Pharmaceuticals & Biotechnology

Source: Refinitiv

Market data

EPIC/TKR	**TRX**
Price (p)	**0.63**
12m high (p)	0.86
12m low (p)	0.34
Shares (m)	7,033
Mkt cap (£m)	44.3
EV (£m)	43.1
Free float*	54%
Country of listing	UK
Market	AIM

**As defined by AIM Rule 26*

Description

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 unique processing technologies attempt to retain the inherent properties of animal/human tissue and bone, leaving safe and sterile scaffolds that can be used to repair diseased or degenerated body parts.

Company information

CEO	Daniel Lee
CFO	David Cocke
Chairman	Jonathan Glenn

+44 330 430 3052

www.tissueregenix.com

Key shareholders

Directors	1.0%
Lombard Odier	14.0%
Harwood Capital	11.3%
R. Griffiths	10.1%
Premier Miton	9.6%
IP Group	9.3%

Diary

Feb'22	Trading update
Apr'22	Final results

Analyst

Martin Hall 020 3693 7075

mh@hardmanandco.com

TISSUE REGENIX

Faster-than-anticipated recovery

Tissue Regenix (TRX) is focused on the development and commercialisation of two proprietary processing technologies for the repair of soft tissue (dCELL) and bone (BioRinse). It has a broad portfolio of marketed regenerative medicine products for the biosurgery, orthopaedics and dental markets. Interim results showed early signs of the benefits of its strategic activities over the past two years – the focus on commercial relationships, capacity expansion, restructuring to service demand, and recovery in elective surgeries after the pandemic. If the demand and sales progress continues, TRX will become EBITDA- and EBIT-positive in fiscal 2022.

- **Strategy:** TRX is building an international regenerative medicine business around its proprietary technology platforms, underpinned by compelling clinical outcomes. Expansion of manufacturing capabilities and some recovery in elective surgeries are driving sales momentum through distribution networks and strategic partners.

- **Interims:** Underlying sales in 1H'21 were ahead of expectations, rising 21%, to £6.80m (£6.09m). Currency headwinds dented the reported numbers. Increased sales, coupled with restructuring benefits, resulted in a 45% improvement in underlying EBIT, to -£1.34m (-£2.42m). Gross cash at the period-end was £6.6m.

- **Outlook:** Given the strong performance in 1H'21, coupled with increased manufacturing capacity and launch of new products, there is an understandable temptation to significantly upgrade forecasts. However, while underlying prospects are positive, our numbers reflect US COVID-19-related hospitalisations.

- **Risks:** There has been some recovery in the number of elective surgeries in the US, but whether the pace of recovery can continue for the remainder of 2021 remains uncertain, especially given recent US data regarding COVID-19 infections and hospitalisations. Also, reported numbers will be impacted by forex headwinds.

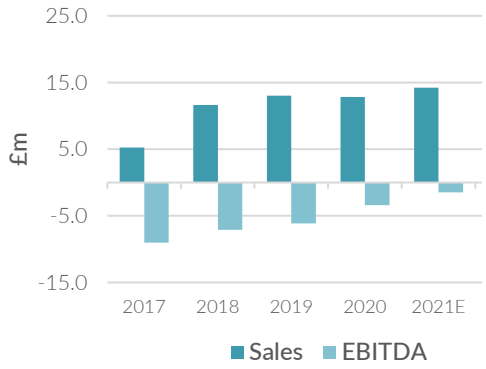
- **Investment summary:** TRX has a portfolio of innovative regenerative products that are in demand from surgeons. Recent product launches and completion of Phase 1 of its capacity expansion programme will add to the positive momentum seen in 1H'21. TRX is extremely well-positioned to deliver sales growth, which is expected to result in further forecast uplifts and a re-rating of the shares when there is more certainty about the recovery in elective surgeries.

Financial summary and valuation

Year-end Dec (£m)	2018	2019	2020	2021E	2022E	2023E
Sales	11.62	13.03	12.84	14.23	19.33	23.38
EBITDA	-7.09	-6.13	-3.40	-1.48	1.60	3.50
Underlying EBIT	-8.27	-7.18	-4.16	-2.30	0.77	2.66
Statutory EBIT	-8.69	-7.20	-9.79	-2.30	0.77	2.66
Underlying PBT	-8.46	-7.64	-4.60	-2.49	0.57	2.55
Statutory PBT	-8.88	-7.66	-10.23	-2.49	0.57	2.55
Underlying EPS (p)	-0.67	-0.60	-0.09	-0.03	0.01	0.04
Statutory EPS (p)	-0.70	-0.61	-0.22	-0.03	0.01	0.04
Net cash/(debt)	7.82	0.09	4.23	1.57	0.41	-2.80
Equity issues	0.00	0.00	14.65	0.00	0.00	0.00
EV/sales (x)	3.7	3.3	3.4	3.0	2.2	1.8
EV/EBITDA (x)	-	-	-12.7	-29.1	27.0	12.3

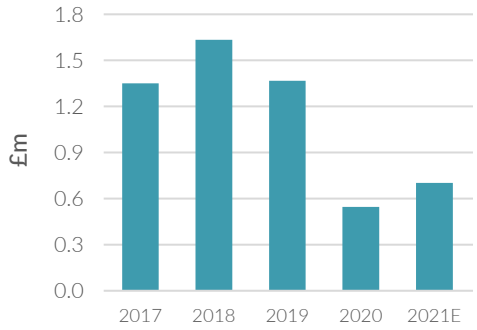
Source: Hardman & Co Life Sciences Research

Sales and EBITDA



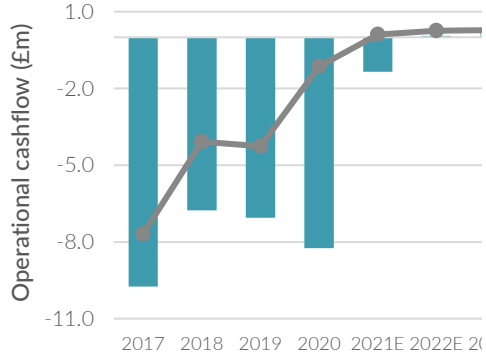
- Sales are dependent on the timing and pace of recovery from the pandemic, and the return of elective surgeries.
- Growth in Orthopaedics & Dental is offsetting the decline in BioSurgery caused by postponement of elective surgeries.
- High gross margin sales, coupled with restructuring of the cost base, is trending EBITDA towards breakeven in 2021.
- Downside to forecasts is limited, while a rapid recovery in elective surgeries would see forecasts moving upwards.

R&D investment



- £22m has been invested in R&D to get the company to where it is today.
- The historical R&D spend was necessary to obtain the US and EU marketing authorisations.
- Future spend will be associated with line extensions and product development, but will be carefully considered.
- About £0.5m annual R&D spend is required to maintain the technologies and make continual product improvements.

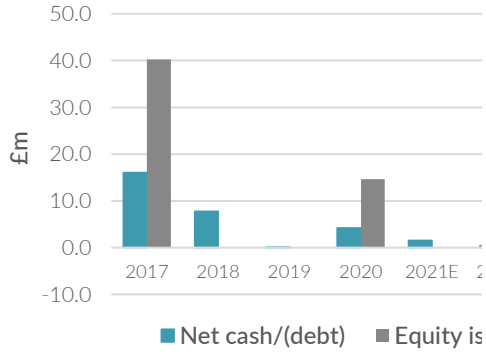
Operational cashflow and OCFPS (rhs)



- The trend in cash burn has been in a positive direction.
- Operational cashflow in 2020 was affected by the increase in inventories as a result of COVID-19.
- Operational cashflow and OCFPS are trending towards neutral over the forecast period.
- There would be a significant leverage effect on cashflows in the event that the timing and pace of recovery in elective surgeries were faster than anticipated.

rhs = right-hand scale

Net cash/(debt) and equity issues



- TRX has raised £103m from investors since inception.
- The company raised £14.6m gross capital in 2020 to fund working capital needs and to invest in capacity expansion in San Antonio.
- Gross cash at 30 June 2021 was £6.6m.
- Conservative forecasts suggest that TRX has sufficient cash through to the end of fiscal 2022. This position would be improved if there were to be a faster recovery in elective surgeries.

Source: Company data, Hardman & Co Life Sciences Research

1H'21 results summary

Key features

Operational and commercial

- **Phase 1 expansion:** The key operational highlight was the completion of Phase 1 of the capacity expansion programme at the end of June, which was both on time and on budget, despite the impact of COVID-19 on construction and supplies. Benefits of this are expected to emerge during 2H'21.
- **Commercial:** TRX has been working closely with its commercial partners throughout the pandemic, and it ensured that they were well-supplied and well-positioned as markets began to "restart".
- **New products:** During 1H'21, TRX introduced DermaPure Meshed and VNEW® through its distributor ARMS Medical. First shipments are due in 3Q'21.

Financials

- **Sales:** Underlying sales exceeded market expectations, rising 21%, to £6.80m (£6.09m). The key driver was the exceptional performance in Orthopaedics & Dental, rising 37%, to £4.26m (£3.42m), compared with our forecast of £3.25m. TRX indicated that US product shipments increased 44% in 1H'21.
- **Forex:** Reported sales numbers were significantly reduced by currency headwinds, with sterling rising 10% and 1% against the US$ and Euro, respectively. However, this also reduced many operating costs, providing natural hedging.
- **COGS:** As expected, there was an increase in COGS, from 51.8% to 54.3% of sales, reflecting product sales mix variances between the periods. COGS are expected to fall as volumes rise.
- **Operating costs:** There was a marked reduction in underlying SG&A costs (excluding share-based costs), which fell 17%, to £4.42m (£5.34m), as the benefits of restructuring began to emerge. Also, there was some temporary pandemic-related reduction in SG&A costs for the biosurgery division.
- **EBIT:** Higher-than-expected sales, coupled with lower SG&A costs, had a leverage effect, which was reflected in a better-than-forecast underlying EBIT, at -£1.34m.
- **Net cash/(debt):** TRX ended the period with gross cash of £6.56m and net cash of £1.19m (including lease liabilities). While these figures were below our forecasts, we had anticipated the working capital requirement (inventories and growth) to fall, which was not the case. Also, there was additional capex on the Phase 1 expansion programme.

Interim results summary – actual vs. expectations

Half-year-end Jun (£m)	1H'20 actual	1H'21 actual	Growth CER	1H'21 forecast	Delta Δ
Orthopaedics	3.42	4.26	+37%	3.25	+1.01
BioSurgery	1.71	1.51	-3%	1.48	+0.03
GBM-V	0.96	1.02	+7%	1.04	-0.02
Group sales	**6.09**	**6.80**	**+21%**	**5.77**	**+1.03**
COGS	-3.15	-3.69	+17%	-3.39	-0.30
SG&A	-4.77	-4.42	-7%	-4.66	+0.24
Share-based costs	-0.02	-0.02	-	0.00	-0.02
Underlying EBITDA	-2.00	-0.93	+54%	-2.02	+1.09
Underlying EBIT	**-2.42**	**-1.34**	**+45%**	**-2.30**	**+0.96**
Gross cash	13.67	6.56	-	7.06	-0.50
Net cash/(debt)	**10.60**	**1.19**	**-**	**2.17**	**-0.98**

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

Corporate update

There are clear signs that the new management team, together with the restructured board, are really starting to deliver. Shipments to commercial and distribution partners increased 44% in 1H'21, which resulted in underlying sales rising 37%, exceeding expectations. With good control of costs, benefiting from the UK and US restructuring programmes, the increased sales had a leverage effect on profitability. With some early benefits from completion of Phase 1 of the capacity expansion programme, this is expected to become even more apparent in 2H'21 and in the full-year numbers.

Poised for growth

In our last report[1], entitled *Poised for growth*, we highlighted how TRX had spent the past two years focusing on the continued development of its commercial strategy, restructuring its operations to service more efficiently the underlying product demand, and commencing a manufacturing capacity expansion programme in its US facilities. The consequences of these factors have resulted in the following:

- Developing an even stronger relationship with tissue banks that are governed in the US by the National Organ Transplant Act (NOTA) to ensure an adequate supply of high-quality human tissue – such as bone, soft tissue and birth tissue.
- A strong product base – both allograft (human-derived) and xenograft (animal-derived) – which preserves the inherent properties of tissue that has been gently processed to retain biological activity.
- Strengthened customer relationships with some of the leading global orthopaedic companies.

All of these outcomes fit well with the management strategy to focus on the four "Ss", which was clearly evident in 1H'21 results.

Focusing on the four "Ss"

Source: TRX presentation

[1] https://www.hardmanandco.com/research/corporate-research/poised-for-growth/

Our last report also highlighted how TRX had been positioning itself to meet the demand for its products and to overcome the surgical backlog when the pace of elective procedures starts to pick up in the post-COVID-19 era. The note also set out the priorities that management had established for 2021. In its interim presentation, TRX updated the market on the accomplishments so far and the future objectives, which are shown in the following graphic.

Four strategic growth areas

	Supply	Sales revenue	Sustainability	Scale
Focus	**Strong relationship with tissue suppliers, fundamental for growth, and tissue procurement must be delivered by the expansion of facility and increase in donor sourcing**	**Diversified portfolio and customer partners generate Company's revenues, to ensure sustainable long-term objectives are met**	**Laser focus on revenue growth critical to realising operational leverage and profitability, with a tight focus on expense management to help accelerate transition to sustainability**	**Allows the Group to pursue strategic growth alternatives and execution of further strategic partners can help with long term growth opportunities**
2020/2021 *Accomplishments*	• Phase one expansion of the San Antonio facility completed on time and on budget • Increased donor storage, final goods & distribution capacity	• Completed development on two additional products and added them to our Biosurgery portfolio • Adapted to our commercial partners needs following the pandemic	• Restructuring of US commercial operations providing savings of US c.$350k in H1 2021 and allowed the Group to be more efficient and in-line with demand	• Key appointments created strong, commercially focused Board and executive leadership team
2021 & beyond *Future objectives*	• Continue to provide products at levels dictated by demand by our existing and potential new customers	• Continue to strengthen product portfolio and clinical data • Cultivate opportunities with existing or new strategic and distribution partners • Execute revenue growth both in the US and outside	• Continue tight monitoring and control of operational and capital expenses • Continue to identify opportunities to be more capital efficient across all aspects of the organization	• Identify opportunities to acquire new technologies and companies • Prepared for post-COVID growth • Initiate Phase 2 expansion as demand approaches our capacity limits

Source: TRX presentation

Capacity expansion programme

New freezer suite

Source: TRX presentation

Investment into storage, manufacturing and distribution capability at its facilities in San Antonio, in order to address the capacity constraints that came to prominence when demand increased, is key to future growth expectations. TRX completed Phase 1 of this investment programme towards the period-end, which was on schedule and on budget. Early benefits of this are already evident.

In order to create the space for the addition of two sterile packaging clean rooms in the existing building, the tissue storage and distribution capabilities were moved into the new, adjacent facility, leased during 2019, and, at the same time, considerably expanded. This modern facility provides three times the tissue storage capacity compared with that contained in the existing facility, which is important given that TRX is sourcing and processing more than double the number of tissue donors per month compared with 18 months ago.

Efficient distribution facility

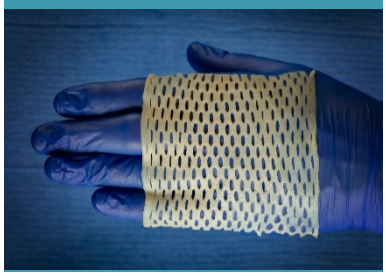
Source: TRX presentation

A new, centralised and more efficient warehousing and distribution function has also been established in the new facility. Given TRX's ever-expanding product range, increased storage capacity necessitated enlarged warehousing from which orders could be dispatched efficiently. Evidence of this can be seen with the 44% increase in shipments to its commercial partners 1H'21.

These activities paved the way for the new clean rooms. The total cost to date, including some Phase 2 construction work that was brought forward to make the entire process more efficient, is $2.7m/£2.1m. It is estimated that this investment has the potential to generate maximum annual revenues of $30m. Completion of Phase 1 provides TRX with flexibility in timing the commencement of Phase 2.

Product update

DermaPure Meshed 3:1



Source: TRX presentation

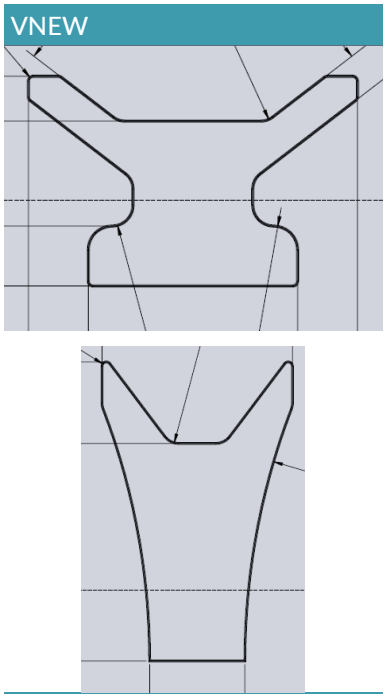
During 1H'21, TRX completed the development of two additional biosurgery products, both using its DermaPure technology platform. Together with OrthoPure XT, a decellularised porcine tendon for the reconstruction of knee ligaments, which received CE marking in 2020, this brings three new products to spur growth for the remainder of 2021 and beyond.

DermaPure Meshed 3:1

DermaPure Meshed 3:1 is designed to provide greater surface area coverage and, at the same times, allows for fluid egress. It is expected to eliminate the current practice of the need for manual meshing, which is extremely time-consuming for the surgeon. This product was made available commercially in June 2021.

VNEW®

VNEW



Source: TRX presentation

VNEW is a pre-cut and pre-shared dermal graft, which is designed to facilitate pelvic organ prolapse (POP) repair procedures. It provides a very pragmatic alternative to the synthetic meshes, which have been used extensively for vaginal repairs in women following childbirth, but were banned by the US FDA in 2019. It will be distributed exclusively through TRX's urogynaecological partner, ARMS Medical, with the first delivery scheduled to take place in 3Q'21.

Changes to forecasts

Following better-than-expected interim results, our forecasts for 2021 have been reviewed. On the one hand, reassessment of the underlying operating performance to reflect the divisional outcomes in 1H'21 has resulted in no change to our underlying numbers. On the other hand, given that it is now October, we have a better feel for the likely outcome of forex for the full year, and, given the strength of sterling, this will have a negative impact on reported sales. However, with an estimated 85%-90% of operating costs being in USD and Euros, these, too, are reduced on translation into GBP, providing a natural hedge to the business, resulting in only a minimal effect on operating profit.

- **Underlying operations:** Our 2021 sales forecast for Orthopaedics and Dental has been increased by ca.3%, while that for BioSurgery has been reduced by 10% to reflect the outcomes at the interim stage. Despite the early signs that elective surgery is recovering, we remain cognisant of the high levels and impact that the COVID-19 delta variant is having on hospitalisations in the US.
- **Forex:** Previous forecasts were based on a constant currency basis. Our revised forecasts have also been updated for the likely impact of currency in 2021, which has a knock-on effect onto future years. The natural hedge means that there is no change at the EBIT level.

Details of our changes to 2021 forecasts can be seen in the following table. While data for fiscal years beyond 2021 are not shown, these changes have a knock-on effect on all subsequent years, but the overall effect on EBIT is again minimal.

Changes to 2021 forecasts

Year-end Dec	2020	2021E			
	Actual	Old	New	Δ	Reported
Orthopaedics	$9.56m	$12.15m	$12.51m	+3.0%	£9.07m
BioSurgery	$4.25m	$4.61m	$4.15m	-10.0%	£3.01m
GBM-v & cardiac	€2.33m	€2.42m	€2.50m	+3.3%	£2.15m
Group sales	**£12.84m**	**£15.20m**	**£15.20m**	**0.0%**	**£14.23m**
Underlying EBIT	-£4.16m	-£2.33m	-£2.30m	+1.3%	-£2.30m

Source: Hardman & Co Life Sciences Research

Financial forecasts

- **Sales:** Despite the very strong pre-pandemic sales performance in 1Q'20, TRX still achieved sales growth in 1Q'21, which accelerated into 2Q'21. While the underlying demand and outlook remain positive, we do have reservations about the sustainability in elective surgery recovery, given recent US COVID-19 data.
- **Natural hedge:** The vast majority of both sales and costs are borne in either US$ or Euros. Consequently, on translation into GBP, they both move in the same direction, providing a natural hedge for the numbers.
- **Trend in EBITDA and EBIT:** There is positive momentum in the business, such that both EBITDA and EBIT are trending towards neutral. In the event that elective surgeries continue to recover in the US in 2H'21, the leverage effect suggests that this could result in TRX reaching EBITDA breakeven by the year-end. However, as noted in this report, we are continuing to adopt a slightly more conservative approach with respect to the recovery in surgeries.

Summary financial forecasts

Year-end Dec (£m)	2018	2019	2020	2021E	2022E	2023E
GBP:USD	1.312	1.278	1.284	1.380	1.380	1.380
GBP:EUR	1.136	1.141	1.125	1.160	1.160	1.160
Income statement						
Sales	**11.62**	**13.03**	**12.84**	**14.23**	**19.33**	**23.38**
COGS	-5.70	-7.01	-6.93	-7.49	-9.94	-11.88
SG&A	-12.61	-11.98	-9.55	-8.34	-7.99	-8.17
R&D	-1.64	-1.37	-0.55	-0.70	-0.63	-0.68
Licensing/royalties	0.00	0.00	0.00	0.00	0.00	0.00
Underlying EBIT	**-8.27**	**-7.18**	**-4.16**	**-2.30**	**0.77**	**2.66**
Share-based costs	0.06	0.15	0.03	0.00	0.00	0.00
Exceptional items	-0.42	-0.02	-5.63	0.00	0.00	0.00
Statutory EBIT	-8.69	-7.20	-9.79	-2.30	0.77	2.66
Net interest	-0.19	-0.46	-0.44	-0.20	-0.20	-0.10
Underlying pre-tax profit	**-8.46**	**-7.64**	**-4.60**	**-2.49**	**0.57**	**2.55**
Tax payable/credit	0.62	0.55	0.53	0.14	0.13	0.07
Underlying net income	-7.84	-7.09	-4.07	-2.35	0.70	2.62
Average no. shares (m)	1,171.6	1,171.9	4,447.7	7,033.1	7,033.6	7,034.6
Underlying basic EPS (p)	**-0.67**	**-0.60**	**-0.09**	**-0.03**	**0.01**	**0.04**
Statutory basic EPS (p)	-0.70	-0.61	-0.22	-0.03	0.01	0.04
Balance sheet (@31 Dec)						
Share capital	5.86	5.86	11.72	11.72	11.72	11.72
Reserves	26.71	18.74	16.13	13.77	14.47	17.09
Capitalised R&D	9.28	8.52	7.45	5.70	7.05	7.86
less: Cash	7.82	2.38	9.55	6.77	5.60	2.40
Invested capital	**34.83**	**33.69**	**31.63**	**30.19**	**33.39**	**40.03**
Cashflow						
Underlying EBIT	-8.27	-7.18	-4.16	-2.30	0.77	2.66
Change in working capital	-0.49	-2.35	-2.94	-0.04	-1.83	-2.06
Tax paid/received	1.23	0.65	0.65	0.68	0.53	0.13
Operational cashflow	**-6.77**	**-7.05**	**-8.24**	**-1.35**	**0.05**	**0.30**
Capital expenditure	-0.29	-0.44	-1.16	-1.00	-1.00	-3.50
Acquisitions	-1.56	0.00	0.00	0.00	0.00	0.00
Equity issues	0.00	0.00	14.65	0.00	0.00	0.00
Change in net debt	**-8.61**	**-7.72**	**4.14**	**-2.66**	**-1.16**	**-3.20**
Opening net cash/(debt)	16.42	7.82	0.09	4.23	1.57	0.41
Closing net cash/(debt)	**7.82**	**0.10**	**4.23**	**1.57**	**0.41**	**-2.80**

Source: Hardman & Co Life Sciences Research

Company matters

Registration

Incorporated in the UK with company registration number 05969271.

UK operations:

Unit 3
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LS25 2GYT

+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

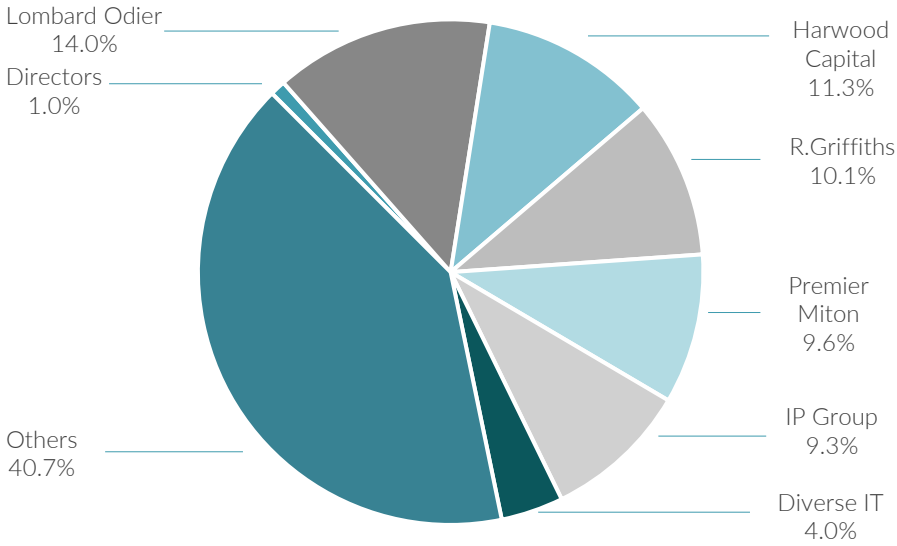
Position	Name	Remuneration	Audit
Chairman	Jonathan Glenn		M
Chief Executive Officer	Daniel Lee		
Chief Financial Officer	David Cocke		
Non-executive director	Shervanthi Homer-Vanniasinkam	M	
Non-executive director	Brian Phillips	M	C
Non-executive director	Trevor Phillips	C	M

M = member, C = chair
Source: Company reports

Share capital

On 18 October 2021, the company had 7,033,077,499 Ordinary shares of 0.1p in issue. There are also 66.92m options and ca.3.10 warrants outstanding.

Shareholders



Source: Company announcements, Hardman & Co Life Sciences Research

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