# TISSUE REGENIX

## On pathway to sustainability

**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 commercial regenerative medicine products for the biosurgery, orthopaedics and dental markets. 2021 results contained the early benefits of TRX's strategic activities over the past two years – the focus on commercial relationships, capacity expansion, restructuring to service demand and recovery in elective surgeries. On the basis of continued sales progression, TRX is forecast to become EBITDA-positive in fiscal 2022 and cash-generative in 2023.**

- **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.

- **2021 results:** Sales in fiscal 2021 were marginally ahead of our forecasts, at $19.75m, up 20% from $16.47m in 2020. The leverage effect of a strong BioRinse sales performance (+33%) saw a marked reduction in EBIT losses in 2H'21. Gross cash at the period-end was $7.7m.

- **Outlook:** The 2021 performance was achieved despite the continuing impact of COVID-19 and some unforeseeable headwinds; this augurs well for the future. Progress is forecast to continue in 2022, resulting in 22% sales growth, which will drive margin expansion towards profitability by the end of 2022.

- **Risks:** Early signs of recovery in the number of elective surgeries in the US were dented by the delta variant, and the emergence of another variant remains a possibility. Forecasts suggest that TRX is nearing profitability and cashflow breakeven, which would eliminate any lingering concerns about the need for a capital increase.

- **Investment summary:** TRX has a broad portfolio of innovative regenerative products that are in demand from surgeons. Completion of Phase 1 of its capacity expansion programme has comforted distribution partners and provided positive momentum. We believe TRX is well-positioned to deliver strong sales growth, which will drive margin expansion and highlight the low rating of the shares. An EV/sales multiple of 4x 2023E sales generates a valuation of $120m/£92m.

### Financial summary and valuation

| Year-end Dec ($m) | 2019 | 2020 | 2021 | 2022E | 2023E | 2024E |
|---|---|---|---|---|---|---|
| Sales | 16.66 | 16.47 | 19.75 | 24.00 | 30.20 | 37.02 |
| EBITDA | -8.17 | -3.20 | -3.00 | -0.80 | 1.63 | 5.29 |
| Underlying EBIT | -9.22 | -4.26 | -4.10 | -2.00 | 0.34 | 3.13 |
| Statutory EBIT | -9.24 | -12.58 | -4.45 | -2.00 | 0.34 | 3.13 |
| Underlying PBT | -9.68 | -4.82 | -4.79 | -2.71 | -0.36 | 2.50 |
| Statutory PBT | -9.70 | -13.15 | -5.14 | -2.71 | -0.36 | 2.50 |
| Underlying EPS (¢) | -0.78 | -0.09 | -0.07 | -0.04 | 0.00 | 0.03 |
| Statutory EPS (¢) | -0.78 | -0.28 | -0.07 | -0.04 | 0.00 | 0.03 |
| Net cash/(debt) | 0.12 | 5.75 | -0.24 | -2.42 | -4.77 | -3.63 |
| Equity issues | 0.00 | 18.67 | 0.00 | 0.00 | 0.00 | 0.00 |
| EV/sales (x) | 3.1 | 3.1 | 2.6 | 2.1 | 1.7 | 1.4 |
| EV/EBITDA (x) | - | - | - | - | 31.5 | 9.7 |

*Source: Hardman & Co Life Sciences Research*

### Pharmaceuticals & Biotechnology


*Source: Refinitiv*

### Market data

| | |
|---|---|
| EPIC/TKR | **TRX** |
| Price (p) | **0.56** |
| 12m high (p) | 0.73 |
| 12m low (p) | 0.28 |
| Shares (m) | 7,033 |
| Mkt cap (£m) | 39.4 |
| EV (£m) | 39.6 |
| Free float* | 54% |
| Country of listing | UK |
| Market | AIM |

*As defined by AIM Rule 26

### Description

TRX is an international medtech company in the field of regenerative medicine, focusing on tissue engineering products using 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 |
| Chairman | Jonathan Glenn |

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www.tissueregenix.com

### Key shareholders

| | |
|---|---|
| Directors | 1.0% |
| Lombard Odier | 13.4% |
| Harwood Capital | 11.1% |
| R. Griffiths | 10.9% |
| IP Group | 9.4% |
| Premier Miton | 7.4% |

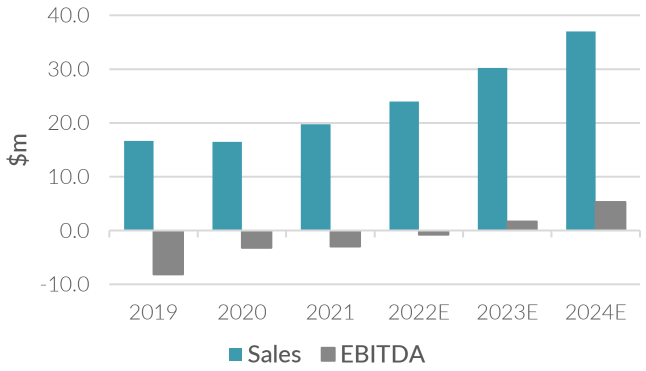
### Diary

| | |
|---|---|
| 26 Apr | AGM |
| Sep'22 | Interim results |

### Analyst

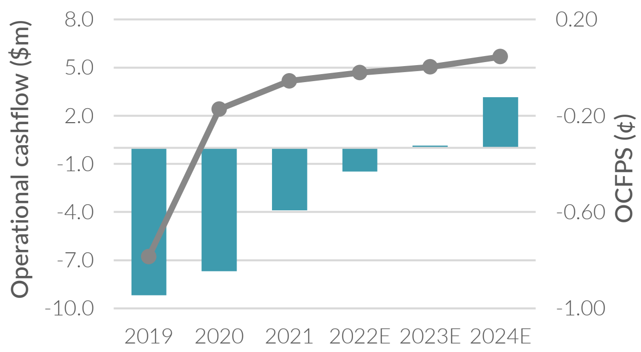

Martin Hall +44 (0)203 693 7075
mh@hardmanandco.com

## Sales and EBITDA



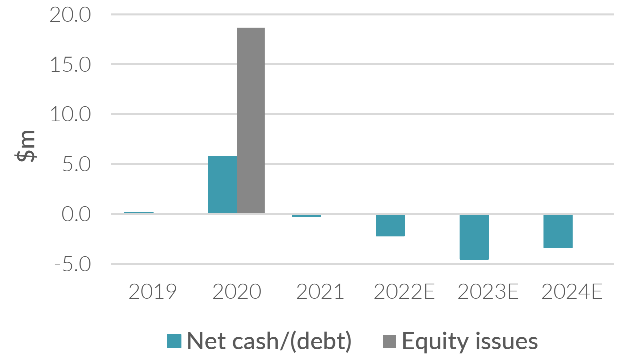

- Increased manufacturing capacity and strong demand from strategic distribution partners are driving BioRinse growth.
- Sales of dCELL products are dependent on the pace of recovery in the number of elective surgeries.
- Sales expansion has a leverage effect on margins, such that EBITDA and EBIT are trending towards profitability in 2022.
- Downside to forecasts is limited, while a rapid recovery in elective surgeries would see forecasts moving upwards.

## Operational cashflow and OCFPS (rhs)




- There has been a positive trend in the rate of cash burn over the past three years.
- While there is a lingering influence of COVID-19, a settled inventory level and reducing working capital needs should have a positive effect on operational cashflow.
- 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.

## 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 31 December 2021 was $7.7m, which is also supported by a revolving credit facility of $5.0m.
- Conservative forecasts suggest that TRX has sufficient cash through to the end of fiscal 2022, at which point the company becomes cash-generative.
- This position would be improved significantly if there were to be a faster recovery in elective surgeries.

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

# 2021 results summary

Note that, from 1 January 2021, the company switched its reporting currency to USD to better reflect the operational activities and eliminate the impact of forex on translation. Figures for prior years have all been restated.

## Key features

### *Operational and commercial*

- **Phase 1 expansion:** The key highlight in 2021 was completion of Phase 1 of the capacity expansion programme at the end of June, which was both on time and on budget. Operational benefits of this investment were evident in 2H'21.
- **Commercial:** The commercial operation of the dCELL segment was reorganised, with the aim of a flatter structure bringing the team closer to customers and sales channel partners. 16 new distributors have been contracted in the past three months, compared with 16 in the prior three years.
- **New products:** During 2021, TRX introduced three new product line extensions – DermaPure Meshed, VNEW® and Matrix ND® – which are being made available through its expanded distribution network.

### *Financials*

- **Sales:** Group sales rose 20% to \$19.75m (\$16.47m in 2020), slightly ahead of our forecasts. These results were achieved despite headwinds beyond TRX's control – COVID-19 and atrocious weather. Growth was led by the BioRinse range (+33% to \$12.7m, from \$9.5m in 2020). The dCELL product range is dependent on elective surgeries, which were affected by the COVID-19 delta variant outbreak in 3Q'21, giving flat sales of \$4.25m.
- **COGS:** As foreseen, there was an increase in COGS, from 54.0% to 57.1% of sales, reflecting increased input costs and a change in product sales mix. COGS is expected to fall as volumes rise; also, a recent price rise was instigated.
- **Administration costs:** Refocusing of the marketing team and careful control of costs were reflected in a 3.8% reduction in underlying SG&A costs.
- **Net cash/(debt):** TRX ended the period with gross cash of \$7.7m and net debt of \$0.2m (including lease liabilities of \$3.5m). There was a marked improvement in cash burn in 2H'21 compared with 1H'21, and this trend is expected to continue in 2022.

**Results summary – actual vs. expectations**

| Year-end Dec ($m) | 2020 actual | 2021 actual | Growth CER | 2021 *forecast | Delta Δ |
|---|---|---|---|---|---|
| BioRinse | 9.56 | 12.71 | +33% | 12.51 | +0.20 |
| dCELL | 4.25 | 4.25 | 0% | 4.15 | +0.10 |
| GBM-v | 2.66 | 2.79 | +1% | 2.94 | -0.15 |
| **Group sales** | **16.47** | **19.75** | **+20%** | **19.60** | **+0.05** |
| COGS | -8.90 | -11.27 | +27% | -10.91 | -0.36 |
| SG&A | -12.96 | -12.46 | -4% | -12.48 | +0.02 |
| Share-based costs | +0.04 | -0.11 | - | -0.04 | -0.07 |
| Underlying EBITDA | -3.20 | -3.00 | +6% | -2.65 | -0.35 |
| **Underlying EBIT** | **-4.26** | **-4.10** | **+4%** | **-3.75** | **-0.35** |
| Gross cash | 12.97 | 7.71 | - | 8.71 | -1.00 |
| **Net cash/(debt)** | **5.75** | **-0.24** | **-** | **0.74** | **-0.98** |

**As previously published in report[2] dated 19 October 2021*
*Note: numbers may not add up exactly due to change in reporting currency and rounding*
*Source: Hardman & Co Life Sciences Research*

# Operational update

TRX's products complement work of surgeons and dentists to improve patient outcomes in surgical applications

TRX is focused on the development and commercialisation of tissue engineering products that have been generated from its two platform technologies and used in regenerative medicine. These products complement the work of surgeons and dentists to improve patient outcomes in a number of surgical applications, including BioSurgery, orthopaedics, dental care, plastic surgery, urology/gynaecology and ophthalmology. Over the past 12 months, the two platform technologies have remained the same from an operational standpoint. Segment reporting is now based on the platform technology.

## dCELL®

TRX's core patented decellularisation technology removes DNA and other cellular material from soft tissue derived from humans and animals to leave an acellular tissue scaffold, which is not rejected by the patient's body and which can be used to repair diseased or damaged body parts. Current applications address many critical clinical needs, such as foot and ankle surgery, orthopaedics, sports medicine, urological-gynaecological and wound care. Products derived from dCELL technology are commercialised under the BioSurgery division.

## BioRinse®

BioRinse technology is used primarily to provide a natural bone filler solution, tested for osteoinductivity, which can stimulate and regenerate native bone growth. This process has the potential to provide superior clinical outcomes, as it contains 100% allograft bone, which is tested to demonstrate the presence of the key natural bone growth factors, and is available in a number of physical forms. Products derived from BioRinse technology are commercialised by the BioRinse segment, and are sold under the CellRight Technologies and other private label brands.

# Path to sustainability

Management team and restructured board started to deliver significantly in 2021

There are clear signs that the new management team, together with the restructured board, really started to deliver in 2021. This was achieved against a number of aforementioned headwinds that were outside the company's control. Shipments to commercial and distribution partners increased 36% in 2021 (+44% in 1H'21, +28% in 2H'21), which resulted in underlying sales rising 20%. With good control of costs, and benefits from the restructuring and reorganisation programmes in both the US and the UK, the increased sales had a leverage effect, greatly reducing underlying operating losses (24% excluding 2020 grant income). The second half of 2021 started to see the early benefits from Phase 1 of the capacity expansion and reorganisation programme, with all orders being processed efficiently and dispatched to customers in a timely manner. This suggest that, in the absence of any further unexpected headwinds, TRX is well on the path to profitability in 2022.

In our previous two reports[1,2], entitled *Poised for growth* and *Faster-than-anticipated recovery*, we highlighted how TRX has 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 investing in manufacturing capacity at its US facilities. A combination of these factors has resulted in the following:

- An even stronger relationship with tissue banks that are governed in the US by the National Organ Transplant Act (NOTA) to ensure adequate supplies of high-quality human tissue – such as bone, soft tissue and birth tissue.

[1] https://www.hardmanandco.com/research/corporate-research/poised-for-growth/
[2] https://www.hardmanandco.com/research/corporate-research/faster-than-anticipated-recovery/

- 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, particularly with some of the leading global orthopaedic companies, and the addition of 16 new distributors over the past three months in the dCELL segment.
- Increased tissue processing activity – e.g. 25% increase in BioRinse processing during 2021.

All of these outcomes fit well with the management strategy to focus on the four "Ss", which are best described in the following graphic.

Focusing on the four "Ss"


*Source: TRX presentation*

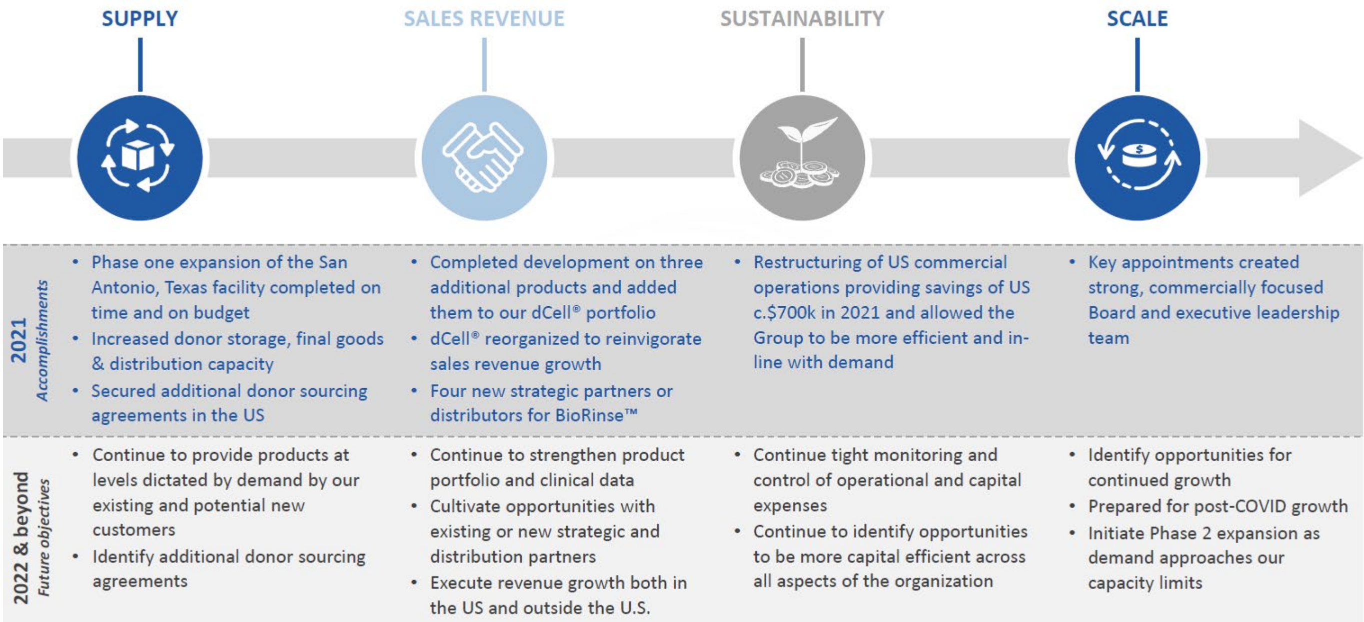
Previous reports[1,2] highlighted how TRX has been positioning itself to meet the demand for its products and to overcome the surgical backlog when the pace of elective procedures starts to pick up in the post-COVID-19 era. These reports also set out the priorities that management had set for 2021.

In its 2021 investor presentation, TRX updated the market on the accomplishments that had been made against those objectives, and it set some future objectives against which performance can be measured.

TRX has made progress with each of its four "S" objectives. On the supply side, the company secured additional donor sourcing agreements, with tissue being stored in the new, expanded, freezer storage facility – three times the old capacity. This will be processed in the updated and expanded manufacturing facility in San Antonio.

Additional product lines and the ability to service increased demand, as evidenced through the rise in customer shipments, were achieved through the increased processing and manufacturing capacity, which resulted in the 20% sales growth in 2021. Given that the increased capacity only came on-stream in July, sales growth of a similar order of magnitude (+22% on our forecasts) can be reasonably expected in 2022, which, together with the leverage effect on profitability, should see TRX become EBITDA-positive in 4Q'22.

Four strategic growth areas




*Source: TRX presentation*

New freezer suite

*Source: TRX presentation*

Efficient distribution facility

*Source: TRX presentation*

# Capacity expansion programme

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 in July 2021, which was on schedule and on budget. The updated and enlarged facility has increased processing capacity by 50%, increasing the sales potential of BioRinse to $30m, which will be sufficient for about the next three years.

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, expanded considerably. 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.

A new, centralised and more efficient finished goods 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 36% increase in shipments to its commercial partners in 2021.

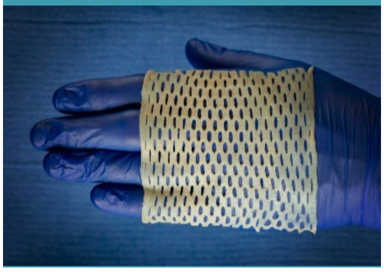
These activities paved the way for the new clean rooms. The total cost of Phase 1, including some Phase 2 construction work that was brought forward to make the entire process more efficient, was $2.7m/£2.1m.

The aim of Phase 2 is to add an additional 10 clean rooms to satisfy anticipated demand covering the next four to seven years. Understandably, management will monitor the progress derived from Phase 1 and commercial prospects before committing investment to start the Phase 2 programme.

# New product launches

During 2021, TRX completed the development of three biosurgery products, all using the dCELL technology platform. Together with OrthoPure XT, a decellularised porcine tendon for the reconstruction of knee ligaments, which received CE marking in 2020, this brings four new products to spur growth in 2022 and beyond.

**DermaPure Meshed 3:1**



*Source: TRX presentation*

## DermaPure Meshed 3:1

DermaPure Meshed 3:1 is designed to provide greater surface area coverage and, at the same time, 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.

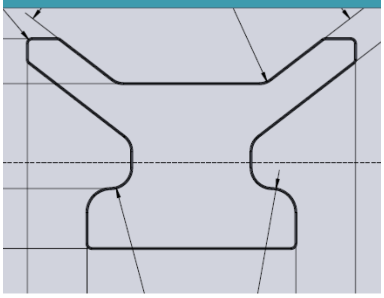
**Matrix ND**

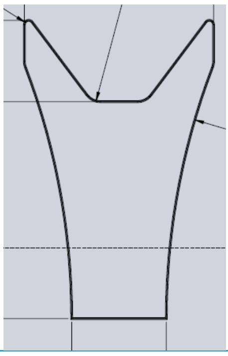

*Source: TRX presentation*

## Matrix ND

Gingival recession is one of the most common mucogingival deformities requiring surgical correction. Although autogenous tissue can be harvested for use in such repairs, it is associated with a number of disadvantages, including post-operative bleeding and pain at the donor site, a limited supply of tissue, and considerably longer operating times. Matrix ND is an acellular dermal matrix substitute that overcomes all of these disadvantages. This dermal graft provides soft tissue coverage, frequently in conjunction with bone grafting procedures, for use in dental indications.

**VNEW**





*Source: TRX presentation*

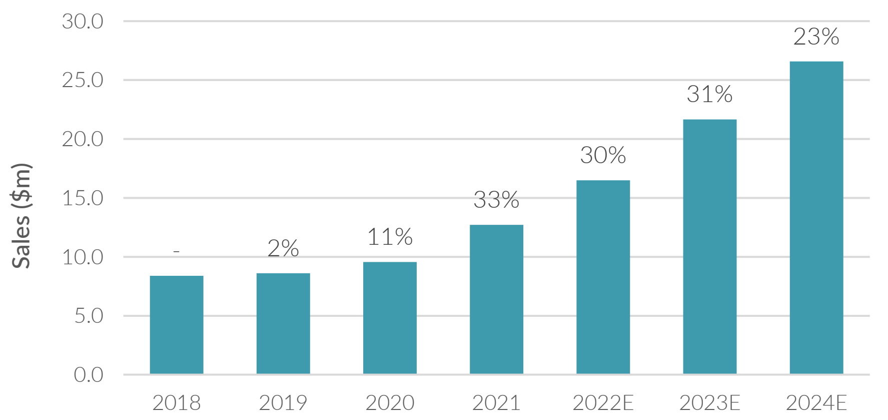
## VNEW®

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 is being distributed exclusively through TRX's urogynaecological partner, ARMS Medical, and the initial order was delivered on schedule in 3Q'21; a reorder was received in 4Q'21.

# Performance of BioRinse

Although the BioRinse division has been affected by COVID-19, the overall impact on sales has been far less than that seen with the other divisions in the group. Moreover, much of TRX's investment in tissue sourcing, manufacturing and marketing over the past two years has benefited BioRinse more quickly. Given the strong relationships and demand, these benefits are expected to continue into the foreseeable future.

**BioRinse sales, 2018-24E**



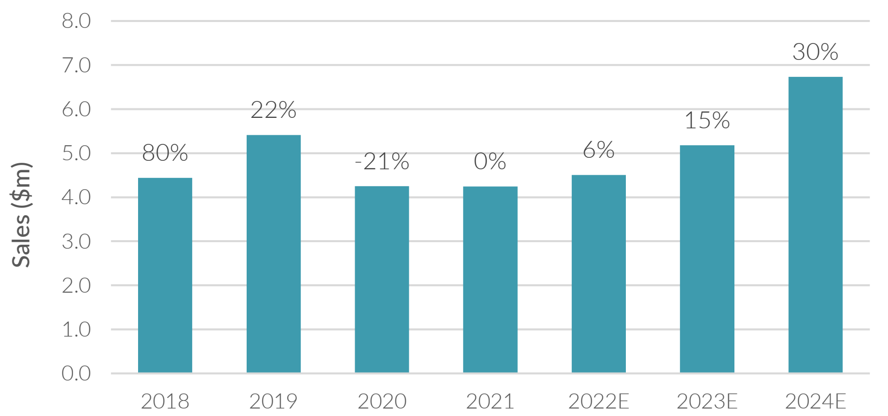

*Source: Hardman & Co Life Sciences Research*

- TRX offers a broad range of products that are attractive to a diverse range of surgical specialties.
- There has been strong demand from its leading specialty partner, Arthrex, and the addition of a number of new distributors.
- Investment in sourcing and manufacturing saw a 25% increase in donor tissue processing during 2021.

# Performance of dCELL

Performance of the dCELL product range is heavily dependent on elective surgeries. Consequently, sales have been affected by the prevalence of COVID-19 over the past two years, as can be seen in the following graphic.

**dCELL sales, 2018-24E**




*Source: Hardman & Co Life Sciences Research*

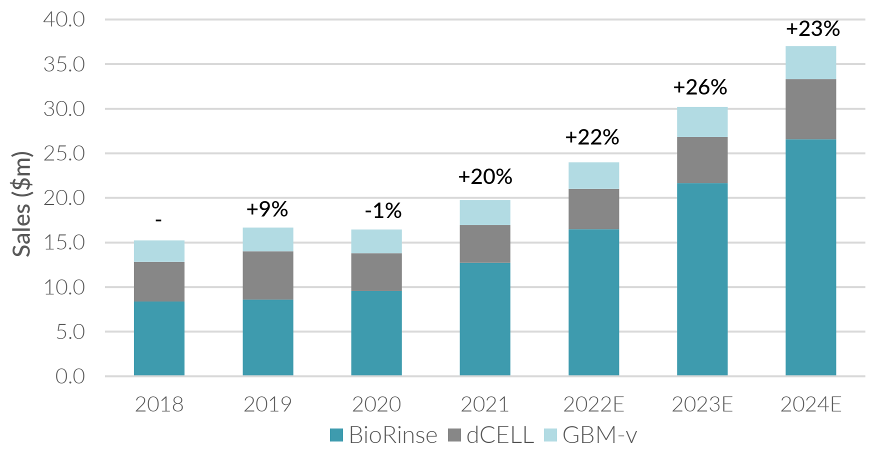
- The dCELL product range is efficacious, time-saving for surgeons and highly differentiated, and so it is well-positioned to recover when elective surgeries return.
- Management has taken the opportunity to reorganise the manufacturing and commercialisation structure with a view to reinvigorating sales growth when surgical activity returns to normal levels.
- Three new product line extensions using dCELL technology were launched in 2021.
- OrthoPure XT is the only commercially available xenograft for sports medicine indications. TRX announced recently that it had added an additional distribution partner, Geistlich Biomaterials, for the exclusive distribution rights for OrthoPure XT in Italy.
- Despite the limitations imposed by the pandemic, sales to its strategic partner, ARMS Medical, increased 24% in 2021.

## Group sales

**Group sales expected to grow 22% in 2022 and 26% in 2023**

BioRinse sales are expected to continue their strong growth pattern going forward. Taken together with a conservative view of the speed of recovery in dCELL and GBM-v, group sales are forecast to grow 22% in 2022 and 26% in 2023. However, we are anticipating that costs will rise at a slower rate; consequently, there should be a significant leverage effect on profitability, which should see TRX become EBITDA-positive by the end of 2022 and cash-generative in 2023. Continued growth around these levels would force the decision to commence Phase 2 of the capacity expansion programme in San Antonio during 2023.

**Group sales, 2018-24E**




*Source: Hardman & Co Life Sciences Research*

# Forecasts and valuation

## Income statement

- **Sales:** The strong performance in the BioRinse segment is expected to continue throughout the forecast period. A return to strong growth in the dCELL segment is dependent on the timing and recovery in elective surgeries. Over the forecast period, underlying sales are expected to grow in the range 22%-26%.
- **Gross margin:** While there will be some manufacturing efficiencies, the focus is on access to the right quantum of high-quality tissue for processing to satisfy the pent-up demand for products. The gross margin is expected to recover over time.
- **SG&A:** Careful control of costs, coupled with organisational restructuring, saw a decline in SG&A costs in 2021. While the emphasis will be to continue with this approach in 2022, there are also some inevitable global economic pressures pushing up costs. On balance, we are expecting a modest increase in SG&A.
- **Trend to profitability:** Despite the external influences beyond management control, there has been a trend towards profitability over the past two years. Although these external factors remain, with increased capacity now on-stream, we expect the positive momentum in 2021 to continue, resulting in TRX becoming EBITDA-positive in 4Q'22.

Income statement

| Year-end Dec ($m) | 2019 | 2020 | 2021 | 2022E | 2023E | 2024E |
|---|---|---|---|---|---|---|
| USD:EUR | 0.893 | 0.877 | 0.846 | 0.846 | 0.846 | 0.846 |
| BioRinse | 8.59 | 9.56 | 12.71 | 16.50 | 21.65 | 26.58 |
| dCELL | 5.41 | 4.25 | 4.25 | 4.50 | 5.18 | 6.73 |
| GBM-v | 2.65 | 2.66 | 2.79 | 3.00 | 3.37 | 3.71 |
| **Group sales** | **16.66** | **16.47** | **19.75** | **24.00** | **30.20** | **37.02** |
| COGS | -8.96 | -8.90 | -11.27 | -13.17 | -15.77 | -19.10 |
| Gross profit | 7.69 | 7.57 | 8.48 | 10.83 | 14.43 | 17.92 |
| Gross margin | 46.2% | 46.0% | 42.9% | 45.1% | 47.8% | 48.4% |
| SG&A | -17.05 | -12.96 | -12.46 | -12.71 | -13.98 | -14.68 |
| Share-based costs | 0.15 | 0.04 | -0.11 | -0.11 | -0.11 | -0.11 |
| Other income | 0.00 | 1.10 | 0.00 | 0.00 | 0.00 | 0.00 |
| **Underlying EBITDA** | **-8.17** | **-3.20** | **-3.00** | **-0.80** | **1.63** | **5.29** |
| Depreciation | -0.48 | -0.32 | -0.37 | -0.47 | -0.57 | -1.43 |
| Amortisation | -0.57 | -0.73 | -0.73 | -0.73 | -0.73 | -0.73 |
| **Underlying EBIT** | **-9.22** | **-4.26** | **-4.10** | **-2.00** | **0.34** | **3.13** |
| Exceptional items | -0.02 | -8.32 | -0.36 | 0.00 | 0.00 | 0.00 |
| Statutory EBIT | -9.24 | -12.58 | -4.45 | -2.00 | 0.34 | 3.13 |
| Net interest | -0.46 | -0.57 | -0.69 | -0.72 | -0.69 | -0.63 |
| **Underlying pre-tax profit** | **-9.68** | **-4.82** | **-4.79** | **-2.71** | **-0.36** | **2.50** |
| Extraordinary items | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Statutory pre-tax profit | -9.70 | -13.15 | -5.14 | -2.71 | -0.36 | 2.50 |
| Tax payable/credit | 0.55 | 0.68 | 0.16 | 0.00 | 0.02 | -0.12 |
| **Underlying net income** | **-9.12** | **-4.14** | **-4.63** | **-2.71** | **-0.34** | **2.37** |
| Statutory net income | -9.14 | -12.46 | -4.99 | -2.71 | -0.34 | 2.37 |
| | | | | | | |
| **Ordinary 0.1p shares:** | | | | | | |
| Period-end (m) | 1,172.0 | 7,033.1 | 7,033.1 | 7,034.1 | 7,035.1 | 7,036.1 |
| Weighted average (m) | 1,171.9 | 4,447.7 | 7,033.1 | 7,033.6 | 7,034.6 | 7,035.6 |
| Fully-diluted (m) | 1,204.4 | 4,514.6 | 7,156.0 | 7,156.5 | 7,157.5 | 7,158.5 |
| | | | | | | |
| **Underlying basic EPS (¢)** | **-0.78** | **-0.09** | **-0.07** | **-0.04** | **0.00** | **0.03** |
| Statutory basic EPS (¢) | -0.78 | -0.28 | -0.07 | -0.04 | 0.00 | 0.03 |
| Underlying fully-dil. EPS (¢) | -0.76 | -0.09 | -0.06 | -0.04 | 0.00 | 0.03 |
| Statutory fully-dil. EPS (¢) | -0.76 | -0.28 | -0.07 | -0.04 | 0.00 | 0.03 |
| DPS (¢) | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |

*Source: Hardman & Co Life Sciences Research*

# Balance sheet

- **Inventories:** The pandemic, increased supply of unprocessed tissue and preparation for the capacity expansion programme resulted in an increase in the levels of inventory in 2020. This has now stabilised, with the balance in 2021 moving from "finished product" to "work in progress", as more tissue is being processed through the increased capacity, and orders are being filled more efficiently. However, these are just point-in-time observations taken from the annual report, which may not properly reflect monthly averages.
- **Net cash/(debt):** At 31 December 2021, TRX had net debt of $0.24m, comprised of gross cash of $7.71m, offset by the MidCap term loan ($2.0m), revolving credit facilities of $2.65m and financial leases of $3.48m. Repayments of the term loan are due to commence in July 2023.
- **Capital requirement:** Based on current forecasts, the gross cash position and the revolving credit facility are expected to be sufficient to satisfy TRX's working capital needs through to profitability towards the end of 2022. Thereafter, we anticipate that the leverage effect of sales growth to generate positive cashflow, allowing the commencement of Phase 2 of the capacity expansion programme in 2023.

**Balance sheet**

| @31 Dec ($m) | 2019 | 2020 | 2021 | 2022E | 2023E | 2024E |
|---|---|---|---|---|---|---|
| Share capital | 7.74 | 15.95 | 15.95 | 15.95 | 15.95 | 15.95 |
| Reserves | 24.75 | 22.32 | 17.45 | 14.73 | 14.39 | 16.76 |
| Provisions/liabilities | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Deferred tax | 0.89 | 0.76 | 0.64 | 0.54 | 0.44 | 0.34 |
| Long-term leases | 0.00 | 3.08 | 3.36 | 3.15 | 2.84 | 1.67 |
| Short-term leases | 0.00 | 0.35 | 0.12 | 0.12 | 0.12 | 0.12 |
| Long-term debt | 2.79 | 3.79 | 4.47 | 4.47 | 4.47 | 4.47 |
| Short-term loans | 0.23 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| *less:* Cash | 3.14 | 12.97 | 7.71 | 5.31 | 2.65 | 2.63 |
| *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** | **33.64** | **35.55** | **36.68** |
| | | | | | | |
| Fixed assets | 3.11 | 4.42 | 5.71 | 5.74 | 7.67 | 8.24 |
| Intangible assets | 23.78 | 15.30 | 15.06 | 15.06 | 15.06 | 15.06 |
| Right-of-use assets | 0.00 | 3.34 | 3.39 | 3.18 | 2.87 | 1.70 |
| Goodwill | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Inventories | 5.53 | 9.60 | 9.72 | 9.92 | 10.49 | 11.06 |
| *Trade debtors* | *2.27* | *2.42* | *2.95* | *3.58* | *4.06* | *4.47* |
| *Other debtors* | *1.08* | *1.17* | *1.16* | *1.16* | *1.16* | *1.16* |
| *Tax liability/credit* | *1.37* | *1.12* | *0.53* | *0.16* | *0.00* | *-0.12* |
| *Trade creditors* | *-2.18* | *-1.32* | *-2.57* | *-3.01* | *-3.46* | *-3.98* |
| *Other creditors* | *-1.94* | *-2.76* | *-1.67* | *-2.15* | *-2.29* | *-0.90* |
| Debtors less creditors | 0.61 | 0.63 | 0.39 | -0.26 | -0.54 | 0.62 |
| **Invested capital** | **33.03** | **33.28** | **34.27** | **33.64** | **35.55** | **36.68** |
| | | | | | | |
| **Net cash/(debt)** | **0.12** | **5.75** | **-0.24** | **-2.42** | **-4.77** | **-3.63** |
| Inventory days | 121 | 168 | 179 | 149 | 123 | 106 |
| Debtor days | 50 | 54 | 50 | 50 | 46 | 42 |
| Creditor days | 89 | 54 | 63 | 77 | 75 | 71 |

*Source: Hardman & Co Life Sciences Research*

# Cashflow

- **Working capital:** Over the past two years, a higher level of inventories has stabilised, positioning TRX to fill customer orders in a timely manner. Consequently, despite the sales growth, there is a lower working capital demand. On the basis of comfortable forecasts, we expect TRX to become cash-generative during 2023.
- **Capital expenditure:** Forecasts for sales growth and profitability suggest that management will have the flexibility and resources to commence Phase 2 of the capacity expansion programme during 2023, which will be spread over two financial years. The significant expansion in the number of clean rooms should be sufficient to satisfy demand over the longer term.

**Cashflow**

| Year-end Dec ($m) | 2019 | 2020 | 2021 | 2022E | 2023E | 2024E |
|---|---|---|---|---|---|---|
| Underlying EBIT | -9.22 | -4.26 | -4.10 | -2.00 | 0.34 | 3.13 |
| Depreciation | 0.48 | 0.32 | 0.37 | 0.47 | 0.57 | 1.43 |
| Amortisation | 0.57 | 0.73 | 0.73 | 0.73 | 0.73 | 0.73 |
| Share-based costs | -0.15 | -0.04 | 0.11 | 0.11 | 0.11 | 0.11 |
| *Inventories* | *-1.86* | *-4.12* | *-0.12* | *-0.20* | *-0.57* | *-0.57* |
| *Receivables* | *1.08* | *-0.26* | *-0.51* | *-0.63* | *-0.48* | *-0.42* |
| *Payables* | *-1.57* | *0.22* | *0.16* | *0.43* | *0.45* | *0.52* |
| Change in working capital | -2.35 | -4.15 | -0.47 | -0.40 | -0.59 | -0.47 |
| 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 | 0.00 | 0.00 | 0.00 |
| **Company op. cashflow** | **-9.47** | **-8.01** | **-3.72** | **-1.09** | **1.15** | **4.93** |
| Net interest | -0.37 | -0.32 | -0.39 | -0.42 | -0.42 | -0.42 |
| Lease payments | 0.00 | -0.24 | -0.40 | -0.50 | -0.58 | -1.38 |
| Tax paid/received | 0.65 | 0.88 | 0.62 | 0.53 | 0.00 | 0.02 |
| **Operational cashflow** | **-9.18** | **-7.68** | **-3.89** | **-1.48** | **0.15** | **3.15** |
| Capital expenditure | -0.44 | -1.57 | -1.55 | -0.50 | -2.50 | -2.00 |
| Capitalised R&D | -0.21 | -0.29 | -0.50 | -0.20 | 0.00 | 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** | **-2.18** | **-2.35** | **1.15** |
| 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** | **-2.18** | **-2.35** | **1.15** |
| Share repurchases | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Equity issues | 0.00 | 18.67 | 0.00 | 0.00 | 0.00 | 0.00 |
| Funding costs | 0.00 | -1.15 | 0.00 | 0.00 | 0.00 | 0.00 |
| Currency effect | -0.02 | 0.08 | -0.05 | 0.00 | 0.00 | 0.00 |
| Cash/(debt) acquired | 0.00 | -2.43 | 0.00 | 0.00 | 0.00 | 0.00 |
| **Change in net debt** | **-9.86** | **5.63** | **-5.99** | **-2.18** | **-2.35** | **1.15** |
| | | | | | | |
| Opening net cash/(debt) | 9.98 | 0.12 | 5.75 | -0.24 | -2.42 | -4.77 |
| **Closing net cash/(debt)** | **0.12** | **5.75** | **-0.24** | **-2.42** | **-4.77** | **-3.63** |
| OCFPS (¢) | -0.78 | -0.17 | -0.06 | -0.02 | 0.00 | 0.04 |

*Source: Hardman & Co Life Sciences Research*

## Valuation

TRX plays valuable niche role for its commercial partners

Valuing a company like TRX is extremely difficult. Although it has been a long ride, the company 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 around $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 1.6p per share has been invested to get the company to where it is today

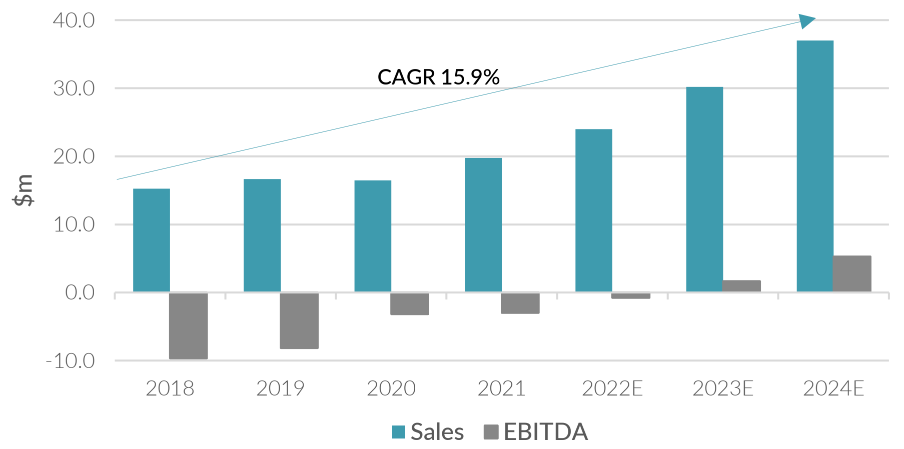
Based on the following facts, TRX, with a market capitalisation of £39.4m/$51.2m, is currently being undervalued by the market:

- To get TRX to where it is today, $150m/£115m – equivalent to 1.6p per share – has been invested into the company.
- The R&D investment by TRX to obtain marketing authorisations for a number of products, excluding all the investment made by CellRight, has been $30m/£23m.
- The marketing and administrative overheads to establish its products in the market (mostly in the US), and to sign up the network of GPOs and distribution partners, have been $107m/£82m.
- The administrative achievement in obtaining the relevant accreditations and licences for the harvesting and processing of human tissue is considerable.

Strong, positive momentum towards EBITDA-positive by end-2022

TRX looks set to become EBITDA-positive by the end of fiscal 2022, on comfortable forecasts, notwithstanding the potential influence of external factors beyond the company's control, and taking a very conservative view about the timing and pace of recovery in elective surgeries.

Sales and EBITDA, 2018-24E




*Source: Hardman & Co Life Sciences Research*

Significant mis-match between valuation and market capitalisation

Close relationships with a number of the major medtech players, who need significant annual product sales in order to justify the relationship, are expected to drive future sales growth, particularly in the BioRinse segment. dCELL segment sales growth is dependent on further recovery in the number of elective surgeries. However, while they can be postponed, demand will inevitably return at some point. Continuation of the recent group sales growth will provide reassurance about reaching profitability, and should see continued upward momentum towards a market capitalisation of $120m/£92m, or 4x prospective 2023 sales.

# Company matters

## Registration

Incorporated in the UK with company registration number 05969271.

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LS25 2GYT

+44 (0)330 430 3052
www.tissueregenix.com

**US operations:**
1808 Universal City Boulevard
Universal City
San Antonio
Texas
78148

## Board of Directors

Board of Directors

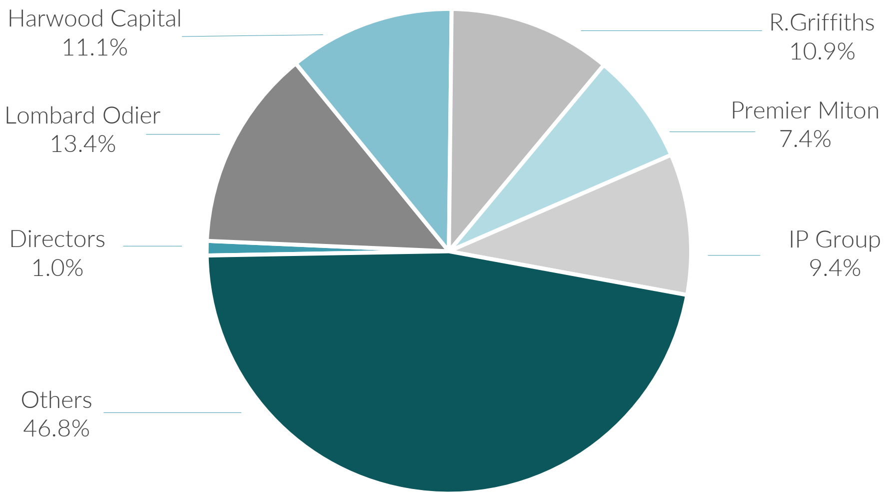
| Position | Name | Remuneration | Audit |
|---|---|---|---|
| Chairman | Jonathan Glenn | | M |
| Chief Executive Officer | Daniel Lee | | |
| Chief Financial Officer | David Cocke | | |
| Non-executive director | Shervanthi Homer-Vanniasinkam | M | |
| Non-executive director | Brian Phillips | M |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

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

## Share capital

On 14 April 2022, the company had 7,033,077,499 Ordinary shares of 0.1p in issue. There are also 171.89m options and 3.10 warrants outstanding.

Shareholders




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

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