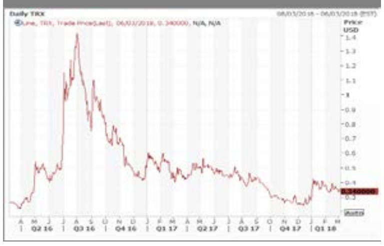
8th March 2018

hardman&co

Pharmaceuticals & Biotechnology



Source: Eikon Thomson Reuters

Market data

EPIC/TKR	**TRX**
Price (p)	8.8
12m High (p)	18.3
12m Low (p)	5.5
Shares (m)	1,171.6
Mkt Cap (£m)	102.5
EV (£m)	77.1
Free Float*	28%
Market	AIM

**As defined by AIM Rule 26*

Description

TRX is a medical device company in regenerative medicine. Its patented dCELL and CellRight technologies remove DNA, cells and other material from animal/human soft and hard tissue leaving an acellular scaffold – not rejected by the body – that can be used to repair diseased or worn-out body parts. Its products have multiple applications.

Company information

CEO	Steve Couldwell
CFO	-
Chairman	John Samuel

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www.tissueregenix.com

Key shareholders

Directors	4.8%
Invesco	28.7%
Woodford Inv. Mgmt.	24.9%
IP Group	13.7%
Baillie Gifford	4.2%

Diary

Oct-17	Hardman report
19th Mch	2017 results

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Tissue Regenix

Full-year 2017: what to look for

TRX has a broad portfolio of regenerative medicine products developed from decellularised human and porcine soft tissues for the wound care, orthopaedics, and cardiac markets. Since the launch of DermaPure, focus has been on expanding in the US wound care and orthopaedic markets: in August 2017, TRX acquired CellRight Technologies, providing synergistic bone regeneration technology. Full-year 2017 results will be the first to reflect the acquisition and will include five months of the enlarged entity. Sales from all three business segments are forecast to be strong (total £5.15m). We set out our underlying growth expectations below.

- **Strategy:** To build a regenerative medicine business with a portfolio of products using proprietary dCELL and CellRight technology, underpinned by compelling clinical and economic outcomes to drive adoption rates, while retaining strategic and corporate flexibility with three therapeutic corporate entities.

- **Full-year expectations:** The next set of results, due 19th March, are important for two reasons: i) they will be the first clean set of comparative numbers based on a December reporting period; ii) they will provide the first indication of how CellRight is performing. Overall, we have no reason to adjust forecasts.

- **Integration of CellRight:** TRX moved quickly to integrate its existing small San Antonio operation into established facilities acquired with CellRight. However, we believe this was simply the initial step of what is likely to be a 12-18-month process to fully integrate management, manufacturing, and infrastructure.

- **Management:** Changes at the top of TRX have resulted in Steve Couldwell being appointed CEO, having been a NED since 2013. He is working closely with Jesús Hernández to implement the correct US structure to maximise commercial opportunities. The search for a new CFO is under way; a temporary FD is in place.

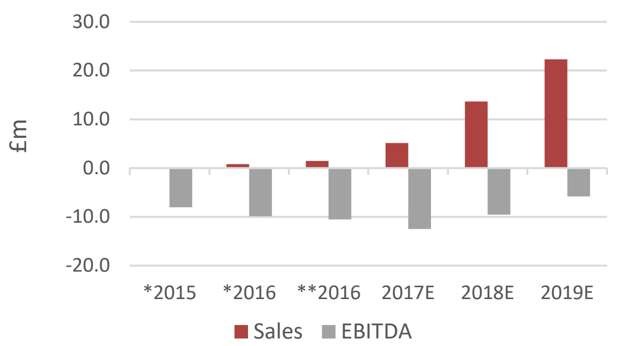
- **Investment summary:** TRX is building commercial momentum through three value drivers: sales of DermaPure in the US; regulatory submission of OrthoPure XT in Europe; agreement of a JV for commercialisation of woundcare and cardiac products in Europe. 2017 numbers will benefit from the CellRight acquisition, which should also hasten the time to reach sustainable profitability.

Financial summary and valuation

Year-end Dec (£000)	*2015	*2016	**2016	2017E	2018E	2019E
Sales	100	816	1,443	5,150	13,666	22,336
EBITDA	-8,038	-9,861	-10,549	-12,493	-9,561	-5,801
Underlying EBIT	-8,189	-10,106	-10,850	-13,411	-11,247	-7,501
Reported EBIT	-8,369	-10,242	-11,060	-15,661	-11,517	-7,791
Underlying PTP	-8,021	-9,893	-10,736	-13,225	-11,191	-7,492
Statutory PTP	-8,201	-10,029	-10,946	-15,475	-11,461	-7,782
Underlying EPS (p)	-1.2	-1.3	-1.3	-1.3	-0.9	-0.5
Statutory EPS (p)	-1.2	-1.3	-1.3	-1.6	-0.9	-0.6
Net cash/(debt)	10,257	19,907	8,173	13,693	2,223	6,625
Capital increases	5	19,019	0	38,000	0	11,400
P/E (x)	-	-	-	-	-	-
EV/sales (x)	-	-	-	15.0	5.6	3.5

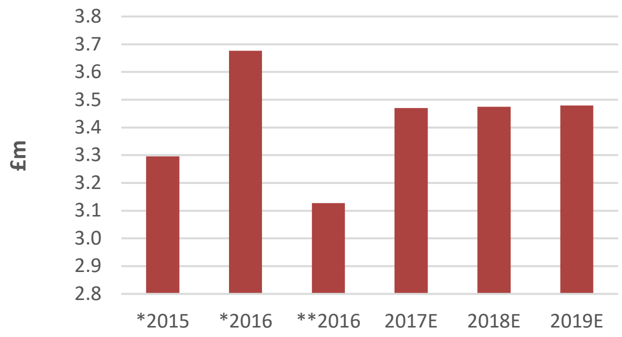
**Year to January, **11-months to December*
Source: Hardman & Co Life Sciences Research

Sales and EBITDA



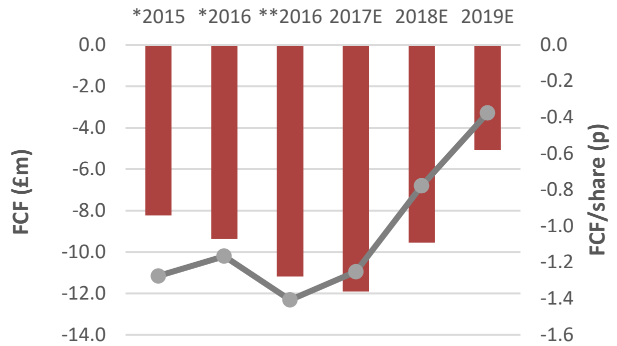
- 1H'17 grew a reported 118% to £1.4m, driven by DermaPure sales in the US and by GBM-V sales in Europe
- *Pro forma* sales growth of DermaPure in the US for full-year 2017 are forecast at 24%, to $2.5m/£1.9m
- Sales of £5.15m are projected for 2017 due to increased US market penetration and consolidation of GBM-V sales, plus inclusion of CellRight from completion (9th August)
- EBITDA losses are expected to become larger in 2017, due primarily to considerable investment in maximising penetration of products to the market

R&D investment



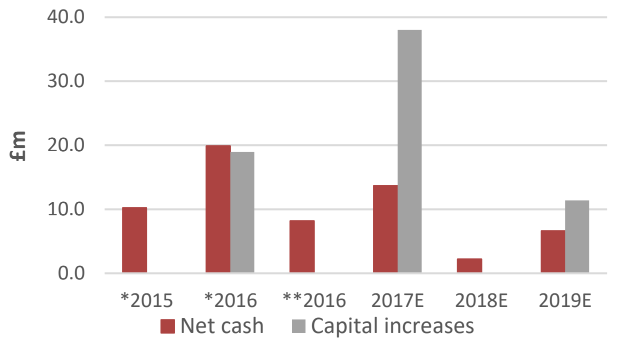
- R&D spend was -£1.8m for 1H'17 and is set to remain steady going forward
- A total of -£12-13m R&D investment is expected over the next three years, largely on US trials of OrthoPure products
- Capitalisation of some R&D spend on approved products is likely to continue

Free cashflow and FCF per share



- Free cashflow was -£4.6m in the interim period (including modest capital expenditure) and is expected to be around -£11.9m for the full year
- Given that TRX continues to invest in commercialising all three segments of the business, there will be cash outflow for the forecast period
- Cashflow starts to improve significantly once sales rise to a level >£20m in 2019E

Net cash and capital increases



- Net cash was £3.6m on 30th June 2017, and is forecast at £13.7m for 2017
- The capital increase in 2017 is the £40m cash raise to fund the CellRight acquisition and working capital needs
- With average monthly cash burn of ca.£0.8-1.0m, forecasts are assuming a further fundraise during 1H 2019
- The deferred CellRight consideration (2 x $2.04m) affects the cash position in each of 2018 and 2019

*Year to January, **11-months to December; Source: Company data, Hardman & Co Life Sciences Research

Full-year 2017 results approaching

Full-year 2017 will be the first clean set of comparator results based on a December reporting period…

On 19th March, Tissue Regenix (TRX) will report its results for the 12 months to December 2017. These will reflect a dynamic period for the company: they will include the five months' performance from the enlarged group following the acquisition of CellRight in the US on 9th August 2017.

Sales projections

…and the first to contain the CellRight acquisition

Hardman & Co pro forma 2016 estimates

Our *pro forma* full-year 2016 sales estimate (£5.58m) for the enlarged group was published previously – *CellRight: Transforming US growth prospects* dated 10th August 2017 – to provide the market with a comparator for the up-coming full-year 2017 results.

Pro forma estimates for 2016 include 12 months of sales for the enlarged entity to December

It should be noted that the 'full-year' 2016 numbers reported by TRX were only for the 11 months to December 2016, given the change in the accounting year-end reference date from January to December. TRX did not provide the market with *pro forma* 12-month numbers for the period to December 2016.

Therefore, our *pro forma* 2016 figure represents an estimate of TRX sales for 12 months to December 2016, plus the sales figure reported by CellRight for the same period. It also includes the modest actual sales (£0.12m) by GBM-V, the JV in Germany, for the six to eight months to the end of December 2016 following its formation.

Underlying growth

Our forecasts for TRX's sales in full-year 2017 are presented in the table below, set against the 2016 *pro forma* estimates for clarity. We note that the following:

We forecast underlying growth of 29.7% for the orthopaedics business for the 2017 full year

- **Underlying growth:** Based on CER, with average US$/£ rates for the woundcare and orthopaedics businesses, and €/£ for the cardiac business ('Other' in table).
- **Orthopaedics business:** The underlying growth of the orthopaedics business includes the CellRight acquisition and is calculated from *pro forma* full-year 2017 ($7.03m) against the actual 2016 sales reported by CellRight ($5.42m).
- **Group sales:** Underlying growth projections for the group are calculated from *pro forma* full-year 2017 (£8.4m) and 2016 estimates (£5.58m)

Key sales figures – what to look for

Division	2016 reported	2016 **pro forma*	2017 forecast	Underlying growth
Woundcare	£1.32m	£1.46m	£1.90m	
(incl. DermaPure)	$1.78m	$1.98m	$2.45m	24%
Orthopaedics		£4.00m	**£2.22m	
(incl. CellRight)		$5.42m	$2.93m	***30%
Other	£0.12m	£0.12m	£1.03m	
(incl. GBM-V)	€0.15m	€0.15m	€1.18m	na
Group sales	**£1.44m**	**£5.58m**	**£5.15m**	****50%**

Na: not applicable. GBM-V set up during 2016
**Hardman & Co pro forma estimates – 12 months of enlarged group to December*
***Year to December (first to include CellRight acquisition)*
****Translated at average US$/£ exchange rate for five months following acquisition*
*****Hardman& Co pro forma estimate for 12 months of enlarged group*
Source: Hardman & Co Life Sciences Research

Orthopaedics

CellRight Technologies, Texas

Source: CellRight Technologies website

The CellRight acquisition will accelerate the route to market for orthopaedic applications in 2018. Commercialisation of pipeline products such as the OrthoPure range is not as advanced in the US as in Europe; however, technology transfer of OrthoPure HT, the human tissue-derived version of OrthoPure XT, to the CellRight facility can now begin. In terms of US regulation, TRX is in positive discussions with the FDA to commence a first-in-man clinical trial for OrthoPure XT in the US in 2018.

The 2017 results will provide visibility on the performance of the US acquisition for the first time. TRX moved quickly to integrate its existing small San Antonio operation into established facilities owned and acquired with CellRight. We believe this was simply the initial step of what is likely to be a 12 to 18-month process to fully integrate management, working cultures, manufacturing, and infrastructure.

In addition, due to circumstances beyond TRX's control, there have been delays in orthopaedics approvals in Europe. There remain bottlenecks in the processing of submissions following changes in 2017 from existing EMA Medical Device Directives to new Regulations. In aggregate, we expect to see sales of around \$2.9m for the orthopaedics business in fiscal 2017, which represents 30% growth on a like-for-like, CER basis.

Woundcare

GPO market access

Source: Hardman & Co Life Sciences Research

Since the launch of DermaPure, focus has been on expanding in the US woundcare markets. 2017 interim results showed organic growth of DermaPure sales, driven by the transition to more in-patient activity via Group Purchasing Organisation (GPO) agreements; underlying DermaPure sales grew 13% in the first half. TRX currently has three GPO agreements in place and is engaged in discussions to increase this number.

In the first half of 2017, additional accounts were successfully signed under the existing GPOs. However, given the time taken to convert new accounts to sales, we reduced forecasts for group sales at the half-year point by 19%. For the full year, woundcare sales are forecast to grow 24% to \$2.45m (\$1.98m).

Other (cardiac)

The European JV, GBM-V, was established in 2H'16 with a tissue bank in Germany. There were, initially, raw material supply constraints at GBM-V, and the first sales reached £121k, made up mainly of cryopreserved human corneas. Future contributions look set be more significant given that all human tissue woundcare and cardiac applications will be processed through here. We forecast full-year 2017 sales of €1.18m/£1.03m.

Conclusion

The market needs comfort on three issues: i) the considerable investment that has been made in DermaPure needs to be reflected in progressive product utilisation and sales; ii) that there has been no aberration in the sales growth at CellRight since acquisition, i.e., a demonstration that wholesalers were not overstocked in the run-up to acquisition in order to boost numbers; iii) after a period of considerable turmoil, an indication that the new management team is settled and that there are clear responsibilities and reporting lines for the newly combined US operations. Going forward, the market needs to see that improved operating performance, combined with elimination of excess costs, will lead to an uptrend in margins over the forecast period and greater visibility about when the company will become profitable and cash-generative.

Financial forecasts

Profit & Loss

Volatility in forecast period…

…due to impact of CellRight acquisition and consolidation of JV

- **Sales:** On a *pro forma* basis, we estimate that sales in fiscal 2017 would be about £8.4m (vs reported sales of £5.15m). Underlying *pro forma* sales growth of TRX products (ex-CellRight) and consolidation of the JV are forecast at 90% in 2017.
- **Gross margin:** There will be volatility over the forecast period. The consolidation of CellRight and GBM-V will both have a one-off impact on the enlarged group spanning a two-year period. Thereafter, margins are expected to trend upwards.
- **SG&A:** Investment in commercialisation will continue to affect the numbers despite the boost that will be received from consolidating CellRight.

Profit & Loss account

Year-end Dec (£000)	*2015	*2016	**2016	2017E	2018E	2019E
GBP:USD		1.523	1.347	1.289	1.289	1.289
Sales	**100**	**816**	**1,443**	**5,150**	**13,666**	**22,336**
COGS	-32	-154	-354	-1,980	-5,417	-7,689
Gross profit	**68**	**662**	**1,089**	**3,170**	**8,249**	**14,647**
Gross margin		81.1%	75.5%	61.5%	60.4%	65.6%
SG&A	-1,766	-7,092	-8,812	-13,111	-16,021	-18,668
R&D	-3,296	-3,676	-3,127	-3,470	-3,475	-3,480
Underlying EBITDA	**-8,038**	**-9,861**	**-10,549**	**-12,493**	**-9,561**	**-5,801**
Depreciation	-151	-245	-301	-418	-485	-500
Amortisation	0	0	0	-500	-1,200	-1,200
Other income	0	0	0	0	0	0
Underlying EBIT	**-8,189**	**-10,106**	**-10,850**	**-13,411**	**-11,247**	**-7,501**
Share based costs	-180	-136	-210	-250	-270	-290
Exceptional items	0	0	0	-2,000	0	0
Statutory operating profit	-8,369	-10,242	-11,060	-15,661	-11,517	-7,791
Net interest	168	213	114	186	56	9
Pre-tax profit	**-8,021**	**-9,893**	**-10,736**	**-13,225**	**-11,191**	**-7,492**
Exceptional items	0	0	0	0	0	0
Reported pre-tax	-8,201	-10,029	-10,946	-15,475	-11,461	-7,782
Tax payable/credit	620	527	1,034	885	886	887
Underlying net income	**-7,401**	**-9,366**	**-9,702**	**-12,340**	**-10,305**	**-6,604**
Statutory net income	-7,581	-9,502	-9,912	-14,590	-10,575	-6,894
Ordinary 0.5p shares:						
Period-end (m)	654	760.1	760.1	1,161.8	1,161.8	1,221.8
Weighted average (m)	637	743.2	760.1	919.7	1,161.8	1,191.8
Fully-diluted (m)	676	784.7	805.1	964.7	1,206.8	1,236.8
Underlying basic EPS (p)	**-1.16**	**-1.26**	**-1.28**	**-1.34**	**-0.89**	**-0.55**
Statutory basic EPS (p)	-1.19	-1.28	-1.30	-1.59	-0.91	-0.58
U/I fully-diluted EPS (p)	**-1.10**	**-1.19**	**-1.21**	**-1.28**	**-0.85**	**-0.53**
Stat. fully-diluted EPS (p)	-1.12	-1.21	-1.23	-1.51	-0.88	-0.56
DPS (p)	0.0	0.0	0.0	0.0	0.0	0.0

**Year to January, **11months to 31 December*
Source: Hardman & Co Life Sciences Research

Balance sheet

- **Net cash:** The net cash position has been improved by the placing (less the acquisition costs). The operational cash burn of the enlarged entity is currently around £1m per month, which suggests that TRX will have net cash of approaching £14.0m at 31st December 2017 – sufficient working capital throughout 2018.
- **R&D:** In a slight change of accounting policy, all continuing R&D investment in products that have received regulatory approval is being capitalised and included in intangible assets, which are then to be amortised in line with IAS38 once the product is launched.
- **Capitalised R&D:** Our stated capitalised R&D in the balance sheet is to allow for the calculation of ROIC, which is based on NOPLAT divided by invested capital, both of which require written-off R&D to be added back and amortised.
- **Capital increase:** Our forecasts assume that the company will raise further working capital early in 2019; this is estimated at £12m (gross), and will give management time to assess how to fund the operations through to profitability by the end of fiscal 2020.

Balance sheet

@31st Dec (£000)	*2015	*2016	2016	2017E	2018E	2019E
Shareholders' funds	11,578	21,239	11,536	36,946	26,371	30,876
Cumulated goodwill	0	0	0	0	0	0
Total equity	11,578	21,239	11,536	36,946	26,371	30,876
Share capital	3,271	3,801	3,801	5,809	5,809	6,109
Reserves	8,307	17,438	7,735	31,137	20,562	24,767
Capitalised R&D	7,450	9,239	10,206	10,701	11,049	11,397
Long-term debt	0	0	0	0	0	0
Short-term loans	0	0	0	0	0	0
less: Cash	10,257	19,907	8,173	13,693	2,223	6,625
Invested capital	**8,771**	**10,571**	**13,569**	**32,373**	**35,196**	**35,648**
Fixed assets	435	901	1,087	3,243	3,197	3,246
Intangible assets	0	0	550	15,935	17,504	19,073
Capitalised R&D	7,450	9,239	10,206	10,701	11,049	11,397
Inventories	34	64	661	1,697	2,715	2,614
Trade debtors	*40*	*398*	*427*	*76*	*202*	*330*
Other debtors	*1,907*	*1,927*	*2,703*	*2,203*	*1,703*	*1,203*
Tax liability/credit	*-73*	*-72*	*-147*	*885*	*886*	*887*
Trade creditors	*-312*	*-501*	*-618*	*-1,020*	*-1,683*	*-2,019*
Other creditors	*-710*	*-1,385*	*-1,300*	*-1,346*	*-1,957*	*-1,083*
Debtors less creditors	852	367	1,065	798	732	-682
Invested capital	**8,771**	**10,571**	**13,569**	**32,373**	**35,196**	**35,648**
Net cash/(debt)	**10,257**	**19,907**	**8,173**	**13,693**	**2,223**	**6,625**

**@31st January*

Source: Hardman & Co Life Sciences Research

Cashflow

TRX's cashburn is in the region of £1m per month in 2017, falling to £0.8m per month in 2018...

- **Cashburn:** Even though cash flow will be boosted by CellRight, TRX remains in an investment phase to commercialise its opportunity, with an average monthly cash burn in the order of £1m per month, dropping to ca.£0.8m in fiscal 2018.
- **Working capital:** Following the acquisition of CellRight, there is likely to be a short-term increase in working capital requirements due to increased inventories and trade debtors.
- **R&D:** Much of the R&D investment has already been made – we are forecasting that it will remain steady at ca.£3.5m per annum. The next key trials will be for OrthoPure XT in the US, expected to commence in late 2018.
- **Amortisation:** Forecasts include the amortisation of goodwill related to the CellRight acquisition being amortised over 10 years, which equates to an estimated £1.2m per annum.

...suggesting that a further fundraise (ca.£12m gross) is needed early in 2019

- **Capital increase:** As stated earlier, our forecasts assume that TRX will raise more working capital in 2019. This needs to be in the order of £12m gross (equivalent to around net £11.4m).

Conditional consideration for CellRight (up to $4.08m) is shown as two equal tranches over two years, although the split is contingent on the actual sales levels achieved

Cashflow

Year-end Dec (£000)	*2015	*2016	**2016	2017E	2018E	2019E
Underlying EBIT	-8,189	-10,106	-10,850	-13,411	-11,247	-7,501
Depreciation	151	245	301	418	485	500
Amortisation	0	0	0	500	1,200	1,200
Inventories	*-34*	*-30*	*-597*	*-1,036*	*-1,018*	*101*
Receivables	*0*	*-596*	*-90*	*351*	*-126*	*-128*
Payables	*0*	*862*	*106*	*402*	*663*	*413*
Change in working cap.	-213	236	-581	-283	-481	387
Other	0	0	0	0	0	0
Company op cashflow	**-8,285**	**-9,625**	**-11,130**	**-12,776**	**-10,042**	**-5,414**
Net interest	168	213	114	186	56	9
Tax paid/received	0	745	319	1,034	885	886
Operational cashflow	**-8,117**	**-8,667**	**-10,697**	**-11,556**	**-9,102**	**-4,519**
Capital expenditure	-114	-711	-487	-352	-440	-549
Sale of fixed assets	0	0	0	0	0	0
Free cashflow	**-8,231**	**-9,378**	**-11,184**	**-11,907**	**-9,541**	**-5,069**
Dividends	0	0	0	0	0	0
Acquisitions	0	0	0	-20,078	-1,581	-1,581
Other investments	0	0	-550	-495	-347	-348
Cashflow after invests.	**-8,231**	**-9,378**	**-11,734**	**-32,480**	**-11,470**	**-6,998**
Share repurchases	0	0	0	0	0	0
Share issues	5	19,019	0	38,000	0	11,400
Change in net debt	**-8,226**	**9,650**	**-11,734**	**5,520**	**-11,470**	**4,402**
Opening net cash	18,483	10,257	19,907	8,173	13,693	2,223
Closing net cash	**10,257**	**19,907**	**8,173**	**13,693**	**2,223**	**6,625**
Hardman FCF/share (p)	-1.3	-1.2	-1.4	-1.3	-0.8	-0.4

**Year to January, **11 months to 31 December*
Source: Hardman & Co Life Sciences Research

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Status of Hardman & Co's research under MiFID II

Some professional investors, who are subject to the new MiFID II rules from 3rd January, may be unclear about the status of Hardman research and, specifically, whether it can be accepted without a commercial arrangement. Hardman's company research is paid for by the companies about which we write and, as such, falls within the scope of 'minor non-monetary benefits', as defined in the Markets in Financial Instruments Directive II.

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 an[sic] 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;'

The fact that we are commissioned to write the research is disclosed in the disclaimer, and the research is widely available.

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 is not inducing the reader of our research to trade through us, since we do not deal in any security.

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