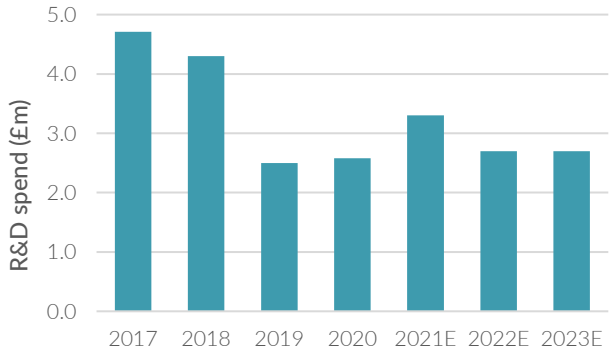
Source: Hardman & Co Life Sciences Research

Product sales and gross profit



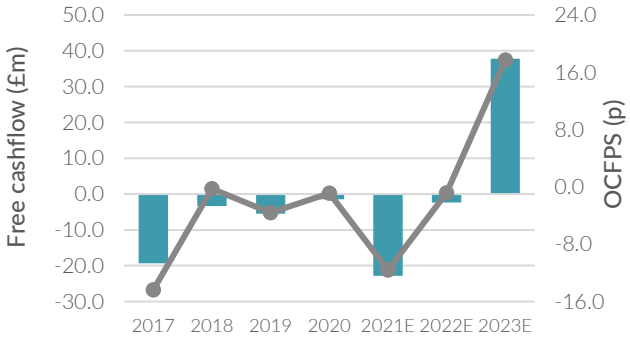
- Until fiscal 2021, product sales represent the royalty stream from commercial partners.
- Future product sales are expected to be dominated by Shield's sales of Accrufer in the US.
- Launch of Feraccru in China is forecast towards the end of 2023 and could generate a significant royalty stream moving forward.
- Sales milestones from commercial partners are not included in these product sales figures.

R&D investment



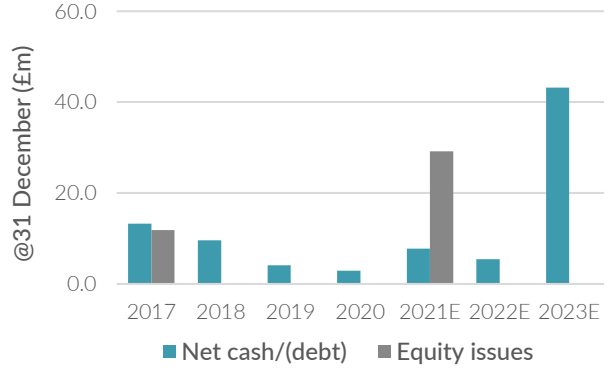
- Underlying R&D spend is around £0.5m-£1.0m p.a.
- R&D spend in 2021 and 2022 is expected to rise, reflecting the regulatory need for a paediatric study.
- The paediatric study is forecast to cost $6.5m/£4.5m over a two-year period, but commencement of the trial will remain flexible.
- When Shield becomes cash-generative, it will have the option to develop its phosphate binder product in the development pipeline.

Free cashflow and OFCPS



- Shield has been cashflow-negative during the build-up of royalties from commercial partners in Europe.
- As soon as there is sales traction in the US, the cashflows of the company are transformed.
- 2021 cashflow is dominated by the initial launch costs associated with Accrufer in the US.
- Surplus cash from fiscal 2023 could be used to develop the phosphate binder asset.

Net cash/(debt) and equity issues



- Net cash at 30 June 2021 was £25.6m.
- The fundraise, in March 2021, raised £27.7m net of expenses.
- Net cash appears to be relatively low again at the end of fiscal 2022, but, by this time, Shield is expected to be cashflow-positive and management will know more about the quarterly cashflows being derived from the US.
- On an organic basis, Shield may not need to return to shareholders for more capital, but it could choose to do so to reduce balance sheet risk.

Source: Company data; Hardman & Co Life Sciences Research

2021 interim results

Operational highlights

- **Capital raise:** The most significant event in 1H'21 was the relatively large equity increase to provide the funds to commercialise Accrufer in the US by itself, thereby retaining more of the forecast profitability for shareholders.
- **Management:** With the funds in place, the consultants used in the US during 2H'20 became full-time employees of Shield. In addition, Tim Watts stepped down as CEO in June 2021 following the appointment Greg Madison, who will be supported by the appointment of a CFO, Hans-Peter Rudolf (March 2021).
- **Feraccru in China:** Shield's partner in China, ASK Pharma, received authorisation from the Chinese regulator to conduct two clinical studies in parallel to support a New Drug Application (NDA). These should be completed by the end of 2022, with a potential launch in 2023.

Financial highlights

- **Product sales:** Underlying sales, effectively royalties on net product sales in European markets from Norgine, were slightly better than forecast, increasing by 113% to £0.48m (£0.23m).
- **COGS:** Manufacturing costs were difficult to predict. The 1H'20 comparator was influenced by a one-off payment to the original IP holder, Vitra Pharmaceuticals (Vitra). In addition, 1H'21 was affected by pre-launch manufacturing activities for Accrufer in the US.
- **SG&A:** Underlying administration expenses were in line with expectations, at -£5.9m (-£4.6m) due to increased costs associated with the build-up of US operations ahead of the Accrufer launch.
- **R&D:** Investment in R&D was marginally higher than expected at -£1.6m (-£0.7m) due to stage 1 of the paediatric Feraccru study, the start of which had been delayed until 2H'20 by COVID-19., and some early work on stage 2.
- **Fund raise:** In order to fund the commercialisation of Accrufer in the US, Shield raised £27.7m (net) new capital in March 2021, at 30p per share.
- **Net cash/(debt):** Shield ended the period with net cash of £22.6m (no debt or financial leases), which is expected to be sufficient to take the company through to profitability and cashflow-breakeven in 2023.

Interim results – actual vs. forecasts

Half-year to June (£m)	1H'20 actual	1H'21 actual	Growth %	1H'21 forecast	Delta Δ
Gross revenue (as reported)	8.92	0.48	n/m	0.35	+0.13
Product sales	0.23	0.48	+113%	0.35	+0.13
COGS	-1.01	-0.41	n/m	-0.50	+0.09
SG&A (underlying)	-4.61	-5.86	+27%	-6.00	+0.14
R&D	-0.68	-1.59	n/m	-1.40	-0.19
Other income	8.69	0.0	n/m	0.0	-
EBITDA	3.67	-6.35	n/m	-6.25	-0.10
Underlying EBIT	2.39	-7.64	n/m	-7.55	-0.11
Underlying EPS (p)	2.67	-3.98	n/m	-4.00	-
Net cash/(debt)	6.52	22.60	-	22.00	+0.60

n/m=not meaningful
Figures may not add up exactly due to rounding
Source: Hardman & Co Life Sciences Research

Five areas of progress

The 2021 interim results were not really about the financial performance, but more about what the new management team had to say about the operational progress at the company in a period that has seen a remarkable level of activity. In our opinion, progress during 2021 – including post-period events – can be divided into five areas.

Accrufer launch in the US

Accrufer launch was a significant achievement

The most significant achievement was the launch of Accrufer on 1 July 2021 into the important US market, which represents a significant commercial opportunity for the company.

In May 2021, we published[1] a detailed review of the US Accrufer opportunity. Following approval by the FDA in July 2019, Shield initially investigated working with a partner for the commercialisation of this drug, taking a similar approach to that adopted for Europe. However, as time passed and, in the absence of suitable terms from potential partners, Shield realised that it could commercialise Accrufer itself, thereby retaining more of the long-term profitability for shareholders. However, it would need a stronger balance sheet in order to achieve this.

In March, the company approached existing and new shareholders, which resulted in a successful equity issue, raising £27.7m, net of expenses, to fund this opportunity. The rest is now history and Accrufer was officially launched in the US on 1 July, which represents a significant accomplishment by the company over a relatively short timeframe.

Market research

Additional market research highlighted medical need for Accrufer…

…but also low awareness among clinicians about its clinical attributes

In making the decision to commercialise Accrufer by itself, Shield, in part, was influenced by some market research that had been undertaken by potential partners and shared with the company. As part of its pre-launch activities and with the relevant financial resource following the fundraise, Shield commissioned its own market research in order to obtain informative reactions and feedback from healthcare professionals and to help it position Accrufer at launch. It was comforting to note that its own research generated similar findings, but also added to the market research generated previously for third parties.

- Clinicians are not satisfied with current oral therapies and are seeking an effective and well-tolerated oral iron product.
- Despite the desire for an improved oral iron therapy, awareness among clinicians about the pending launch of Accrufer was very low.
- On hearing about the clinical attributes of Accrufer, there was a favourable response from clinicians and considerable interest in learning more about the product.

Accrufer positioned as second-line oral therapy

These outcomes helped Shield with the positioning of Accrufer at launch as both a first-line oral therapy and as a second-line oral therapy to be used after a traditional iron salt OTC or prescription had failed but before moving to intravenous iron replacement.

[1] https://www.hardmanandco.com/research/corporate-research/accrufer-launch-on-schedule/

Marketing material

Marketing initiatives reflect feedback from market research

At launch, and during the subsequent 12 months, Shield has embarked upon three key marketing tactics:

- promotional tools for healthcare professionals to significantly improve awareness of Accrufer and its clinical profile;
- patient access material to help reduce the cost of Accrufer for specific categories of patients – notably flexible pharmacy options, CoAssist (co-pay) and a simple saving programme; and
- digital marketing.

Shield's marketing tactic to promote awareness of Accrufer is the strapline: "Discover the legend of tolerable oral iron" as can be seen below in the advertising literature for clinicians and healthcare professionals.

Key marketing strapline: "Discover the legend of tolerable oral iron"

Source: Shield interim results presentation

12-month targets

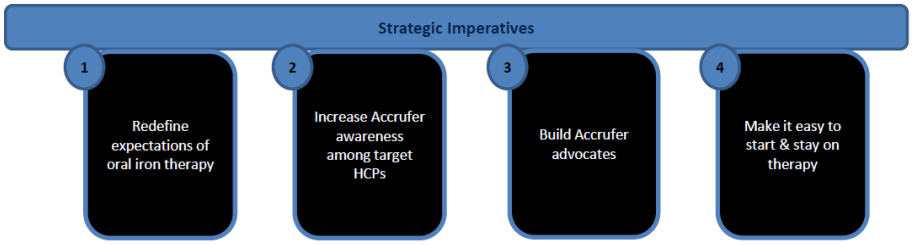
Although the company, understandably, did not go into any details about its 12-month targets for Accrufer, it was reassuring to know that the launch had been well thought through despite the limited time that had been available, and that the key areas of focus were to:

- increase the awareness of Accrufer;
- generate clinical experience with patient access programmes; and
- establish payor coverage.

Management has defined near-term critical success factors

It was also reassuring to note that management recognised where the risks lay, and that it had determined which are the critical success factors, as highlighted in the following graphic, included in its presentation.

Critical success factors



Source: Shield interim results presentation

Working with Norgine

Royalties on European sales received from Norgine in 1H'21, at £0.48m, were up 113% (CER) compared with 1H'20, which was affected by the global lockdown caused by COVID-19. This suggests that in-market sales are running at an annualised rate of ca.€10m. There will always be timing differences between the receipt from Norgine and actual in-market sales of packs of Accrufer. For example, Shield stated that the sale of in-market packs rose 51% during the period.

Overall, from an analyst's perspective, the performance of Feraccru in Europe has been disappointing with most sales coming from Germany and the UK only. However, Norgine's hands have been tied over the past 18 months by the slow rate of agreement on reimbursement in a number of countries, which, itself, was also hampered by COVID-19.

Nevertheless, progress is being made and Feraccru is now available in Germany, with reimbursement negotiations either under way or due to start in five additional European countries – Scandinavia, Benelux, France, Italy, and Spain. Despite this, our forecasts will remain on a conservative basis – i.e. slow and steady adoption.

Development in China

ASK Pharma already made progress in China

In January 2020, Shield announced a development and commercialisation licence deal for Feraccru in China (but also including Hong Kong, Macau and Taiwan) with Beijing Aosaikang Pharmaceutical Co (ASK Pharma; XSEC:002755). Apart from providing local expertise to support the approval process in the world's second-largest pharmaceuticals market, this deal was important for a number of reasons:

- **Strategy validation:** It progresses Shield's stated strategy to out-license Feraccru to specialist organisations as part of its geographical expansion.
- **Cash injection:** The upfront payment from ASK Pharma provided a much-needed cash injection.
- **Reduced risk:** The deal reduced Shield's clinical and regulatory risk in China, where ferric maltol is not approved.
- **Local manufacturing:** It also removed Shield's responsibility to finance the development and control manufacturing and supply in China, where it does not have expertise, and where there are regulatory mechanisms in place in favour of drugs manufactured within China (e.g. exclusivity periods).

ASK Pharma is responsible for the costs associated with the clinical and regulatory activities, in addition to manufacturing and distribution in the territory.

Time to launch appears less than originally anticipated

Progress has been made, with the National Medical Products Administration (NMPA; formerly CFDA) confirming to ASK Pharma the development programme required to achieve regulatory approval for Feraccru in China. An Investigational New Drug (IND) was submitted in 2020, and the regulator has confirmed that a single 12-week clinical study in 120 IBD patients is required, together with a pharmacokinetic/pharmacodynamic study, to support an NDA. Both studies are being performed in parallel and ASK Pharma has started to screen patients for entry into the study, which is expected to complete by the end of 2022, potentially allowing launch in 2023.

Ongoing deal terms

- **Regulatory milestone:** $11.4m/£8.7m upon approval of Feraccru in China.
- **Sales milestones:** Up to $40.0m/£30.5m payable upon specified cumulative sales targets (undisclosed).
- **Royalties:** 10% or 15% of net sales for the duration of the IP in China, tiered, based on specified sales.
- **COGS:** Manufacturing costs will be paid by ASK Pharma and there is no royalty on net sales payable to Vitra.

Korea licensing deal

Upfront payment about to be received imminently

Post the period-end, Shield announced that it had signed an exclusive licensing deal for the development and commercialisation of Accrufer in the Republic of Korea with Korea Pharma Co. Ltd (Korea Pharma). This was achieved by Korea Pharma following a competitive process. As with the deal in China, Korea Pharma is responsible for all the activities required to obtain regulatory approval in this territory. It will also be responsible for the manufacture and distribution of the drug when it is approved. Consequently, the terms of the deal reflect these costs being borne by Korea Pharma:

Korea Pharma deal terms

- **Upfront payment:** $0.5m upfront on signing the deal – expected to be received imminently.
- **Regulatory/commercial milestone:** £1.5m on first commercial sale in Korea following regulatory approval.
- **Sales milestones:** Up to £4.0m payable upon specified cumulative sales targets (undisclosed).
- **Royalties:** 15% of net sales in Korea, however Shield will incur its royalty obligation to Vitra on sales in Korea.
- **COGS:** Manufacturing and distribution costs will be paid by Korea.

Paediatric study

Stage 1 complete…

…with stage 2 due to start in September

As part of the regulatory approval of Feraccru/Accrufer in both Europe (Paediatric Investigation Plan (PIP)) and the US (Paediatric Development Plan (PDP)), Shield is required to perform a paediatric study. Initially, the company had planned to start this study in 1H'20, but it was delayed, understandably, by the pandemic and ended up commencing in 2H'20. A single Phase III trial is required to evaluate the safety, tolerability and efficacy of the product in infants, children and adolescents, aged between 1 month and 17 years. The trial is divided into two stages:

- **Stage 1:** To develop an age-appropriate formulation suitable for small children and infants and to demonstrate therapeutic equivalence with the adult capsule formulation in a cross-over study.
- **Stage 2:** Main part of the study looking at efficacy in 110 patients.

Stage 1 was completed during 1H'21 and Shield is now in the recruitment planning phase for stage 2 to commence in September 2021. The overall cost is expected to be $6.5m/£4.5m spread over 24-30 months, which, in part, is reflected in the large (134%) increase in R&D spend in 1H'21, albeit from a relatively low, COVID-19-affected comparator for 1H'20.

Financial summary

- **Product sales:** Reported figures represent a blend of product supply to commercial partners and royalties received from partners on net sales. Consequently, there is likely to be a time lag between drug use and receipt of royalties. Pack utilisation has shown a consistent upward trend.
- **Costs:** COGS in 2020 contained a one-off payment to Vitra; in 2021, there will be some short-term manufacturing costs for the US launch. The rise in SG&A reflects the boost to sales and marketing required for the launch of Accrufer.
- **Cash runway:** Gross cash at 30 June 2021 was £22.6m reflecting the fund raise in March. Shield is expected to become cash-generative by fiscal 2023E.
- **Forecasts:** No material changes to forecasts since our latest publication, apart from a modest re-evaluation of the split of R&D costs expected over the coming 18 months.

Financial summary

Year-end Dec (£m)	2018	2019	2020	2021E	2021E	2022E
Profit & Loss						
Gross revenues	11.88	0.72	10.39	4.60	34.90	85.20
Product sales	0.86	0.62	0.73	4.60	34.90	72.60
COGS	-0.31	-0.49	-1.35	-0.82	-3.75	-7.51
Gross profit	**0.55**	**0.13**	**-0.63**	**3.73**	**31.16**	**65.09**
Gross margin	63.7%	21.6%	33.6%	82.0%	89.3%	89.7%
SG&A	-9.52	-6.32	-7.84	-24.42	-31.84	-34.37
Share-based payments	-1.01	-0.46	-0.77	-1.00	-1.00	-1.00
R&D	-4.30	-2.50	-2.58	-3.30	-2.70	-2.70
Other income	11.03	0.10	9.66	0.00	0.00	12.55
EBITDA	-2.47	-6.41	0.55	-22.28	-1.68	42.27
Underlying EBIT	-3.26	-9.04	-2.15	-24.99	-4.38	39.57
Net interest	0.01	-0.03	0.00	0.40	0.20	0.30
Underlying PBT	**-3.26**	**-9.07**	**-2.15**	**-24.59**	**-4.19**	**39.87**
Tax payable/credit	3.36	0.27	-0.74	0.66	-0.40	-6.57
Underlying net income	0.10	-8.80	-2.20	-23.93	-4.59	33.30
Weighted avg. shares (m)	116.43	116.99	166.73	194.85	215.84	215.84
Underlying EPS (p)	**0.09**	**-7.52**	**-1.32**	**-12.28**	**-2.13**	**15.43**
Fully diluted EPS (p)	0.09	-7.26	-1.29	-12.02	-2.08	15.07
Balance sheet (@ 31 Dec)						
Share capital	1.75	1.76	1.76	3.24	3.24	3.24
Reserves	38.68	30.39	28.51	32.31	27.72	61.03
Provisions	0.00	0.00	0.00	0.00	0.00	0.00
Debt	0.00	0.00	0.00	0.00	0.00	0.00
less: Cash	9.78	4.14	2.94	7.82	5.47	43.21
Invested capital	**30.80**	**28.02**	**27.36**	**27.76**	**25.52**	**21.08**
Net cash/debt	9.63	4.12	2.91	7.79	5.44	43.18
Cashflow						
Underlying EBIT	-3.26	-9.04	-2.15	-24.99	-4.38	39.57
Non-cash items	1.81	3.08	3.48	3.71	3.71	3.69
Change in working capital	-0.26	0.56	-2.77	-1.97	-1.98	-4.87
Tax & interest	1.86	1.27	-0.09	0.69	0.86	-0.10
Operational cashflow	**-1.84**	**-5.29**	**-1.32**	**-23.25**	**-2.66**	**38.40**
Capital expenditure	0.00	0.00	0.00	-0.25	-0.50	-0.50
Free cashflow	-3.32	-5.51	-1.46	-22.86	-2.35	37.74
Acquisitions	-0.35	-0.03	-0.02	0.00	0.00	0.00
Equity issues	0.00	0.03	0.01	29.20	0.00	0.00
Change in net debt	**-3.67**	**-5.51**	**-1.21**	**4.88**	**-2.35**	**37.74**
OCFPS (p)	-0.27	-3.59	-0.87	-11.61	-0.86	17.72

Source: Hardman & Co Life Sciences Research

Company matters

Registration

Incorporated in the UK with company registration number 09761509

Registered office:

Northern Design Centre
Baltic Business Quarter
Gateshead Quays
Newcastle
NE8 3DF

+44 (0) 191 511 8500

www.shieldtherapeutics.com

Board of Directors

Board of Directors

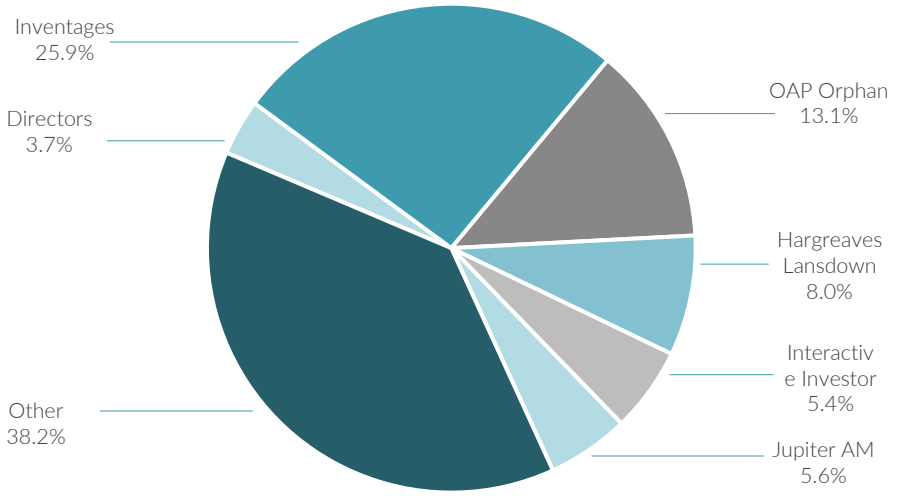
Position	Name	Nominations	Remuneration	Audit
Chairman	Hans Peter Hasler	C	M	M
Chief Executive Officer	Greg Madison			
Non-executive director	Fabiana Lacerca-Allen			M
Non-executive director	Peter Llewellyn-Davies	M		C
Non-executive director	Anders Lundstrom		C	
Non-executive director	Christian Schweiger	M		
Chief Financial Officer	Hans-Peter Rudolf*			

**An officer of the company but not presently a board member*
M = member, C = chair
Source: Company reports

Share capital

On 18 August 2021, there were 215,885,024 Ordinary shares in issue. In addition, there are 3.95m options outstanding.

Share register



Source: Hardman & Co Life Sciences Research

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research@hardmanandco.com

1 Frederick's Place
London
EC2R 8AE

+44 20 3693 7075

www.hardmanandco.com