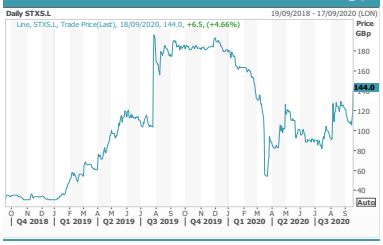
Pharmaceuticals & Biotechnology



Source: Refinitiv

Market data	
EPIC/TKR	**STX**
Price (p)	**140.0**
12m High (p)	193.0
12m Low (p)	55.5
Shares (m)	117.2
Mkt Cap (£m)	164.1
EV (£m)	157.5
Free Float*	41%
Market	AIM

**As defined by AIM Rule 26*

Description

Shield Therapeutics (STX) 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. Sales are made by distribution and commercialisation partners in return for royalties.

Company information

CEO	Tim Watts
CFO	-
Chairman	James Karis

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www.shieldtherapeutics.com

Key shareholders

Directors	0.2%
W. Health	47.8%
MaRu AG	10.7%
C.Sterritt	8.8%
Universities SS	4.3%
Jupiter AM	3.7%

Diary

2H'20	US licensing deal

Analyst

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SHIELD THERAPEUTICS

Optimism over US deal

STX is a commercial-stage company delivering specialty products that address patients' unmet medical needs, with an initial focus on treating iron deficiency (ID). Feraccru/Accrufer has been approved by the regulators in both Europe and the US. The company has an established commercial relationship with Norgine for Europe and signed a licensing deal with ASK Pharm for the Chinese market in 1H'20. Management has indicated that several discussions are ongoing to secure an optimal commercial deal for the US, which reassured the market. Meanwhile, on current assumptions, STX has a cash runway into 1Q'21.

- **Strategy:** STX's strategy is to out-license the commercial rights to its products to partners with marketing and distribution expertise in target markets. These deals allow STX to retain its intellectual property (IP) and to keep investing in its R&D pipeline, while benefiting from immediate and long-term value.

- **Interims:** STX indicated that there remains a positive trend in Feraccru use in Europe with packs sold by Norgine up 50% over the previous six-month period. Both COGS and SG&A costs were higher than expected for specific reasons, yet STX still recorded an underlying profit of £2.8m (-£3.7m) for 1H'20.

- **Deal update:** Discussions between ASK and the regulator in China have indicated that the development programme for Feraccru might be less onerous than anticipated, making a launch in 2023 possible. Discussions with multiple interested parties in the US continue, suggesting that a deal is not too far away.

- **Risks:** All drug companies carry development risk, but STX's has been limited by regulatory approvals in the EU and the US. The biggest risk now is commercial execution. Having achieved deals in Europe and China, securing a partner for Accrufer in the US remains the top priority for 2020.

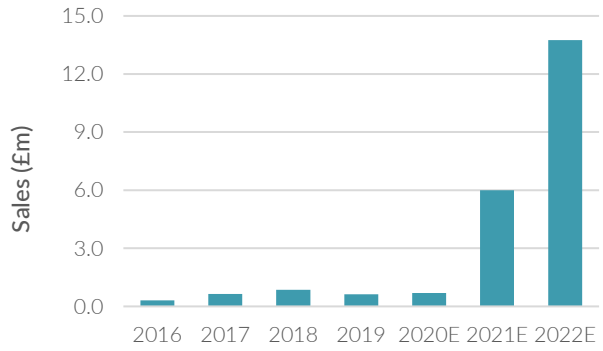
- **Investment summary:** Interim results confirmed the market's expectations and reiterated the length of STX's current cash runway in the absence of a US licensing deal. In these uncertain times, Feraccru provides a really good option to physicians seeking alternative therapies for ID patients reluctant to attend hospitals/clinics for intravenous (iv) iron therapy. Meanwhile, management reassured the market that progress is being made towards closing a US commercial deal in the near future.

Financial summary and valuation

Year-end Dec (£m)	2017	2018	2019	2020E	2021E	2022E
Gross revenues	0.64	11.88	0.72	9.39	6.00	13.75
Product sales	0.64	0.86	0.62	0.70	6.00	13.75
R&D	-4.71	-4.30	-2.50	-3.00	-3.60	-4.00
Other income	0.00	11.03	0.10	8.69	0.00	0.00
EBITDA	-18.48	-2.47	-6.41	-1.18	-4.22	1.96
Underlying EBIT	-18.90	-3.26	-9.04	-3.72	-6.76	-0.58
Reported EBIT	-20.95	-5.17	-9.04	-3.72	-6.76	-0.58
Underlying PBT	-18.91	-3.26	-9.07	-3.23	-6.80	-0.63
Statutory PBT	-20.99	-5.16	-9.07	-3.23	-6.80	-0.63
Underlying EPS (p)	-15.58	0.09	-7.52	-2.24	-5.19	0.15
Statutory EPS (p)	-17.43	-1.55	-7.52	-2.24	-5.19	0.15
Net (debt)/cash	13.30	9.63	4.12	1.59	-2.49	3.75

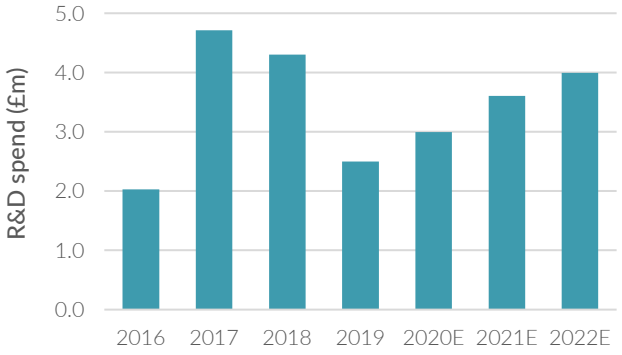
Source: Hardman & Co Life Sciences Research

Product sales



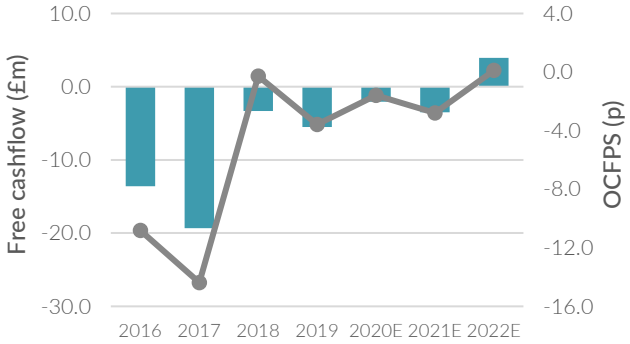
- From 2019, sales simply reflect a blend of supply agreements and royalties derived from Feraccru/Accrufer.
- Accelerated growth expected in 2020 is due to launches planned in additional European countries and the US.
- Out of the royalty stream, STX has to bear the manufacturing costs of Feraccru for supply to Norgine.

R&D investment



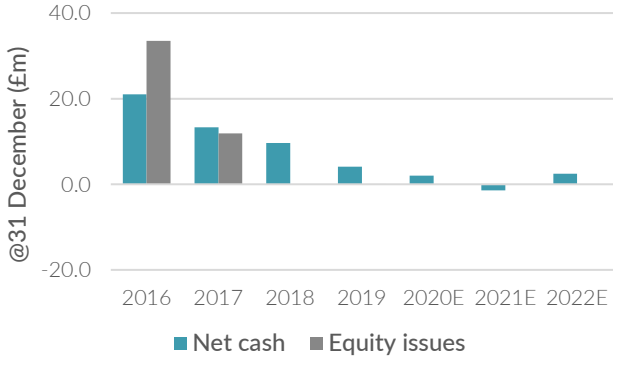
- A delay to the initiation of the paediatric Phase III study has altered the phasing of R&D spend between 2020 and 2021.
- Spend in 2017 and 2018 reflected investment in the AEGIS-CKD and AEGIS-H2H studies.
- Future R&D investment timing is flexible based on available resources, but it could include progression of the phosphate assets or development towards a once-a-day dose of Feraccru.

Free cashflow and OFCFPS



- On current forecasts, STX has a cash runway into 2021; a US commercialisation deal is expected by the year-end, which could significantly alter this situation.
- STX is forecast to achieve stable positive cashflows once substantial royalties are received from Feraccru/Accrufer sales across both Europe and the US.

Net cash/(debt) and equity issues



- At IPO in 2016, STX raised £32.5m gross (£30.1m net), which was boosted in 2017 by a Placing of new Ordinary shares to raise £12.5m gross (£11.9m net).
- Commercial deals with Norgine and ASK Pharm have greatly boosted STX's cash position in the past two years.
- In the unlikely absence of any upfront payment with the US licensing deal, STX would require an injection of new capital.

Source: Company data; Hardman & Co Life Sciences Research

2020 interim results

Operational highlights

- **China deal:** In January 2020, STX exclusively licensed the development and commercial rights in China to ASK Pharm (ASK). STX received an upfront payment of $11.4m/£8.7m, to be followed by further milestones and royalties.
- **Norgine progress:** Sales of Feraccru in Europe by its licensing partner, Norgine, for the first six months of 2020 increased by 50% on the previous six months, despite the global COVID-19 pandemic lockdown.
- **AEGIS H2H re-analysis:** Data confirmed that Feraccru/Accrufer did not meet the primary endpoint of non-inferiority to iv iron at 12 weeks. However, by 24 weeks, in the intention-to-treat (ITT) population, 65% of patients on Feraccru had normal levels of haemoglobin compared with 68% of patients in the iv-treated arm, confirming that this drug is a suitable alternative to iv iron.
- **US licensing deal:** Progress continues to be made to secure agreement with a US commercialisation partner for Accrufer to maximise shareholder returns from this important drug market.

Financial highlights

- **Product sales:** Sales, effectively royalties on net product sales from Norgine, were broadly in line with forecasts at £0.22m.
- **COGS:** Manufacturing costs were markedly high than anticipated. This was because of a one-off payment – 10% of any upfront or 5% royalties on net sales – due to the original IP holder, Vitra Pharmaceuticals (Vitra), following the licensing deal with ASK in China.
- **SG&A:** Administration expenses were also considerably higher than expected. This was due to one-off factors such as deal costs in China and the US. We believe that the underlying annualised rate of SG&A (ex-D&A) is ca.-£4.5m.
- **R&D:** Activity was relatively subdued in 1H'20 and mostly involved formulation activities. The first stage of the paediatric Feraccru study was delayed by COVID-19 until 2H'20, with stage two now likely to start in 1H'21.
- **Upfront receipt:** STX received $11.4m/£8.7m cash from ASK in March.
- **Net cash/(debt):** STX ended the period with net cash of £6.52m (no debt), which provides a sufficient cash runway through to 1Q'21 based on current assumptions and expectations. This does not include any upfront payments included in any potential US licensing deal.

Interim results – actual vs. forecasts

Half-year to June (£m)	*1H'19 actual	1H'20 actual	Growth %	1H'20 forecast	Delta Δ
Gross revenue (as reported)	0.43	8.92	n/m	9.07	-0.15
Product sales	0.33	0.22	-31%	0.30	-0.08
COGS	-0.31	-1.01	139%	-0.15	-0.86
SG&A (underlying)	-2.29	-4.61	35%	-3.20	-1.41
R&D	-1.27	-0.68	-47%	-0.60	-0.08
Other income	0.10	8.69	n/m	8.70	-0.01
EBITDA	-3.18	3.67	n/m	5.94	-2.27
Underlying EBIT	-3.70	2.39	n/m	4.89	-2.50
Underlying EPS (p)	-2.70	2.67	n/m	3.30	-0.63
Net cash/(debt)	6.61	6.52	-	6.80	-0.28

**Restated to reflect repayment of Norgine milestone*
Figures may not add up exactly due to rounding
Source: Hardman & Co Life Sciences Research

Deal update

China

Traditional deal in China with upfront, milestones and royalties

On 8 January, STX announced an exclusive licensing deal with Beijing Aosaikang Pharmaceutical Co (ASK, XSEC:002755) for the development and commercialisation of Feraccru in China, Hong Kong, Macau and Taiwan.[1]

- **An up-front payment:** $11.4m/£8.7m was received from ASK shortly after the deal closed, which was recognised in the P&L account in 1H'20.
- **Regulatory milestone:** $11.4m/£8.7m upon regulatory 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. The timeframe for receipt of royalties is either for 10 years from first commercial sales or for the duration of IP, whichever is longer.
- ASK will be responsible for the costs of further clinical and regulatory activities, in addition to manufacturing and distribution in the territory.

Time to launch may be less than originally anticipated

Since the deal was concluded, ASK has been liaising with the CFDA to define the development programme required in order to achieve regulatory approval for Feraccru in China. The CFDA has indicated that it may require only a Phase III study in inflammatory bowel disease and that neither a pharmacokinetic study nor a Phase III study in chronic kidney disease (CKD) will be needed. This is important news, which, if confirmed, could lead to the filing of an NDA in 1H'22 for launch in 2H'23, much earlier than originally expected.

US

Priority for 2020: US commercial deal

The key priority for 2020 has been to secure a US commercial partner for Accrufer, which has been approved already by the FDA. STX indicated that, as part of this process, it is engaged with a number of companies, many of whom have signed confidentiality agreements. To date, some have submitted non-binding offers leading to more detailed discussions.

Deal should reflect the de-risking investment made by STX

When coming to a decision, STX is looking for a partner that can exploit Accrufer across the full set of indications where ID is prevalent, rather than a multiple number of companies with experience in a single indication. The ultimate aim of management is to secure optimal financial terms that reflect the investment made by STX into a fully de-risked drug, which would be in the best interest of shareholders.

STX indicated that it has already ordered US launch stock from its manufacturer, which will be available towards the end of 2020. This is a positive indication that a deal will be forthcoming.

Positive indications, but no US sales likely in 2020

How does this news compare with expectations? On the one hand, the ordering of launch stock and the update relating to discussions is positive; on the other hand, no US sales are likely in fiscal 2020, which reduces our forecasts by £0.2m. However, this update from STX does indicate that there is a high probability of a deal being reached and that such a deal is not too far away.

[1] www.hardmanandco.com/research/corporate-research/taking-on-china/

Re-analysis of AEGIS-H2H results

The unexpected head-to-head announcement was a disappointment…

The market was surprised when the company announced, in March, that it needed to clarify the results published in 2019 from its head-to-head study of Feraccru against iv iron (Ferinject). This study was designed primarily to generate data that could be used in health economic analyses, pricing and reimbursement applications as well as for marketing purposes.

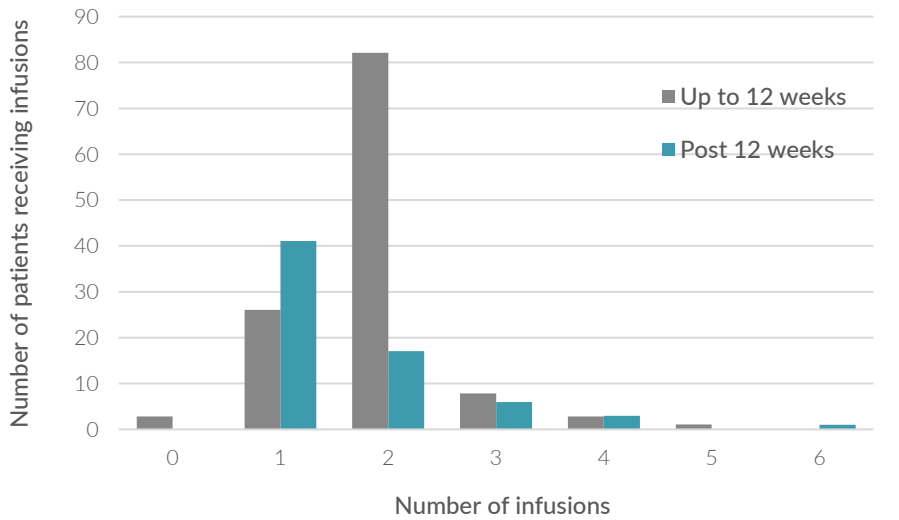
…but independent re-analysis of the data has cleared the picture

Whereas the company had originally thought that the study had reached its primary end-point, which required achievement of non-inferiority at 12 weeks in both the "intention to treat" (ITT) and "per protocol" (PP) populations, on re-examination of the data by Norgine during reimbursement discussions, it came to light that non-inferiority was not demonstrated in the ITT population and hence the overall study failed to meet its primary endpoint. Consequently, an independent re-analysis of the results was commissioned.

Summary of re-analysis

- Primary non-inferiority endpoint at 12 weeks was not achieved in either the ITT or PP populations.
- Average haemoglobin (Hb) levels had returned to the normal range by 12 weeks in the ITT populations for both Feraccru and iv iron groups.
- As would be expected, the change in Hb levels was faster in the iv-treated group up to 12 weeks after treatment; thereafter, there was no difference in the change of Hb levels between iv and oral iron replacement.
- The number of patients needing supplementary iv iron infusions was significantly reduced after 12 weeks of treatment.

AEGIS-H2H – Number of patients needing iv infusions (ITT population)



Source: Adapted from company reports, Hardman & Co Life Sciences Research

Feraccru/Accrufer is a suitable alternative to iv iron

Overall, by 24 weeks in the ITT population, 65% of patients on Feraccru had normal levels of haemoglobin compared with 68% of patients in the iv-treated arm. Therefore, re-analysis of the results concluded that, based on the secondary endpoints, Ferracru is a suitable alternative to iv iron. This is potentially important in the current climate where it is difficult for patients, or they are unwilling to take the risk, to attend hospital to receive an iv iron infusion.

Forecast 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:** Short-term COGS were higher than expected due to the one-off Vitra payment. Also, SG&A in 1H'20 was affected by one-off deal costs for both China and the US. Both these are expected to drop out in fiscal 2021.
- **Cash runway:** Gross cash at 30 June was £6.5m providing a cash runway into 1Q'21, even in the absence of licensing income from any US or RoW deals.
- **Forecasts:** No material changes to forecasts since our last publication. US sales for 2020 have been eliminated. Higher one-off SG&A costs have been included.

Financial summary

Year-end Dec (£m)	2017	2018	2019	2020E	2021E	2021E
GBP:EUR	1.14	1.13	1.14	1.14	1.14	1.14
Profit & Loss						
Gross revenues	0.64	11.88	0.72	9.39	6.00	13.75
Product sales	0.64	0.86	0.62	0.70	6.00	13.75
COGS	-0.16	-0.31	-0.49	-1.22	-1.80	-2.75
Gross profit	0.48	0.55	0.13	-0.52	4.20	11.00
Gross margin	75.7%	63.7%	21.6%	50.0%	70.0%	80.0%
SG&A	-14.12	-9.52	-6.32	-8.43	-6.90	-7.13
Share-based payments	-0.56	-1.01	-0.46	-0.46	-0.46	-0.46
R&D	-4.71	-4.30	-2.50	-3.00	-3.60	-4.00
Other income	0.00	11.03	0.10	8.69	0.00	0.00
EBITDA	-18.48	-2.47	-6.41	-1.18	-4.22	1.96
Underlying EBIT	-18.90	-3.26	-9.04	-3.72	-6.76	-0.58
Net interest	0.00	0.01	-0.03	0.49	-0.05	-0.05
Underlying PBT	**-18.91**	**-3.26**	**-9.07**	**-3.23**	**-6.80**	**-0.63**
Tax payable/credit	1.41	3.36	0.27	0.60	0.72	0.80
Underlying net income	-17.50	0.10	-8.80	-2.63	-6.08	0.17
Weighted avg. shares (m)	112.36	116.43	116.99	117.19	117.19	117.19
Underlying EPS (p)	**-15.58**	**0.09**	**-7.52**	**-2.24**	**-5.19**	**0.15**
Fully diluted EPS (p)	-15.58	0.09	-7.26	-2.16	-5.00	0.14
Balance sheet (@ 31 Dec)						
Share capital	1.75	1.75	1.76	1.76	1.76	1.76
Reserves	39.46	38.68	30.39	27.76	21.67	21.85
Provisions	0.26	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	13.30	9.78	4.14	1.59	-2.49	3.75
Invested capital	**28.31**	**30.80**	**28.02**	**27.93**	**25.92**	**19.86**
Net cash/debt	13.30	9.63	4.12	1.59	-2.49	3.75
Cashflow						
Underlying EBIT	-18.90	-3.26	-9.04	-3.72	-6.76	-0.58
Non-cash items	0.43	1.81	3.08	3.00	3.00	3.00
Change in working capital	-0.29	-0.26	0.56	-3.02	-0.07	0.07
Tax & interest	1.99	1.86	1.27	1.44	-0.05	-0.05
Operational cashflow	**-17.99**	**-1.84**	**-5.29**	**-3.74**	**-3.83**	**2.48**
Capital expenditure	0.00	0.00	0.00	0.00	0.00	4.00
Free cashflow	-19.33	-3.32	-5.51	-2.52	-4.07	6.23
Acquisitions	-0.24	-0.35	-0.03	-0.03	0.00	0.00
Equity issues	11.88	0.00	0.03	0.00	0.00	0.00
Change in net debt	**-7.68**	**-3.67**	**-5.51**	**-2.55**	**-4.07**	**6.23**
OCFPS (p)	-14.38	-0.27	-3.59	-1.98	-3.31	2.08

Source: Hardman & Co Life Sciences Research

Company matters

Registration

Incorporated in the UK with company registration number 09761509

Registered office:

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London office:

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Board of Directors

Board of Directors

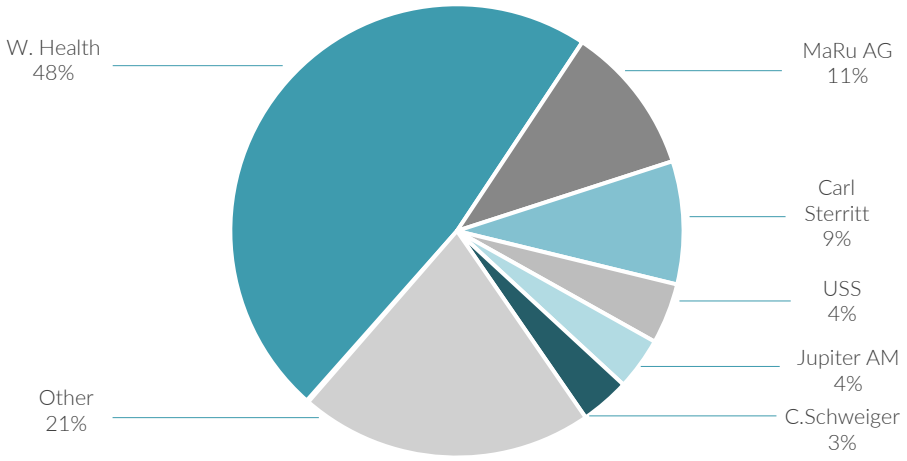
Position	Name	Nominations	Remuneration	Audit
Chairman	James Karis	M	M	
Chief Executive Officer	Tim Watts			
Chief Financial Officer	-			
Non-executive director	Hans Peter Hasler	C		M
Non-executive director	Rolf Hoffmann	M	C	
Non-executive director	Peter Llewellyn-Davies	M		C

M = member; C = chair
Source: Company reports

Share capital

On 17 September 2020, there were 117,188,657 Ordinary shares in issue. In addition, there are 3.94m options outstanding.

Share register



Source: Hardman & Co Life Sciences Research

Notes

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In particular, Article 12(3) of the Directive states: 'The following benefits shall qualify as acceptable minor non-monetary benefits only if they are: (b) 'written material from a third party that is commissioned and paid for by a corporate issuer or potential issuer to promote a new issuance by the company, or where the third party firm is contractually engaged and paid by the issuer to produce such material on an ongoing basis, provided that the relationship is clearly disclosed in the material and that the material is made available at the same time to any investment firms wishing to receive it or to the general public…'

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The full detail is on page 26 of the full directive, which can be accessed here: http://ec.europa.eu/finance/docs/level-2-measures/mifid-delegated-regulation-2016-2031.pdf

In addition, it should be noted that MiFID II's main aim is to ensure transparency in the relationship between fund managers and brokers/suppliers, and eliminate what is termed 'inducement', whereby free research is provided to fund managers to encourage them to deal with the broker. Hardman & Co is not inducing the reader of our research to trade through us, since we do not deal in any security or legal entity.

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