Pharmaceuticals & Biotechnology

Source: Refinitiv

Market data	
EPIC/TKR	**TRX**
Price (p)	**0.37**
12m High (p)	4.45
12m Low (p)	0.25
Shares (m)	7,033
Mkt Cap (£m)	26.0
EV (£m)	12.9
Free Float*	46%
Market	AIM

**As defined by AIM Rule 26*

Description

Tissue Regenix (TRX) is a pioneering international medical device company focused on the development of regenerative products based on its two platform technologies – dCELL® and BioRinse®. These decellularisation technologies remove DNA, cells and other material from animal/human tissue and bone, leaving scaffolds that can be used to repair diseased or worn-out body parts.

Company information

CEO (interim)	Gareth Jones
GFD	Kirsten Lund
Chairman (interim)	Jonathan Glenn

+44 330 430 3052
www.tissueregenix.com

Key shareholders

Directors	3.9%
Lombard Odier	16.0%
IP Group	13.7%
R.Griffiths	10.1%
Premier Miton	10.1%

Analyst

Martin Hall 020 7194 7632
mh@hardmanandco.com

TISSUE REGENIX

Funded through to profitability

TRX is focused on the development and commercialisation of two proprietary decellularisation technologies for repair of soft tissue (dCELL) and bone (BioRinse). It has a broad portfolio of approved regenerative medicine products for the biosurgery, orthopaedics and dental markets. Over the past two years, TRX has revised its commercial strategy, restructured to service demand, and commenced a capacity expansion programme in its US facilities. As some benefits were beginning to emerge, COVID-19 caused the postponement of elective surgeries on which much of TRX's core business is derived. Despite the challenges, TRX is well positioned for growth.

- **Strategy:** TRX is building an international regenerative medicine business around its proprietary technology platforms, underpinned by compelling clinical outcomes. Work has begun to expand production capabilities, enabling the business to grow its distribution networks, via strategic partnerships, to drive sales momentum.

- **Interims:** 1H'20 results were broadly in line with our expectations, with reported sales of £6.1m (£6.1m) and a greatly reduced underlying EBIT loss of £2.4m (£4.2m loss). The net cash position, after taking into account the Placing completed in June, was £10.6m and in line with our forecast.

- **Expansion:** During 2019, TRX moved to two-shift manufacturing and restarted outsourcing some of its DermaPure production. Alongside this, in July 2020, an expansion programme to satisfy product demand through investment in its US facilities was started, with should see benefits from 1H'21.

- **Commercial:** In May 2020, TRX announced a white label manufacturing agreement with a top-10 global healthcare company. Following receipt of CE marking for OrthoPure XT® in June 2020, TRX has concluded a UK distribution agreement with a speciality supplier of orthopaedic and biologic products.

- **Investment summary:** TRX has a portfolio of innovative regenerative products with regulatory approval in both the US and EU. Realignment of the commercial strategy to maximise sales potential through strategic and distribution partnerships has been successful, resulting in increased demand for its products. TRX now has the necessary funding to scale up manufacturing capacity, leaving it well positioned to deliver on future milestones, which should result in a re-rating.

Financial summary and valuation

Year-end Dec (£m)	2017	2018	2019	2020E	2021E	2022E
Sales	5.23	11.62	13.03			
EBITDA	-9.01	-7.09	-6.13			
Underlying EBIT	-9.72	-8.27	-7.18			
Reported EBIT	-10.82	-8.69	-7.20			
Underlying PBT	-9.67	-8.46	-7.64			
Statutory PBT	-10.77	-8.88	-7.66	Forecasts under review		
Underlying EPS (p)	-0.90	-0.67	-0.60			
Statutory EPS (p)	-1.02	-0.70	-0.61			
Net (debt)/cash	16.42	7.82	0.09			
Equity issues	40.25	0.00	0.00			
P/E (x)	-	-	-			
EV/sales (x)	-	2.3	0.9			

Source: Hardman & Co Life Sciences Research

Disclaimer: Attention of readers is drawn to important disclaimers printed at the end of this document

1H'20 results summary

Key features

Operational and commercial

- **Strategic collaboration:** On 11 May, TRX announced a strategic collaboration with a top-10 global healthcare company for the white label manufacture of a new product line for soft tissue orthopaedic repairs. This agreement is expected to provide a material contribution to TRX's sales over the next two years.

TRX now has regulatory approved products in both Europe and the US

- **OrthoPure XT:** On 1 June, TRX received CE marking for OrthoPure XT, a decellularised porcine tendon, for use in revision or multi-ligament procedures. This regulatory certification is an important milestone in the evolution of TRX's product portfolio. It was followed by a UK distribution agreement in August.
- **COVID-19:** As with all businesses, TRX has been affected by the COVID-19 pandemic, and there remains some uncertainty around the level of disruption that this will continue to cause, in particular, to elective surgeries in the US.

Financial

- **Sales:** Underlying sales were in line with our expectations and, with currency modestly beneficial, reported sales were flat at £6.1m (£6.1m). Orthopaedics continued to see good growth (+9% CER), whereas COVID-19 reduced the level of elective surgery, which was reflected in the Biosurgery numbers.
- **COGS:** Despite the impact of COVID-19 on normal working practice and the need for social distancing, COGS were carefully managed, down 5% in CER, due to a combination of product mix and operational efficiencies, with the gross margin increasing 1.3 percentage points, from 46.9% to 48.2%.

Overhead cost reduction initiatives really starting to come through

- **SG&A:** The reduction in overhead costs, which was first showing in 2H'19, was even more apparent in 1H'20, with underlying SG&A falling 24% to £4.8m (£6.3m), following a cost base reduction primarily in the UK corporate overhead. Additional changes in UK facilities should reduce this further in 2H'20.
- **Placing and Subscription:** In May, TRX announced a significant fund raise through the issue of 5.85bn new Ordinary shares at 0.25p per share to raise £14.6m gross new funds, or £13.8m net after expenses. This capital increase was completed in June 2020 following shareholder approval.
- **Net cash/(debt):** TRX ended the period with gross cash of £13.7m and net cash of £10.6m, compared with £0.1m at 31 December 2019, as forecast.

Interim results summary – actual vs. expectations

Half-year-end Jun (£m)	1H'19 actual	1H'20 actual	Growth CER	1H'20 forecast	Delta Δ
Biosurgery	1.96	1.71	-15%	1.85	-0.14
Orthopaedics	3.05	3.42	+9%	3.25	+0.17
GBM-V	1.06	0.96	-10%	0.90	+0.06
Group sales	**6.07**	**6.09**	**-3%**	**6.00**	**+0.09**
COGS	-3.23	-3.15	-5%	-3.20	+0.05
SG&A	-6.26	-4.77	-24%	-5.30	+0.53
Share-based costs	-0.02	0.00	-	-0.00	-
R&D	-0.74	-0.59	-21%	-0.50	-0.09
Underlying EBITDA	-3.63	-2.00	+45%	-2.50	+0.50
Underlying EBIT	**-4.18**	**-2.42**	**+42%**	**-3.02**	**+0.50**
Gross cash	10.08	13.67	-	14.30	-0.63
Net cash/(debt)	**4.29**	**10.60**	**-**	**10.90**	**-0.30**

Note: numbers may not add up exactly due to rounding
Source: Hardman & Co Life Sciences Research

Growth strategy

Four strategic growth drivers

Following the acquisition of CellRight, management refocused the company's commercial strategy, with a greater focus on growth. The aim was to:

- accelerate US market penetration;
- exploit the global market potential;
- increase the number of, and broaden, strategic partnership opportunities; and
- strengthen the product portfolio.

Progress during 1H'20

Good progress in 1H'20, despite external events beyond its control,...

Despite having this well-defined growth strategy, adverse external events beyond the control of the company made it difficult for TRX to raise the necessary capital for its investment plans, placing constraints on working capital and impacting the operational performance of the group. The successful Placing in June has significantly altered TRX's shareholder base and allowed the management team to move forward with its important strategic growth plans.

...with each of its four pillars of growth

Even with the negative impact of COVID-19, TRX still made good operational progress with each of its four growth pillars during 1H'20: i) US market penetration has the potential to be increased by securing a number of new accounts during 1H'20; ii) where opportunities have arisen internationally, the group has looked to capitalise on export opportunities; iii) the announcement of the strategic collaboration to manufacture a new product line for soft tissue orthopaedic repairs with a top-tier global healthcare company has the potential to provide strong sales growth, and was the consequence of a long-term R&D collaboration between TRX and the partner; and iv), in addition to the strategic collaboration, TRX obtained CE certification for OrthoPure XT, allowing it to be sold in Europe and in countries that recognise CE marking – this was an important milestone, because it means that TRX has obtained both European and US regulatory approvals for its products.

Four strategic growth drivers

	US Market Penetration	Geographic Expansion	Strategic Partnerships	Strengthen Portfolio
Focus	**Drive growth in US sales of current products through current direct and indirect distribution channels and increasing GPO relationships**	**Continue to build global sales reach through expansion of distribution partnerships and licensing agreements**	**Pursue further and develop existing distribution, licensing or IP collaboration partnerships**	**Bring new products to market from pipeline of products currently in development, and product line extensions**
H1 Achievements	✓ **Secure funding to allow investment into US capacity expansion** ✓ **Number of new accounts secured**	✓ **Target additional territories for distribution and licensing opportunities – Latin America, Cyprus, Taiwan**	✓ **Sign up additional strategic partnerships for OEM and product collaboration opportunities**	✓ **OrthoPure® XT CE Mark for launch into European markets** ✓ **Launch new product with top 10 Global healthcare Company**
H2 Milestones	✓ Commence Phase 1 of capacity expansion build out	• Launch OrthoPure® XT into the UK market • Secure additional distribution agreements for OrthoPure® XT in Europe	✓ Increase licensing and strategic partnerships	• OrthoPure® XT 2 year clinical data publicly available
2021 Milestones	• Phase 1 of capacity expansion comes on stream • Review timeline for commencement of Phase 2	• Commence supply of OrthoPure® XT into Continental Europe	• New strategic partner / major expansion with strategic partner	• Urogyn product line extension • Dermis product line extension • Clinical data publications

Source: Tissue Regenix 1H'20 results presentation

Outlook for 2H'20

At the time of writing, there remains considerable uncertainly with respect to the continuing impact of COVID-19 over the remainder of 2020 and, quite likely, into 2021. However, TRX is continuing with its strategic plans.

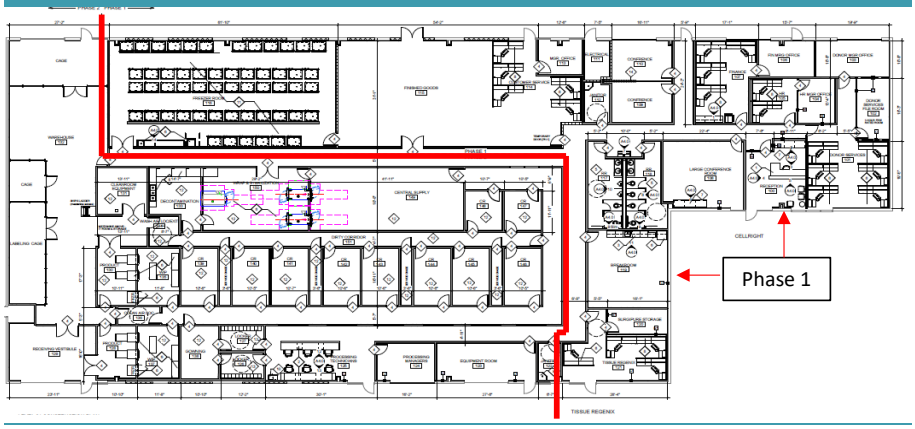
Expansion programme in San Antonio

Part of the fundraise proceeds is being used to commence the facility expansion project in San Antonio. This programme has been divided into two phases, in order to deploy working capital in the most efficient manner and bring capacity on stream in a managed process to meet demand, while causing as little disruption to the current business as possible. Phase 1 of this programme commenced in July 2020, and is expected to take six months to fit out. However, it should be noted that, due to the osteoinductive testing required for the BioRinse product portfolio, sales will take a further three to four months to materialise.

Phase 1 requires freezer capacity to be moved and extended threefold

Given that TRX is now sourcing and processing more than double the number of tissue donors per month compared with a year ago, pressure has been put on its existing freezer storage capacity. To overcome this constraint, phase 1 of the reorganisation of San Antonio involves moving freezers into the new building. This will provide three times more freezer capacity and free up space in the existing facility for the installation of additional sterile packaging clean rooms.

Phase 1 of San Antonio expansion project



Source: Tissue Regenix

Phase 1 to add two new clean rooms at a cost of $1.3m and take six months

Phase 1 will result in the addition of two sterile packaging clean rooms within the existing facility. Once fully operational, these additional clean rooms are expected to increase the group's current BioRinse processing capacity by ca.50%. It is expected that completion of phase 1 would allow for the revenue generation potential required for the group to reach breakeven.

TRX will also benefit from a $0.3m local University City grant to assist with implementation of the infrastructure for utilities, etc., needed to support this project.

Phase 2 adds up to 10 clean rooms at a cost of $4.5m-$5.5m and will take ca.12 months

Phase 2 of the project will add up to 10 additional clean rooms in the new facility adjacent to the current manufacturing site. This phase is expected to take approximately 12 months to complete at a cost of $4.5m-$5.5m/ca.£4.0m.

Expansion completion has potential to add up to $36m p.a. to sales

The total cost of the expansion project is expected to be $6.4m/£5.1m. However, once fully operational and validated, it is expected that the completed expansion project will increase the revenue generation potential by up to $36m p.a.

Licensing and strategic partnerships

Having received CE certification for OrthoPure XT in June 2020, TRX moved quickly to secure a distribution agreement for this product in the UK.

UK distribution deal for OrthoPure XT satisfies two of the strategic growth drivers

Two of the four strategic growth goals of TRX are to expand its product range and to increase the number of strategic partnerships. This deal satisfies both of these goals. OrthoPure XT is a decellularised porcine tendon, developed using the group's patented dCELL technology. The partner will distribute OrthoPure XT to both the NHS and private healthcare sectors in the UK. Rollout into other key European countries will be done on gradual basis.

Although a modest order for OrthoPure XT has been placed for delivery in 4Q'20, a greater impact is anticipated during 2021, when there is likely to be increased demand from the UK and more distributors are added for Europe.

Effect of COVID-19

COVID-19 had a significant impact…

There is no doubt that this pandemic had a significant impact on the group. In April 2020, just after the start of the global lockdown, TRX stated that reported sales in 1Q'20 had increased 18% (16% on an underlying basis) compared with 1Q'19, despite the company experiencing a cyber-security breach at its US facility in January 2020, which had a short-term impact on the group's ability to service demand. For the half year, underlying sales were slightly reduced, which implies that 2Q'20 sales, when the COVID-19 impact was greatest, were -18%. However, management responded quickly to this unforeseeable event, and processing continued without disruption at the facility in San Antonio throughout. While there remains uncertainty, TRX has done everything possible, and is now in a stronger position to manage its way through the pandemic.

…which was mitigated by a rapid response to the pandemic

US business

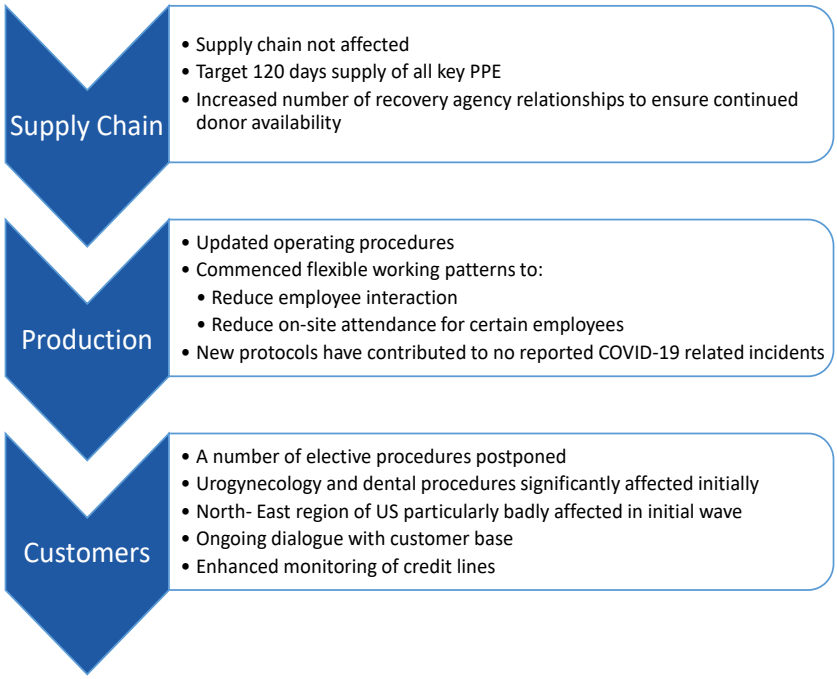
Processing continued without disruption in San Antonio

Initiatives implemented previously ensured that the group's supply chain remained unaffected throughout the lockdown period, with the successful procurement of donors and the required processing materials. Owing to the nature of processing techniques, PPE is required, and the group has successfully built up a significant supply of the this equipment to ensure that processing can continue.

By introducing updated operating procedures and staggering shift start times to minimise the number of employees on site at any one time, the group was able to maintain its production capabilities throughout the reporting period.

However, the company has no control over the ability of healthcare providers to perform elective surgical procedures, such as dental work or urogynaecological surgery, which has had an impact on sales flow-through for the group.

Navigating the COVID-19 landscape – US operations



Source: Tissue Regenix 1H'20 results presentation

It is just a question of time before elective procedure activity returns to historical levels

At the time of writing, there has been some recovery in the number of elective procedures being performed in some states but, overall, the picture remains complex, with different approaches being adopted at individual county levels within states, meaning that they still remain well below historical levels. The key for TRX is that elective procedures have only been postponed, and, at some point in the future, they are likely to be performed to improve a patient's wellbeing.

UK business

In the UK, operational and technical staff were furloughed, in line with the UK Government guidance, given that sufficient inventory of products had been built.

- The Leeds facility was closed, and operational and technical staff were furloughed during April through July. A day rota has been introduced to minimise the number of staff on site and to ensure social distancing.
- Office-based staff were moved to working-from-home, which is continuing.
- Operational procedures and health & safety guidelines were all updated to allow the facility to re-open in July 2020.
- A sufficient level of PPE has been procured to ensure that the supply chain remains unaffected, and no material loss of business has been experienced.

COVID-19 outlook

Although TRX is thought to have navigated the complex landscape of the pandemic successfully to date, there remains a risk that a second wave and further lockdown periods around the world may occur.

Financial summary

Equity issue

In June 2020, the company completed the reorganisation of its share capital, and successfully raised £14.6m gross (£13.8m net of expenses) new capital through a Placing and Subscription of Ordinary shares at 0.25p per share.

Impact of equity issue	
Ordinary shares of 0.5p (before capital reorganisation into 0.1p shares)	1,171,971,322
Placing, Subscription and PrimaryBid Ordinary shares of 0.1p issued	5,859,626,212
Total shares in issue immediately following equity raise	**7,031,597,534**

Source: Hardman & Co Life Sciences Research

US Government-backed loan

In order to assist with the overhead cost base during the global COVID-19 lockdown, TRX received ca.$1m (in two tranches) from a US Government-backed loan scheme, which, if used to support employee payroll, healthcare, utilities and rent payments in the US, would be converted into a grant and not require repayment. The group is expected to have satisfied these criteria and, therefore, repayment of this loan should not be required.

Overhead cost base management

During 2019, TRX initiated a programme of initiatives to appropriately size its overhead cost base. The 1H'20 results showed a significant reduction of £1.7m, driven largely by the organisational restructuring undertaken in 4Q'19 and also a reduction in the overall plc costs. This programme is ongoing, and the next significant milestone will be the relocation of the company's UK head office and manufacturing facilities from Swillington (Leeds) to nearby Garforth, in November 2020. This is expected to deliver annualised savings of ca.£400k from 2021.

Core strategic priorities to deliver breakeven	Achieved	Further improvements
Revenue **Ensuring that there is sufficient capacity and opportunity to increase top line growth in a post-COVID market**	• **Commenced capacity expansion plan** • **Top 10 global healthcare company collaboration opportunity** • **Launch of OrthoPure XT into European market**	• **Additional strategic partnerships** • **Product line extension opportunities**
COGs Driving increased efficiency with the manufacturing facilities	• San Antonio efficiency programme • CTS yields showing notable improvement (outsourcing partner for DermaPure) • Non-Oriented DermaPure utilises previously un-used donor tissue improving yields and product availability	• San Antonio efficiency programme • Processing efficiencies to drive COGs improvements
Overhead Cost Management Appropriately sizing the overhead cost base to reduce non-critical spend and focus on return on investments	• Q4 2019 employee headcount reduced by 18 • Relocation of UK facility – annualized savings of over £400k • Review of Corporate overheads	• Ongoing review of Corporate overhead spend • Challenging R&D and clinical spend • Capital expenditure focused on improving efficiencies for continued reduction in overhead spend

Source: Tissue Regenix 1H'20 results presentation

Forecasts

Owing to the uncertainty that has arisen because of the COVID-19 pandemic and associated global lockdown, the company is not providing any financial guidance to the market and, although we have our own independent view, given that there are so many potential scenarios, Hardman & Co has decided not to show numbers at this stage.

Meanwhile, management is continuing to forge ahead with its strategic goals and to deliver a breakeven position as soon as possible.

Summary financial data – historical						
Year-end Dec (£m)	2017	2018	2019	2020E	2021E	2022E
GBP:USD	1.289	1.312	1.278			
Profit & Loss						
Sales	**5.23**	**11.62**	**13.03**			
COGS	-2.63	-5.70	-7.01			
SG&A	-10.94	-12.61	-11.98			
R&D	-1.35	-1.64	-1.37			
Licensing/Royalties	0.00	0.00	0.00			
Underlying EBIT	**-9.72**	**-8.27**	**-7.18**			
Share-based costs	-0.03	0.06	0.15			
Exceptional items	-1.10	-0.42	-0.02			
Statutory EBIT	-10.82	-8.69	-7.20			
Net interest	0.05	-0.19	-0.46			
Underlying pre-tax profit	**-9.67**	**-8.46**	**-7.64**			
Tax payable/credit	1.35	0.62	0.55			
Underlying net income	-8.32	-7.84	-7.09			
Average no. shares (m)	920.5	1,171.6	1,171.9			
Underlying basic EPS (p)	**-0.90**	**-0.67**	**-0.60**			
Statutory basic EPS (p)	-1.02	-0.70	-0.61			
Balance sheet (@31 Dec)						
Share capital	5.86	5.86	5.86			
Reserves	33.67	26.71	18.74			
Capitalised R&D	10.21	9.28	8.52			
less: Cash	16.42	7.82	2.38			
Invested capital	**34.76**	**34.83**	**33.69**			
Cashflow						
Underlying EBIT	-9.72	-8.27	-7.18			
Change in working capital	-1.25	-0.49	-2.35			
Tax paid/received	1.54	1.23	0.65			
Operational cashflow	**-9.74**	**-6.77**	**-7.05**			
Capital expenditure	-0.13	-0.29	-0.44			
Acquisitions	-19.95	-1.56	0.00			
Equity issues	40.25	0.00	0.00			
Change in net debt	**8.25**	**-8.61**	**-7.72**			
Opening net cash/(debt)	7.80	16.42	7.82			
Closing net cash (debt)	**16.05**	**7.82**	**0.10**			

Source: Hardman & Co Life Sciences Research

Company matters

Registration

Incorporated in the UK with company registration number 05969271.

UK operations:

Unit 1&2
Astley Lane Industrial Estate
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LS26 8XT

+44 330 430 3052

www.tissueregenix.com

US operations:

1808 Universal City Boulevard
Universal City
San Antonio
Texas
78148

Board of Directors

Board of Directors

Position	Name	Remuneration	Audit
Chairman	Jonathan Glenn (interim)		
Chief Executive Officer	Gareth Jones (interim)		
Non-executive director	Alan Miller	M	C
Non-executive director	Randeep Singh Grewal	C	M
Non-executive director	Shervanthi Homer-Vanniasinkam	M	M

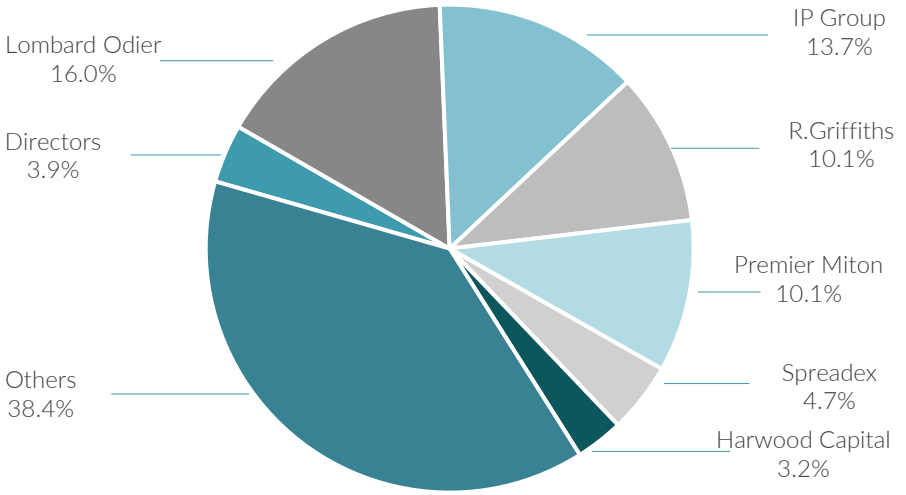
M = member, C = chair
Source: Company reports

The Group Finance Director and Company Secretary is Kirsten Lund.

Share capital

At 7 October 2020, the company had 7,032,985,756 Ordinary shares of 0.1p in issue. There are also 32.57m options and ca.2.97 warrants outstanding.

Shareholders



Source: Company announcements, Hardman & Co Life Sciences Research

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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…'

The fact that Hardman & Co is 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 & 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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