18 September 2023

# TISSUE REGENIX

## Continuation of the positive momentum

**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 regenerative medicine products for the biosurgery, orthopaedics and dental markets. 1H'23 results highlighted the benefits and efficiencies being derived from investment and reorganisation in manufacturing capacity, with the first underlying EBITDA-positive reporting period. With further strong growth forecast in 2H'23, TRX is on the cusp of achieving profitability. Phase 2 of its capacity expansion programme is expected to be completed in 2025.**

- **Strategy:** TRX is building an international regenerative medicine business around its proprietary technology platforms, underpinned by compelling clinical outcomes. Phase 1 of its manufacturing capacity expansion programme came on stream in 2021 to satisfy demand from distribution partners for its innovative products.

- **1H'23 results:** Underlying sales rose 19%, to $14.1m ($11.8m). Growth was derived from its core BioRionse and dCELL divisions. Operating efficiencies and tight cost control saw TRX become EBITDA-positive in 1H'23. Gross cash at the period-end was $4.1m.

- **Outlook:** These results demonstrate the success of TRX's "4S" strategy to drive sales growth and sustainability. Although the main focus remains the US, TRX is looking to extend its geographical reach through commercial distribution agreements elsewhere, making the company profitable and cash-generative.

- **Risks:** There remain localised issues with respect to the number of elective surgical procedures, staff shortages in healthcare institutions and supply chain issues, although investment in capacity by TRX has mitigated some of these risks. Also, TRX is not immune from global economics and wage inflation.

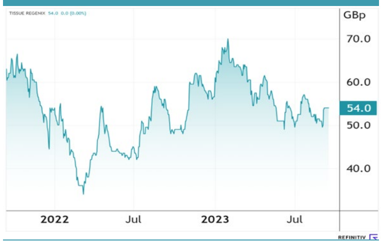
- **Investment summary:** TRX has now been EBITDA profitable over the past 12 months. Continuing the positive momentum will see the company report its first full year of EBITDA profitability in 2023, which will be a significant milestone. Three more six-month periods of consecutive growth will generate overall profitability. An EV/sales multiple of 4x 2024E sales generates a valuation of $138m/£110m, which suggests significant upside potential.

### Financial summary and valuation

| Year-end Dec ($m) | 2019 | 2020 | 2021 | 2022 | 2023E | 2024E |
|---|---|---|---|---|---|---|
| Sales | 16.66 | 16.47 | 19.75 | 24.48 | 29.11 | 34.55 |
| Underlying EBITDA | -8.17 | -3.20 | -3.00 | -0.88 | 0.73 | 2.38 |
| Underlying EBIT | -9.22 | -4.26 | -4.10 | -2.01 | -0.23 | 1.38 |
| Statutory EBIT | -9.24 | -12.58 | -4.45 | -2.01 | -0.23 | 1.38 |
| Underlying PBT | -9.68 | -4.82 | -4.79 | -2.83 | -1.39 | 0.50 |
| Statutory PBT | -9.70 | -13.15 | -5.14 | -2.83 | -1.39 | 0.50 |
| Underlying EPS (¢) | -0.78 | -0.09 | -0.07 | -0.04 | -1.80 | 0.67 |
| Statutory EPS (¢) | -0.78 | -0.28 | -0.07 | -0.04 | -1.80 | 0.67 |
| Net cash/(debt) | 0.12 | 5.75 | -0.24 | -3.66 | -5.48 | -6.37 |
| Equity issues | 0.00 | 18.67 | 0.00 | 0.01 | 0.05 | 0.00 |
| EV/sales (x) | 3.2 | 3.2 | 2.7 | 2.2 | 1.8 | 1.5 |
| EV/EBITDA (x) | - | - | - | -60.9 | 72.5 | 22.3 |

*Source: Hardman & Co Life Sciences Research*

### Pharmaceuticals & Biotechnology




*Source: Refinitiv*

### Market data

| | |
|---|---|
| EPIC/TKR | **TRX** |
| Price (p) | **54.0** |
| 12m high (p) | 70.0 |
| 12m low (p) | 48.0 |
| Shares (m) | 70.57 |
| Mkt cap (£m) | 38.1 |
| EV (£m) | 42.4 |
| Free float* | 61% |
| Reporting currency | USD |
| Country of listing | UK |
| Market | AIM |

**As defined by AIM Rule 26*

### Description

Tissue Regenix (TRX) is a global medtech company in the field of regenerative medicine, with two platform technologies, dCELL®, addressing soft tissue needs, and BioRinse®, providing sterile bone allografts. These unique processing technologies 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 |
| Chair | Jonathan Glenn |

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www.tissueregenix.com

### Key shareholders

| | |
|---|---|
| Directors | 1.1% |
| Harwood Capital | 15.2% |
| R. Sneller (Inthallo) | 13.0% |
| R. Griffiths | 9.7% |
| IP Group | 9.3% |
| Lombard Odier | 8.3% |

### Diary

| | |
|---|---|
| Jan'24 | Trading update |

### Analyst

Dr Martin Hall
mh@hardmanandco.com

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# Interim 2023 results summary

**On course to report first full year of EBITDA profitability in 2023**

On 17 July 2023, TRX informed the market, with a trading update, that underlying sales had increased 19% in 1H'23, representing the sixth consecutive six-month period of growth for the group. This performance was slightly ahead of our forecast. TRX also confirmed that, after reporting its first quarter of EBITDA profitability in 4Q'22, it expected to report EBITDA profitability for 1H'23.

## Key features

### *Operational and commercial*

- **Efficiencies:** The 1H'23 sales and EBITDA performance confirms that TRX is continuing to benefit from the recent Phase 1 investment programme to increase manufacturing capacity, improve source material and overall site reorganisation. Significant improvements were seen in the gross margin.
- **Business activity:** Feedback from TRX's distributors, partners and customers indicate that business activity is returning to pre-COVID-19 levels, notwithstanding that there are still challenges in the supply chain, regulatory affairs and personnel.
- **OrthoPure XT:** Following a number of distribution deals in Europe and Asia, early orders have been received for OrthoPure XT, which is benefiting the dCELL results. This is expected to be an additional growth driver in 2024.

### *Financials*

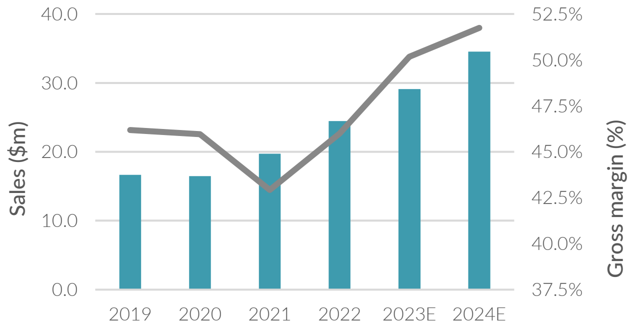
- **Sales:** Underlying group sales rose 19%, to $14.1m ($11.8m), slightly ahead of our original forecasts. Strong growth was seen in the BioRinse (+20%, to $9.4m) and dCELL (+29%, to $3.1m) divisions, offsetting lower-than-anticipated sales at GBM-V (+2%, to $1.6) due to short-term supply difficulties.
- **COGS:** Greater efficiencies from the reorganised manufacturing facility, coupled with an improved product mix, resulted in a drop in COGS, with the gross margin rising significantly from 45.8% in 1H'22 to 49.1% in 1H'23.
- **Administration costs:** Management has stated consistently that it expects marketing and administration costs to rise more slowly than sales. This was again evident with a rise of only 7% in underlying SG&A to $7.05m ($6.60m).
- **Net cash/(debt):** TRX ended the period with gross cash of $4.06m and net debt of $5.43m (including lease liabilities of $3.3m). Although the gross cash was lower than anticipated, this was reciprocated by lower-than-expected debt.

**Interim results summary – actual vs. expectations**

| Half-year-end Jun ($m) | 1H'22 actual | 1H'23 actual | Change CER | 1H'23 *forecast | Delta Δ |
|---|---|---|---|---|---|
| BioRinse | 7.90 | 9.37 | +20% | 9.30 | +0.07 |
| dCELL | 2.40 | 3.11 | +29% | 2.90 | +0.21 |
| GBM-V | 1.50 | 1.61 | +2% | 1.80 | -0.19 |
| **Group sales** | **11.84** | **14.10** | **+19%** | **14.00** | **+0.10** |
| COGS | -6.42 | -7.17 | +12% | -7.50 | +0.33 |
| SG&A | -6.60 | -7.05 | +7% | -7.00 | -0.05 |
| Share-based costs | -0.11 | -0.11 | - | -0.05 | -0.06 |
| Underlying EBITDA | -0.65 | 0.25 | nm | 0.05 | +0.20 |
| **Underlying EBIT** | **-1.29** | **-0.23** | **+82%** | **-0.45** | **-0.22** |
| Gross cash | 6.17 | 4.06 | - | 6.00 | -1.94 |
| **Net cash/(debt)** | **-2.39** | **-5.43** | **-** | **-5.00** | **-0.43** |

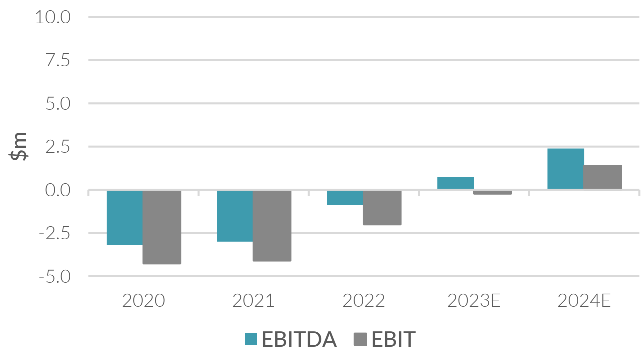
**Prior to release of trading update on 17 July 2023*
*Note: numbers may not add up exactly due to rounding*
*Source: Hardman & Co Life Sciences Research*

## Sales and gross margin



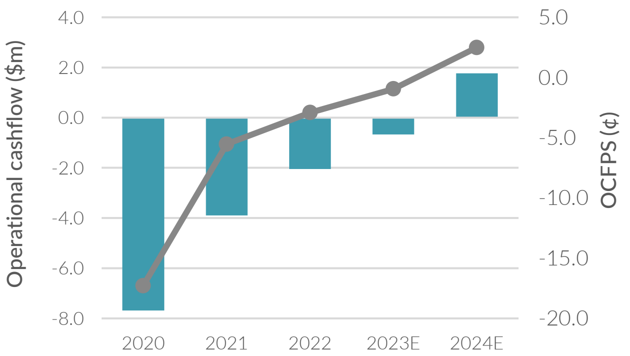

- Increased sources of higher-quality tissue and improved processing capacity, coupled with strong demand, are generating strong sales growth across all divisions.
- Continued recovery in elective surgeries and new product launches are generating strong sales growth.
- Gross margins are on a positive upward trajectory as more manufacturing efficiencies are being realised.

## EBITDA and underlying EBIT



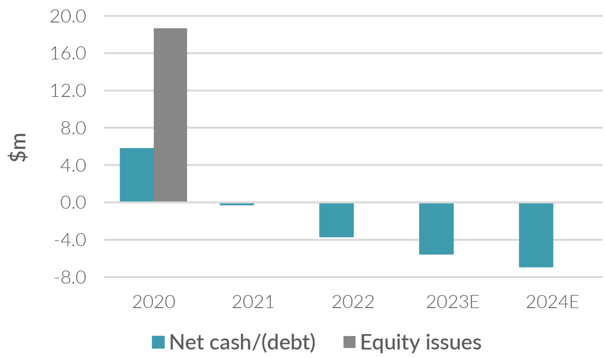

- TRX has turned EBITDA-positive over the past 12 months and is expected to be EBITDA-positive for the full-year 2023, a major milestone.
- Positive sales momentum is expected to see TRX become profitable at both the EBIT and PBT levels in 2024.
- The leverage effect of $0.25m (+1%) of additional sales would make TRX EBIT-positive in 2023.

## Operational cashflow and OCFPS




- There has been a positive trend in lowering the rate of cash burn over the past three years.
- In the event that elective surgeries continue to recover at a faster rate, there would be a significant leverage effect on cashflows.
- Forecast cash generation is expected to allow the commencement of Phase 2 of the capacity expansion programme in 2024.

## Net cash/(debt) and equity issues




- TRX has raised $134m/£103m from investors since inception, the latest being $18.7m/£14.6m gross capital in 2020 to invest in capacity expansion.
- Gross cash at 30 June 2023 was $4.1m, which is also supported by a revolving credit facility of $10.0m.
- Our forecasts suggest that TRX has sufficient cash to deliver the current business plan.

*Source: Company data, Hardman & Co Life Sciences Research*

# Operational overview

## "4S" strategy

**"4S" strategy is generating momentum**

Management's "4S" strategy is the foundation for growth. Its aim has been to develop a strong commercial strategy to create solid relationships with major distributors, thereby creating good underlying demand for products. This necessitated the reorganisation of its operations and investment into capacity expansion at its US facilities. All of this came together in 2022, and has moved further forward in 1H'23, with TRX generating 19% sales growth and being EBITDA-positive. Further progress is expected in 2H'23.

**Highly regulated market with big barriers to entry**

TRX operates in a highly regulated market with enormous barriers to entry. Some of the large, commercial operators do not want to get involved in the complexities associated with the supply of human tissue, preferring to leave this to specialists. But they do need certainty of supply of quality products. This has been an area for key investment by TRX. Over the past two years, the company has been building an even stronger relationship with tissue banks that are governed in the US by the National Organ Transplant Act (NOTA), in order to ensure adequate supplies of high-quality human tissue – such as bone, soft tissue and birth tissue.

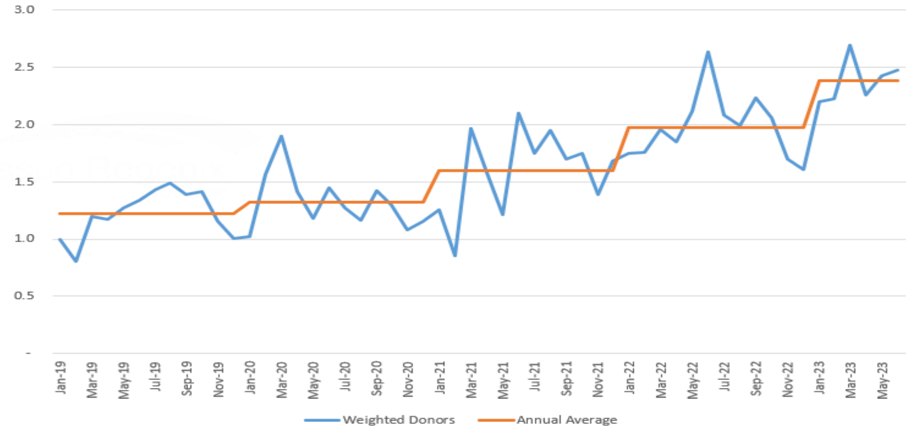
The consequence of this is that TRX now accesses a sufficient supply of donor tissue, both in terms of quantity and quality, which produces higher yields when processed. Phase 1 of the capacity expansion programme has increased the processing capability, which, in turn generates more products. In its 1H'23 results presentation, TRX showed that there has been a three-fold increase in the (weighted) donor tissue being processed (see next page). In addition, greater flexibility and training of the workforce has resulted in a 100% increase in the number of donors processed per employee compared with pre-pandemic levels (see page 7). Originally, the capacity investment was expected to generate up to $30m of sales, but, with these increased efficiencies, this figure has been increased to $40m.

### Progress with the four "S's"

| | SUPPLY | SALES REVENUE | SUSTAINABILITY | SCALE |
|---|---|---|---|---|
| **H1 2023** *Accomplishments* | • **15% year-on-year increase** in processing throughput in US operations<br>• **37% increase** in finished product availability for OrthoPure XT<br>• Signed one **new donor supply contracts** for BioRinse in the H1 2023 | • BioRinse division returned **20% growth in the period**, continuing to take market share<br>• Commercial reorganisation of dCELL division continues to show benefits with **29% sales growth** in the H1 2023 | • **Positive Adjusted EBITDA for the last twelve months** due to sales growth and tight expense management<br>• Increased capacity from Phase One expansion **allows Phase Two capital expenditure to be pushed out**<br>• **Cash position supports current business plan** | • Identified and are in the process of **establishing a third-party logistics provider** to provide distribution services to the European Union and the UK<br>• Increased credit facility with MidCap from $5.0m to $10.0m to support **future working capital growth** |
| **2023** *Future objectives* | • Construction of Phase 2 expansion has been pushed to 2025 as a result of the capacity created by Phase 1<br>• Phase 2 will include an additional ten clean rooms | • Continue double-digit growth, following the same trajectory as the Company's other US business | • Continue tight monitoring and control of operational and capital expenses<br>• Continue to identify opportunities to be more capital efficient across all aspects of the organisation | • Distribute allograft tissue products in markets outside the US |

*Source: TRX presentation*

Donors processed (weighted by donor type) per FTE




*January 2019 baseline*
*Source: TRX interim results presentation*

Commencement of Phase 2 is expected to begin in 2024 for completion in 2025 and to cost in the range $3.5-$4.0m spread over two fiscal years, with the initial $2.0m capital expenditure included in our 2024 cashflow forecast.

## *Increased confidence*

**Customer confidence in ability to supply in timely manner**

With six consecutive six-monthly reports of well-above market average growth, customers clearly have confidence that TRX can supply the required quality of the desired product in a timely manner. New distributors are being signed up and trained at a fast rate, such that TRX may well exceed its target of 32 new distributors in the US in 2023 – 25 on board by the end of June.

## *Geographical expansion*

**Potential to expand into non-US markets**

TRX has made progress in its strategy to expand selectively on a geographical basis. OrthoPure XT has approvals and distributors in Italy, Germany and the UK. Also, partners were signed in China (plus Hong Kong) and Australia in 1H'23 for a range of TRX products, although they must go through the regulatory process before they can be launched.

## *Big addressable markets*

**Identification of additional efficiencies has moved start date for Phase 2 of capacity expansion into 2024**

TRX has products that are targeting the large and well-established bone graft market. While there is strong competition, TRX's offering is differentiated and its products are being commercialised by extremely strong global partners. Additionally, it is targeting the soft tissue repair market, with a particular emphasis on wound management, sports-related injuries and urogynaecology. Again, its products are differentiated and desired, as evidenced by a sales growth rate that is 3x-5x the average market growth rate, and by commercial partners requesting specific new products that can resolve a specific condition.

## *Trend towards profitability*

**EBITDA-positive for 12 months…**

**…expected to follow-through into full-year 2023…**

**…and on the cusp of EBIT-positive in 2023**

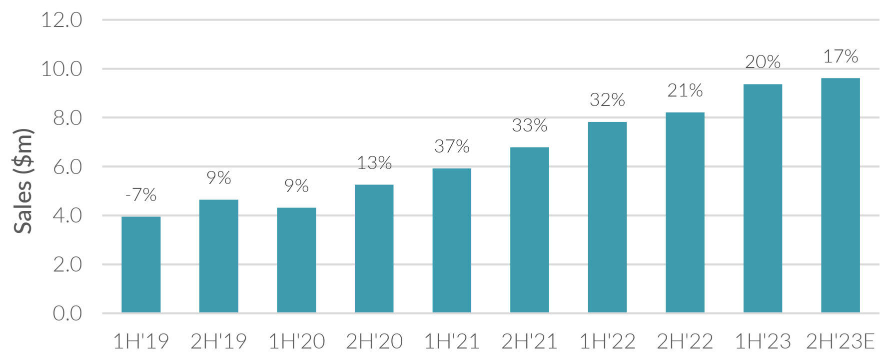
TRX has now been EBITDA-positive for the 12-months to end-June 2023 and with a strong start to 2H'23, this is expected to follow through to the full year. Although current forecasts suggest that TRX will not quite reach overall EBIT profitability in 2023, it will be very close, with the leverage effect of an extra $0.25m (+1%) of sales sufficient to reach profitability in 2023. Even without this, it seems certain that the company will be both EBIT- and PBT-positive in 2024.

# BioRinse

**Strong upward momentum**

Given its more readily available source material, a diverse range of differentiated bone scaffold products and strong commercial partners, BioRinse continues to benefit from the expansion programme to increase tissue storage and processing capacity. This has been borne out by results from the past five six-month reporting periods, with sales growth rates as follows: 1H'21 +37%; 2H'21 +33%; 1H'22 +32%; 2H'22 +21%; and now 1H'23 +20%. Growth has been supported by industry reputation and commercial partner confidence across all its surgical specialties – orthopaedics, sports medicine, spine, dental and trauma.

**Half-yearly performance in BioRinse sales, 1H'19-2H'23E**




*Source: Hardman & Co Life Sciences Research*

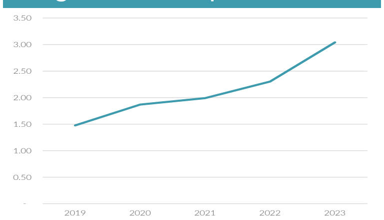
Confidence in the superior performance of BioRinse products and the ability of TRX to supply them in a timely manner is recognised by TRX's existing strategic commercial partners and new customers. This has been exemplified by a range of new soft tissue allografts announced today for the sports medicine market that was requested by strategic partners to fulfil a particular need in the market.

With the additional capacity and smooth running of operations, management is looking to expand the BioRinse offering into a select band of other countries. To that end, TRX engaged a third-party logistics partner and has commenced the necessary regulatory approval processes for expansion into Europe.

**Slight seasonal effect on growth rates**

With 20% growth in 1H'23, one could argue that the 17% growth rate forecast for 2H'23 is somewhat conservative. However, for the past two years, the growth in BioRinse sales has been stronger in 1H versus 2H, indicating that there may be a slight seasonal trend for these products.

**Weighted donors processed**




*Baseline: January 2019*
*Source: TRX presentation*

Since 2019, the number of weighted donors being processed through the enlarged facility has doubled. This improved capacity coupled with greater efficiencies means that TRX has the ability to respond rapidly to shifts in market demand. It is also reflected in the improvement to gross margins, with a 3.7pp gain to 51.4% in 1H'23. In addition, a slower rate of rise in marketing and administration compared with sales growth, led to the underlying (excluding amortisation charge) BioRinse EBIT more than doubling to $1.06m.

**Margins expected to expand further**

For 2023, we are not changing our forecast overall sales growth rate of 18% for the BioRinse division. However, even at this level of growth, this division should see further leverage to the EBIT margin. Overall, we are forecasting an underlying EBIT of $3.0m for BioRinse.

# dCELL

**Benefits from reorganisation and capacity expansion showed in 2H'22 and continued into 1H'23**

Benefits from the commercial reorganisation of the dCELL division really began to show through in 2H'22, with sales rising by an exceptional 35%. This generated an overall growth rate of 25% for the full-year. Growth has continued into 1H'23, with sales rising 29% to $3.1m, which was $0.2m ahead of expectations. In addition, there was a 6.0pp gain in the gross margin to 50.5% and careful control of marketing and administration costs delivered a first profit for the dCELL division.

**Performance of dCELL division, 2022-2023E**

| Reporting period ($m) | 1H'22 | 2H'22 | 2022 | 1H'23 | 2H'23E | 2023E |
|---|---|---|---|---|---|---|
| Sales | 2.41 | 2.89 | 5.30 | 3.11 | 3.68 | 6.80 |
| Gross profit | 1.07 | *1.22 | *2.28 | 1.57 | 2.04 | 3.61 |
| Gross margin | 44.4% | 42.2% | 43.0% | 50.5% | 55.3% | 53.1% |
| SG&A | -1.32 | -1.95 | -3.27 | -1.46 | -2.21 | -3.47 |
| **EBIT** | **-0.24** | **-0.30** | **-0.55** | **0.12** | **0.03** | **0.14** |
| EBIT margin | 10.1% | -10.5% | -10.4% | 3.7% | 0.7% | 2.1% |

**Excludes one-off cost of terminating a supplier contract*

*Source: Hardman & Co Life Sciences Research*

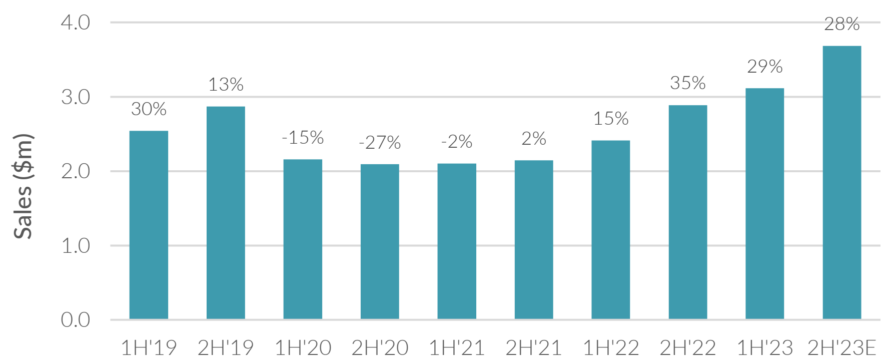
Following on from a successful 2H'22, TRX has signed up and trained a further 25 distribution partners in the US during 1H'23, leaving it well-placed to hit the full-year target of 32. The flat organisational structure that was introduced in 2022 means that the sales team works more closely with its customers.

Reinvigoration of the underlying sales growth has been complemented by the first contribution from OrthoPure XT through orders to some of its distribution partners – out-licensed in the UK, Italy, Germany, China, Hong Kong and Australia.

**Attractive offering enticing more distributors**

Being dependent on elective surgeries, the dCELL division was severely impacted by the COVID-19 lockdown. However, as normality has been restored in elective surgeries, manufacturing capacity greatly increased, alongside the launch of some new products, so the sales have recovered, as can be seen in the following chart. 1H'23 represents the third consecutive six-month period of strong growth, which is expected to continue.

**Sales performance of dCELL, 1H'19-2H'23E**




*Source: Hardman & Co Life Sciences Research*

## *Approaching profitability*

**Improving underlying gross margin has moved dCELL into profitability in 1H'23**

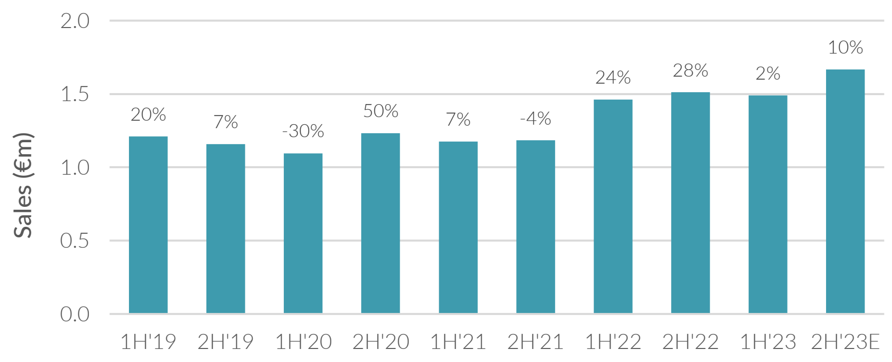
Early signs of the leverage effect of strong sales growth were evident in 2022 with the dCELL approaching profitability. This has been consolidated in 1H'23 with the division profitable at the EBIT level for the first time.

# GBM-V

**Improved supply of tissue**

Following problems associated with the supply of corneal tissue seen in 2021, there was a recovery in 2022, which also benefited from an improvement in the yield, to generate a record year of distributed corneal grafts by GBM-V. This had been expected to continue. However, donor supply became an issue again in 1H'23, limiting underlying sales growth to 2% (flat on a reported basis). However, this is thought to be a temporary issue and a return to growth is expected in 2H'23. Having said this, our full-year expectations have been tempered slightly to reflect the $0.2m shortfall reported for 1H'23.

**Sales performance of GBM-V, 1H'19-2H'23E**




*Source: Hardman & Co Life Sciences Research*

**Growth dependent on supply of donor corneal tissue**

When the supply of corneal tissue reverts to normal, sales growth is expected to return to low double-digits, with a corresponding modest increase in profitability.

**Performance of GBM-V, 2019-2024E**

| Year-end Dec ($m) | 2019 | 2020 | 2021 | 2022 | 2023E | 2024E |
|---|---|---|---|---|---|---|
| Sales | 2.65 | 2.66 | 2.79 | 3.13 | 3.30 | 3.80 |
| COGS | -1.79 | -1.59 | -1.89 | -1.96 | -2.20 | -2.45 |
| *Gross margin* | *32.4%* | *40.4%* | *32.4%* | *37.5%* | *34.0%* | *35.0%* |
| SG&A | -1.27 | -1.42 | -1.06 | -0.76 | -0.75 | -0.80 |
| **EBIT** | **-0.41** | **-0.34** | **-0.15** | **0.41** | **0.35** | **0.55** |

*Source: Hardman & Co Life Sciences Research*

# Other matters

## Revolving credit facility

**Greater financial flexibility**

At the end of 2022, TRX had borrowings of $6.26m through its debt facility with MidCap, and lease liabilities of $3.35m for its manufacturing facilities and office space in San Antonio. To provide the company with additional flexibility, in January 2023, TRX increased its revolving debt facility from $5.0m to $10.0m. At the time, management stressed that there was no intention of using this facility, based on the period-end cash position and its business plan. Additionally, the term of this loan facility has been extended from 2024 to 2028. By the end of June, the level of debt was lower than our forecast.

## Analysis of net cash/(debt)

The gross cash position at the end of the period was less than expected. However, so were the gross debts. The following table highlights the differences in cash and debt compared with forecasts at 30 June 2023. In addition, the gross cash was affected by a modest investment ($0.22m) in R&D, which was capitalised, and an exit fee ($0.25m) for repaying a loan early, neither of which were known about or forecast. Despite this, the cash position is comfortable, which, together with the increased revolving credit facility mentioned above, provide the group with sufficient working capital through to internal sustainability.

Analysis of net cash/(debt)

| $m | @31 Dec'22 actual | @30 Jun'23 actual | @30 Jun'23 forecast | Delta Δ |
|---|---|---|---|---|
| Gross cash | 5.95 | 4.06 | 6.07 | **-2.01** |
| Short-term debt | -1.00 | -0.25 | -1.20 | +0.95 |
| Long-term debt | -5.26 | -5.96 | -6.50 | +0.54 |
| Short-term leases | -0.13 | -0.14 | -0.13 | -0.01 |
| Long-term leases | -3.22 | -3.15 | -3.22 | +0.07 |
| **Net cash/(debt)** | **-3.66** | **-5.43** | **-5.00** | **-0.46** |
| Gross debt | | -9.50 | -11.05 | -1.55 |
| Capitalised R&D | - | -0.22 | 0.00 | -0.22 |
| Loan termination exit fee | - | -0.25 | 0.00 | -0.25 |
| **Reconciliation to cash** | **-** | **-** | **-** | **-2.01** |

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

The exit fee paid to MidCap also affected the interest payable line in the income statement in 1H'23, which has been carried through to the full year.

## Share consolidation

**1-for-100 share consolidation**

As a reminder, in April, TRX completed a share consolidation, whereby each 100 shares of 0.001p nominal value were replaced by 1 share of 0.1p. The board felt that this move would be more conducive to an orderly market in the shares and make them more attractive to investors. Following the consolidation, there were 70,357,949 Ordinary shares in issue (recently increased modestly through the exercise of share options).

# Financial summary

## Income statement

- **Sales:** Well-above market average sales growth of 19% in 1H'23, and a strong start to 2H'23, augurs well for fiscal 2023. Future growth is dependent on tissue supply, the activities of customers and healthcare providers, and the expansion of both product range and geographically into selected markets.
- **COGS:** Gross margins are on an upward trend as sales volumes increase and further manufacturing efficiencies evolve from Phase 1 of the capacity investment. The 49.1% margin in 1H'23 is back above pre-pandemic levels. Further margin improvement is expected as volumes expand further.
- **SG&A:** Although TRX continues to invest in marketing and commercial partnerships, the general administration costs are rising at a slower rate than sales – although we are mindful of global inflation and pressure on wage costs.
- **Profitability:** Having broken through the EBITDA-positive milestone for the past 12 months, the next goal is to become EBIT- and PBT-positive. This is expected, currently, to occur in 2024, but only a modest 1% increase in sales (+$0.25m) is required to hit the EBIT breakeven milestone in 2023.

Income statement

| Year-end Dec (£m) | 2019 | 2020 | 2021 | 2022 | 2023E | 2024E |
|---|---|---|---|---|---|---|
| USD:EUR | 0.893 | 0.877 | 0.846 | 0.952 | 0.952 | 0.952 |
| BioRinse | 8.59 | 9.56 | 12.71 | 16.05 | 19.00 | 22.35 |
| dCELL | 5.41 | 4.25 | 4.25 | 5.30 | 6.80 | 8.49 |
| GBM-V | 2.65 | 2.66 | 2.79 | 3.13 | 3.31 | 3.71 |
| **Sales** | **16.66** | **16.47** | **19.75** | **24.48** | **29.11** | **34.55** |
| COGS | -8.96 | -8.90 | -11.27 | -13.22 | -14.51 | -16.67 |
| Gross profit | 7.69 | 7.57 | 8.48 | 11.26 | 14.61 | 17.88 |
| Gross margin | 46.2% | 46.0% | 42.9% | 46.0% | 50.2% | 51.7% |
| SG&A | -17.05 | -12.96 | -12.46 | -13.02 | -14.58 | -16.04 |
| Share-based costs | 0.15 | 0.04 | -0.11 | -0.25 | -0.25 | -0.45 |
| Other income | 0.00 | 1.10 | 0.00 | 0.00 | 0.00 | 0.00 |
| **Underlying EBITDA** | **-8.17** | **-3.20** | **-3.00** | **-0.88** | **0.73** | **2.38** |
| Depreciation | -0.48 | -0.32 | -0.37 | -0.52 | -0.51 | -0.53 |
| Amortisation | -0.57 | -0.73 | -0.73 | -0.62 | -0.45 | -0.47 |
| **Underlying EBIT** | **-9.22** | **-4.26** | **-4.10** | **-2.01** | **-0.23** | **1.38** |
| Exceptional items | -0.02 | -8.32 | -0.36 | 0.00 | 0.00 | 0.00 |
| Statutory EBIT | -9.24 | -12.58 | -4.45 | -2.01 | -0.23 | 1.38 |
| Net interest | -0.46 | -0.57 | -0.69 | -0.82 | -1.17 | -0.89 |
| **Underlying pre-tax profit** | **-9.68** | **-4.82** | **-4.79** | **-2.83** | **-1.39** | **0.50** |
| Extraordinary items | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Statutory pre-tax profit | -9.70 | -13.15 | -5.14 | -2.83 | -1.39 | 0.50 |
| Tax payable/credit | 0.55 | 0.68 | 0.16 | 0.23 | 0.13 | -0.02 |
| **Underlying net income** | **-9.12** | **-4.14** | **-4.63** | **-2.60** | **-1.27** | **0.47** |
| Statutory net income | -9.14 | -12.46 | -4.99 | -2.60 | -1.27 | 0.47 |
| | | | | | | |
| **Ordinary 0.1p shares:** | | | | | | |
| Period-end (m) | 11.7 | 70.3 | 70.3 | 70.3 | 70.6 | 70.7 |
| Weighted average (m) | 11.7 | 44.5 | 70.3 | 70.3 | 70.5 | 70.6 |
| Fully-diluted (m) | 12.0 | 45.1 | 71.6 | 71.6 | 71.7 | 71.9 |
| | | | | | | |
| **Underlying basic EPS (¢)** | **-77.84** | **-9.31** | **-6.58** | **-3.69** | **-1.80** | **0.67** |
| Statutory basic EPS (¢) | -78.02 | -28.03 | -7.09 | -3.69 | -1.80 | 0.67 |
| Underlying fully-dil. EPS (¢) | -75.73 | -9.17 | -6.47 | -3.63 | -1.77 | 0.66 |
| Statutory fully-dil. EPS (¢) | -75.91 | -27.61 | -6.97 | -3.63 | -1.77 | 0.66 |
| DPS (¢) | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |

*Source: Hardman & Co Life Sciences Research*

## Balance sheet

- **Inventories:** At 30 June, inventories had increased 2% compared with the position at 31 December 2022. This was ahead of expectations, but reflects both the growth of the company and a build-up in OrthoPure XT to supply orders from distribution partners. Despite this, there is a downward trend in the number of inventory days.
- **Working capital:** Overall, there is a reasonable balance between increased inventories and trade receivables versus the increase in payables, as expected for a growth company. The increased revolving credit facility adds further flexibility to TRX's working capital needs.
- **Net cash/(debt):** At 30 June 2023, TRX had net debt of $5.43m, comprised of gross cash of $4.06m, offset by long-term loans and leases and the expanded revolving credit facilities of $9.50m. Repayments of the term loan are due to commence in January 2024.
- **Capital requirement:** Given that TRX is approaching cashflow breakeven based on current forecasts, the gross cash position and the revolving credit facility are expected to be sufficient to satisfy the company's future needs to fulfil its business plan. The aim is to generate sufficient cash over the next two years to enable Phase 2 of the capacity expansion programme to start in 2024, which will require capital expenditure of about $3.5-$4.0m spread over two years.

**Balance sheet**

| @31 Dec (£m) | 2019 | 2020 | 2021 | 2022 | 2023E | 2024E |
|---|---|---|---|---|---|---|
| Shareholders' funds | 32.49 | 38.27 | 33.39 | 30.40 | 29.18 | 29.66 |
| Cumulated goodwill | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Total equity | 32.49 | 38.27 | 33.39 | 30.40 | 29.18 | 29.66 |
| | | | | | | |
| Share capital | 7.74 | 15.95 | 15.95 | 15.95 | 15.95 | 15.95 |
| Reserves | 24.75 | 22.32 | 17.45 | 14.45 | 13.23 | 13.71 |
| Provisions/liabilities | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Deferred tax | 0.89 | 0.76 | 0.64 | 0.52 | 0.42 | 0.32 |
| Long-term leases | 0.00 | 3.08 | 3.36 | 3.22 | 3.01 | 2.76 |
| Short-term leases | 0.00 | 0.35 | 0.12 | 0.13 | 0.13 | 0.13 |
| Long-term debt | 2.79 | 3.79 | 4.47 | 5.26 | 5.96 | 5.46 |
| Short-term loans | 0.23 | 0.00 | 0.00 | 1.00 | 0.25 | 0.00 |
| *less:* Cash | 3.14 | 12.97 | 7.71 | 5.95 | 3.87 | 1.98 |
| less: Deposits | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| less: Non-core invests. | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| **Invested capital** | **33.03** | **33.28** | **34.27** | **34.58** | **35.08** | **36.34** |
| | | | | | | |
| Fixed assets | 3.11 | 4.42 | 5.71 | 5.74 | 5.98 | 7.85 |
| Intangible assets | 23.78 | 15.30 | 15.06 | 15.06 | 15.06 | 15.06 |
| Right-of-use assets | 0.00 | 3.34 | 3.39 | 3.20 | 2.99 | 2.74 |
| Goodwill | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Inventories | 5.53 | 9.60 | 9.72 | 10.88 | 11.65 | 11.89 |
| *Trade debtors* | *2.27* | *2.42* | *2.95* | *3.65* | *3.91* | *4.18* |
| *Other debtors* | *1.08* | *1.17* | *1.16* | *1.15* | *1.20* | *1.20* |
| *Tax liability/credit* | *1.37* | *1.12* | *0.53* | *0.40* | *0.23* | *-0.02* |
| *Trade creditors* | *-2.18* | *-1.32* | *-2.57* | *-2.57* | *-2.96* | *-3.40* |
| *Other creditors* | *-1.94* | *-2.76* | *-1.67* | *-2.94* | *-2.98* | *-3.15* |
| Debtors less creditors | 0.61 | 0.63 | 0.39 | -0.31 | -0.60 | -1.20 |
| **Invested capital** | **33.03** | **33.28** | **34.27** | **34.58** | **35.08** | **36.34** |
| | | | | | | |
| **Net cash/(debt)** | **0.12** | **5.75** | **-0.24** | **-3.66** | **-5.48** | **-6.37** |
| Inventory days | 121 | 168 | 179 | 154 | 141 | 124 |
| Debtor days | 50 | 54 | 50 | 49 | 47 | 43 |
| Creditor days | 89 | 54 | 63 | 71 | 71 | 70 |

*Source: Hardman & Co Life Sciences Research*

# Cashflow

- **Operational cashflow:** Although EBITDA-positive, TRX will still be cash negative (<$1.0m) at the operational level, including financing costs. On current forecasts, operational cashflow turns positive in 2024 and beyond.
- **Capex:** With modern manufacturing and administration facilities, only modest maintenance capex is required. $3.5-$4.0m will be invested in capex over a two-year period when Phase 2 begins during the course of 2024, for completion in 2025.
- **Capitalised R&D:** The company continues to make modest investment into R&D for new product variants, but, as the core products are already approved and commercialised, this cost is being capitalised.

**Cashflow**

| Year-end Dec (£m) | 2019 | 2020 | 2021 | 2022 | 2023E | 2024E |
|---|---|---|---|---|---|---|
| Underlying EBIT | -9.22 | -4.26 | -4.10 | -2.01 | -0.23 | 1.38 |
| Depreciation | 0.48 | 0.32 | 0.37 | 0.52 | 0.51 | 0.53 |
| Amortisation | 0.57 | 0.73 | 0.73 | 0.62 | 0.45 | 0.47 |
| Share-based costs | -0.15 | -0.04 | 0.11 | 0.25 | 0.25 | 0.45 |
| *Inventories* | *-1.86* | *-4.12* | *-0.12* | *-1.16* | *-0.77* | *-0.24* |
| *Receivables* | *1.08* | *-0.26* | *-0.51* | *-0.70* | *-0.26* | *-0.27* |
| *Payables* | *-1.57* | *0.22* | *0.16* | *1.25* | *0.39* | *0.44* |
| Change in working capital | -2.35 | -4.15 | -0.47 | -0.62 | -0.64 | -0.06 |
| Exceptionals/provisions | 1.31 | -0.45 | -0.36 | 0.00 | 0.00 | 0.00 |
| Disposals | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Other | -0.12 | -0.16 | 0.00 | -0.19 | 0.00 | 0.00 |
| **Company op. cashflow** | **-9.47** | **-8.01** | **-3.72** | **-1.44** | **0.34** | **2.77** |
| Net interest | -0.37 | -0.32 | -0.39 | -0.44 | -0.92 | -0.63 |
| Lease payments | 0.00 | -0.24 | -0.40 | -0.36 | -0.49 | -0.51 |
| Tax paid/received | 0.65 | 0.88 | 0.62 | 0.19 | 0.40 | 0.13 |
| **Operational cashflow** | **-9.18** | **-7.68** | **-3.89** | **-2.05** | **-0.67** | **1.76** |
| Capital expenditure | -0.44 | -1.57 | -1.55 | -0.38 | -0.75 | -2.40 |
| Capitalised R&D | -0.21 | -0.29 | -0.50 | -0.71 | -0.50 | 0.00 |
| Sale of fixed assets | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| **Free cashflow** | **-9.84** | **-9.55** | **-5.94** | **-3.14** | **-1.92** | **-0.64** |
| Dividends | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Acquisitions | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Disposals | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Other investments | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| **Cashflow after invests.** | **-9.84** | **-9.55** | **-5.94** | **-3.14** | **-1.92** | **-0.64** |
| Share repurchases | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Equity issues | 0.00 | 18.67 | 0.00 | 0.01 | 0.05 | 0.00 |
| Funding costs | 0.00 | -1.15 | 0.00 | 0.00 | 0.00 | 0.00 |
| Currency effect | -0.02 | 0.08 | -0.05 | -0.29 | 0.00 | 0.00 |
| Cash/(debt) acquired | 0.00 | -2.43 | 0.00 | 0.00 | 0.00 | -0.50 |
| **Change in net debt** | **-9.86** | **5.63** | **-5.99** | **-3.42** | **-1.87** | **-1.14** |
| | | | | | | |
| Opening net cash/(debt) | 9.98 | 0.12 | 5.75 | -0.24 | -3.66 | -5.48 |
| **Closing net cash/(debt)** | **0.12** | **5.75** | **-0.24** | **-3.66** | **-5.53** | **-6.62** |
| OCFPS (¢) | -0.78 | -78.37 | -17.27 | -5.53 | -0.94 | 2.49 |

*Source: Hardman & Co Life Sciences Research*

## Valuation

TRX plays valuable niche role for its commercial partners

As a rule-of-thumb, I do not use the word "unique" very often, largely because there is always another company somewhere in the world using similar technology and/or "know-how" to generate similar and competitive products. However, TRX does appear to be the exception and it has developed an incredibly interesting niche for itself based on supply and processing of tissue and the differentiated products that it creates. Consequently, it is a difficult company to value. Although it has been a long ride, TRX has achieved a number of significant accomplishments, while converting its technologies into commercially useful medical products and devices.

To get the company to where it is today, TRX has invested ca.$120m, plus $30m for the acquisition of CellRight in 2017. However, these simple numbers ignore the significant hurdles that have been overcome, notably the supply, storage and processing of human tissue, and the inherent manufacturing "know-how". Although its large commercial partners could undertake this work, they prefer to leave the complex supply, manufacturing and regulatory issues to a niche player like TRX. This places TRX in a strong position with its partners.

The equivalent of 170p per share has been invested to get the company to where it is today

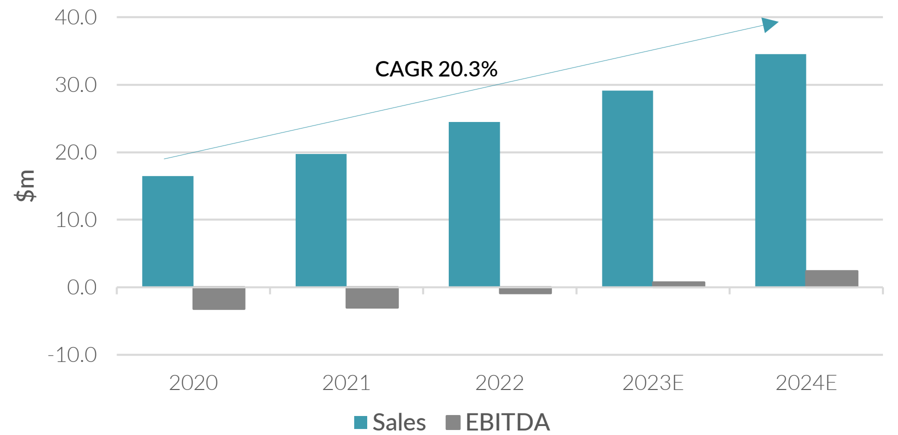
Based on the following facts, TRX, with a market capitalisation of £38.8m/$48.7m, is currently being undervalued by the market:

- To get TRX to where it is today, $150m/£120m – equivalent to 170p per share – has been invested into the company.
- R&D investment to obtain marketing authorisations for a number of products, excluding all the investment made by CellRight, has been ca.$30m/£25m.
- SG&A to establish its products in the market (mostly in the US), and to sign up the network of GPOs and distribution partners, have been $135m/£108m.
- The administrative achievement in obtaining the relevant accreditations and licences for the harvesting and processing of human tissue is considerable.

Strong, positive momentum has left TRX on the cusp of profitability

At this point in time, TRX is on the cusp of the major milestone of becoming EBIT-positive, and is expected to be PBT-positive in 2024. Only a small increase in sales against forecasts is needed for this to happen in fiscal 2023.

Sales and underlying EBITDA, 2020-24E




*Source: Hardman & Co Life Sciences Research*

Significant mis-match between valuation and market capitalisation

Close relationships with a number of the major global medtech players, who need significant annual product sales in order to justify the relationships, are expected to drive future sales growth. A unique, fast-growth, company such as TRX should command a prospective EV/sales multiple of 4.0x 2024E sales, suggesting an enterprise value of $138m/£110m.

# Company matters

## Registration

Incorporated in the UK, with company registration number 05969271.

**UK operations:**

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LS25 2GYT

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www.tissueregenix.com

**US operations:**

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Universal City
San Antonio
Texas
78148

## Board of Directors

**Board of Directors**

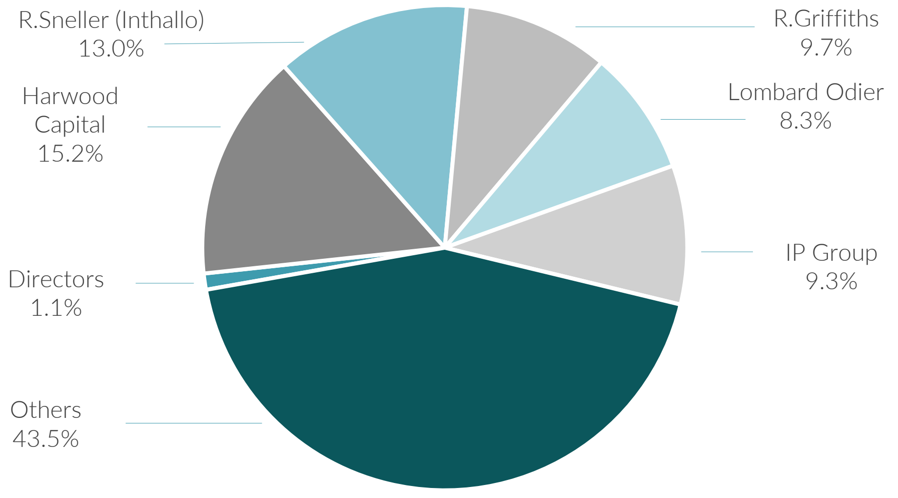
| Position | Name | Remuneration | Audit |
|---|---|---|---|
| Chairman | Jonathan Glenn | | M |
| Chief Executive Officer | Daniel Lee | | |
| Chief Financial Officer | David Cocke | | |
| Non-executive director | Shervanthi Homer-Vanniasinkam | M | |
| Non-executive director | Brian Phillips | M |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

*M = member, C = chair*
*Source: Company reports*

## Share capital

On 6 September 2023, the company had 70,574,468 Ordinary shares of 0.1p in issue. There are also 1.72m options and 0.031m warrants outstanding.

**Shareholders**




*Source: Company announcements, Hardman & Co Life Sciences Research*

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