Pharmaceuticals & Biotechnology

Source: LSEG

Market data

EPIC/TKR	**TRX**
Price (p)	**61.5**
12m high (p)	73.0
12m low (p)	48.0
Shares (m)	70.57
Mkt cap (£m)	43.4
EV (£m)	47.2
Free float*	60%
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

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

Key shareholders

Directors	1.1%
Harwood Capital	15.0%
Lombard Odier	11.0%
R. Sneller (Inthallo)	14.0%
R. Griffiths	9.7%
IP Group	9.3%

Diary

25 April	AGM

Analyst

Dr Martin Hall
mh@hardmanandco.com

TISSUE REGENIX

Six consecutive periods of >20% growth

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 products used in biosurgery, orthopaedics and dental markets. Investment in tissue processing, manufacturing capacity and strong commercial partners, together with its "4S" strategy, has generated six consecutive reporting periods of strong growth, with TRX turning EBITDA-positive in 2023. Further growth in 2024 will deliver a fully profitable, cash-generative, group. Cash will be re-invested to expand capacity even further through Phase 2, starting in 2025.

- **Strategy:** TRX is building a global regenerative medicine business around its proprietary technology platforms, underpinned by compelling clinical outcomes. Phase 1 of its investment programme has grown sales to a point where TRX is cash-generative, which will be used to expand capacity further with Phase 2.

- **2023 results:** Sales rose 20%, to $29.5m ($24.5m), with BioRinse (+25%) the main growth driver, supported by dCELL (+17%). Operating efficiencies and good cost control saw TRX become EBITDA-positive in 2023. Gross cash was above forecast at $4.65m, with flexibility provided by a $10m revolving debt facility.

- **Outlook:** Management will continue to build on its successful "4S" strategy to drive sales growth and sustainability. The US remains the main driver, but TRX is looking to expand its geographical reach further in 2024 through commercial distribution agreements, accelerating the profitability and cash generation.

- **Risks:** The long recovery from the pandemic appears to be over. TRX is carefully managing its supply chain and its ability to recruit staff has improved; however, with limited ability to raise prices, increased supply and labour costs must be offset by greater efficiencies. TRX has no need for a capital injection.

- **Investment summary:** 2023 was a milestone year when TRX was fully EDITDA-positive and cash-generative in 2H'23. Further anticipated growth in 2024 will see the group become EBIT-positive and generate additional cash, which will be used to expand processing and manufacturing further through Phase 2 of its investment programme in 2025. An EV/sales multiple of 4x 2025E sales generates a valuation of $158m/£125m.

Financial summary and valuation

Year-end Dec ($m)	2020	2021	2022	2023	2024E	2025E
Sales	16.47	19.75	24.48	29.49	34.49	39.50
Underlying EBITDA	-3.20	-3.00	-0.88	0.58	1.90	3.18
Underlying EBIT	-4.26	-4.10	-2.01	-0.39	0.89	2.11
Statutory EBIT	-12.58	-4.45	-2.01	-0.39	0.89	2.11
Underlying PBT	-4.82	-4.79	-2.83	-1.67	0.06	1.37
Statutory PBT	-13.15	-5.14	-2.83	-1.67	0.06	1.37
Underlying EPS (¢)	-9.31	-6.58	-3.69	-2.35	-0.42	1.09
Statutory EPS (¢)	-28.03	-7.09	-3.69	-2.35	-0.42	1.09
Net cash/(debt)	5.75	-0.24	-3.66	-4.75	-4.80	-6.38
Equity issues	18.67	0.00	0.01	0.07	0.00	0.00
EV/sales (x)	3.7	3.1	2.5	2.0	1.7	1.5
EV/EBITDA (x)	-	-	-	102.3	31.4	18.8

Source: Hardman & Co Life Sciences Research

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2023 results summary

Milestone year being EBITDA-positive and cash-generative

On 25 January 2024, TRX issued a trading update which stated that sales increased 20.6% to $29.5m in 2023 and that the group was EDITDA-positive and cash-generative, resulting in gross cash of $4.5m at the period-end. The gross cash position was better than our previously published forecast (September 2023).

Key features

Operational and commercial

- **BioRinse:** The BioRinse range of products was the main growth driver with sales rising 25% to $20.1m ($16.1m). The top five families of products all grew >20% with strategic commercial partners growing demand. Greater production efficiencies led to a 77% rise in EBIT.
- **dCELL:** New products and line extensions led to a 17% rise in sales to $6.18m ($5.30m). The division was also boosted by sales of OrthoPure XT in Europe. This division also turned from an EBIT loss of $0.99m to a profit of $0.34m in 2023.
- **GBM-V:** Sales growth was restrained in 2023 to 2%, due to regulatory restrictions on the supply of donor corneal tissue. However, demand outweighs supply, so recovery is anticipated in 2024 with improved supply of corneal tissue.
- **Efficiencies:** TRX is not immune to the global macro-economics and wage inflation. However, increased supply and labour costs have been offset by increased efficiencies derived from Phase 1 of the capacity expansion programme.

Financials

- **Sales:** Group sales were better than forecast, but the mix was different. BioRinse greatly exceeded expectations; whereas dCELL was below our forecast. We believe that this reflects the greater flexibility that TRX has over tissue processing and manufacturing to satisfy abnormal buying patterns of its partners.
- **COGS:** Flexibility in the product mix, coupled with increased processing efficiencies, resulted in a 1.6pp improvement in gross margins to 47.6% (46.0%).
- **Administration costs:** Underlying SG&A and central costs, excluding the share-based payments, increased 8.2%, to $14.1m, with wage inflation being offset by operational efficiencies.
- **Net cash/(debt):** Period-end gross cash was $4.65m, giving net debt of $4.75m, both better than forecast, through careful management of working capital.

Results summary – actual vs. expectations

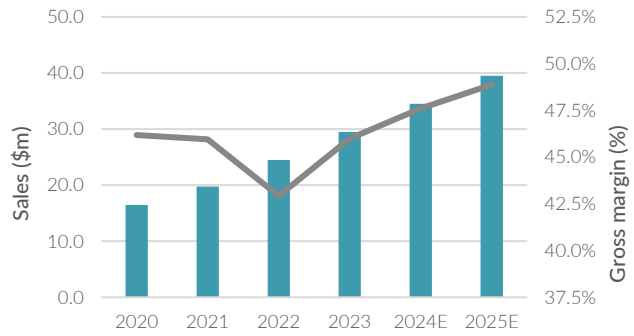
Year-end Dec ($m)	2022 actual	2023 actual	Growth CER	2023 *forecast	Delta Δ
BioRinse	16.05	20.13	+25%	19.00	+1.13
dCELL	5.30	6.18	+17%	6.80	-0.62
GBM-V	3.13	3.18	+2%	3.31	-0.13
Group sales	**24.48**	**29.49**	**+21%**	**29.11**	**+0.38**
COGS	-13.22	-15.45	+17%	-14.51	-1.06
SG&A	-13.02	-14.09	+8%	-14.58	+0.49
Share-based costs	-0.25	-0.34	-	-0.25	-0.09
Underlying EBITDA	-0.88	0.58	n/m	0.73	-0.15
Underlying EBIT	**-2.01**	**-0.39**	**+81%**	**-0.23**	**-0.16**
Gross cash	5.95	4.65	-	3.87	+0.78
Net cash/(debt)	**-3.66**	**-4.75**	**-**	**-5.48**	**+0.73**

**As previously published in report dated 18 September 2023*

Note: numbers may not add up exactly, due to change in reporting currency and rounding

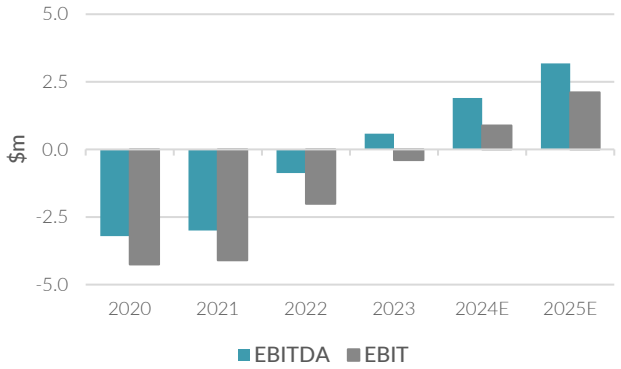
Source: Hardman & Co Life Sciences Research

Sales and gross margin



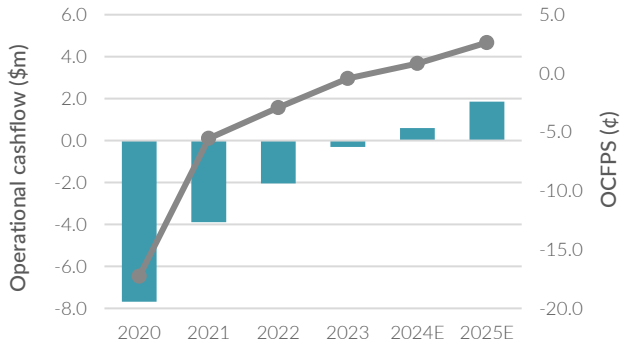
- Sales: 21.4% CAGR 2020-23 expected to continue ca.20% through forecast period.
- Strong US sales growth from existing customer base boosted by new product launches, line extensions and geographical expansion.
- Gross margin is on an upward trend as the full benefits of the capacity investment continue to materialise.

EBITDA and underlying EBIT



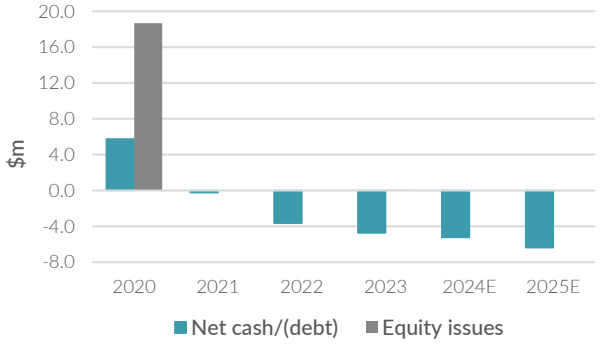
- TRX initially turned EBITDA-positive in 4Q'22, but was overall EBITDA-positive in fiscal 2023.
- Leverage effect of strong sales growth is expected to see EBITDA rise rapidly throughout the forecast period.
- All three divisions were profitable before central costs for the first time in 2023.
- On our current forecasts, TRX will become EBIT-positive at the group level in fiscal 2024.

Operational cashflow and OCFPS



- Strong operating momentum has seen a significant reduction in cash burn over the past three years.
- Careful working capital management in 2023 generated an almost neutral position in operational cashflow.
- Rapid growth in EBITDA through the forecast period is expected to be reflected in cash generation.
- Cash generation, coupled with existing debt facility, is expected to fund Phase 2 of the capacity expansion programme, obviating any need for a capital injection.

Net cash/(debt) and equity issues



- TRX has raised $150m/£118m from investors since inception, the most recent being $18.7m/£14.6m gross capital in 2020 to invest in capacity expansion.
- Gross cash, at 31 December 2023, was $4.65m, which is supported by a revolving credit facility of $10.0m.
- Our forecasts suggest that TRX has sufficient cash to deliver the current business plan, including the $3.6m-$3.8m cost of Phase 2 of the capacity expansion programme.

Source: Company data, Hardman & Co Life Sciences Research

Operational overview

"4S" strategy bearing fruit

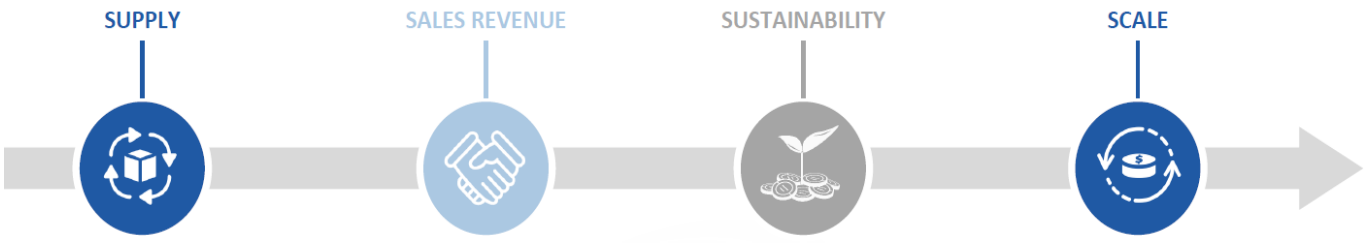
First introduced in 2020, TRX has not wavered from its "4S" strategy, which has been the foundation of the business plan to drive sales and grow. Results in 2023 represented the sixth consecutive six-month trading period of >20% sales growth, highlighting the foresight and strength of the company's progressive "4S" strategy. This strategy has been emphasised in each of our four previous reports on TRX, showing regular and consistent progress against targets. The whole objective was to develop a strong commercial and operational strategy to create solid relationships with major distributors, thereby creating good underlying demand for its products. Over the past two years, with increased capacity expansion at its US facilities coming on stream and driving sales growth, coupled with the reorganisation of its operations, the emphasis within "4S" has changed slightly, with greater attention now going onto sustainability and scale.

"4S" strategy

For the past three years, TRX's business plan to drive sales has revolved around its "4S" strategy. As a reminder, it is based on the following characteristics:

- **Supply:** Highlighted by the fundamental ability to source donor tissue and having the capacity to process it and produce differentiated graft products.
- **Sales:** To distribute the finished grafts and scaffolds to clinicians and institutions that need these products to treat patients.
- **Sustainability:** To manage sales and costs to generate a profitable entity that does not need additional external capital to operate.
- **Scale:** To utilise the first three "Ss" to continue to invest in and grow the business, and to license or acquire new products, technologies and companies.

Progress with the four "S's"



	SUPPLY	SALES REVENUE	SUSTAINABILITY	SCALE
2023 Accomplishments	• **31% increase** in musculoskeletal and dermis donor sourcing • Signed two **new donor supply contract** for BioRinse in 2023 • Continued increase in **processing efficiencies**	• BioRinse division returned **25% growth in the period**, continuing to take market share • Commercial reorganisation of dCELL division continues to show benefits with **17% sales growth** in 2023. **Added 66 new distributors; 206% of plan.** • **13% increase in shipments** of finished goods units	• **Positive Adjusted EBITDA for 2023** due to sales growth and tight expense management • Increased capacity from Phase One expansion **allows Phase Two capital expenditure to be pushed out** • **Cash position increased in H2 2023**	• **Established a third-party logistics provider** to provide distribution services to the European Union and the UK • Increased credit facility with MidCap from $5.0m to $10.0m to support **future working capital growth**
2024 Future objectives	• Phase 2 expansion has been pushed to 2025 as a result of the capacity created by Phase 1 • Planning and commitments for Phase 2 expansion	• Support continue growth of base business • Continue taking market share with above-market, double digit growth rates	• Continue tight monitoring and control of operational and capital expenses • Continue to identify opportunities to be more capital efficient across all aspects of the organisation	• Distribute allograft tissue products in markets outside the US • Distribute xenograft tissue in markets outside of the EU

Source: TRX presentation

Highly regulated market with big barriers to entry

TRX operates in a highly regulated market with enormous barriers to entry. Most 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. However, they do need certainty of supply of quality products, which has been an area for key investment by TRX.

During the early part of the "4S" programme, TRX focused on building stronger relationships 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 donor tissue – such as bone, soft tissue and birth tissue. For example, in 2022, TRX improved supply by sourcing 124% more donors overall. This was followed, in 2023, with the sourcing of 31% additional musculoskeletal and dermis donors. Interestingly, when TRX has surplus donor tissue, it provides this to other tissue processors once medical checks have been completed, thereby improving the efficient use of this precious commodity. In 2023, release of donor tissue increased by 38% compared with 2022.

With greater assurance about supply of donor tissue, the next stage was to derive greater efficiency from its investment in capacity expansion. In 2023, this resulted in a 28% increase in tissue processing throughput.

US remains core growth driver with BioRinse benefiting from manufacturing flexibility

Looking at the US in isolation, group sales grew 22.3% in 2023. This was driven largely by BioRinse sales, which grew 22.7%, with underlying demand being satisfied by the flexibility in manufacturing. For its dCELL product range, TRX continued to strengthen its commercial relationships, adding a further 66 distributors in 2023.. This compares with its target of 32. Together with a return to more normal levels of elective surgeries, dCELL sales growth in the US was mid-teens.

Increased confidence

Customer confidence in ability to supply in timely manner

Commercial partners now have confidence in TRX's ability to supply them with quality products in a timely manner. Also, with the investment in tissue storage, processing and overall manufacturing capacity, TRX has the flexibility to cope with fluctuations in timing and size of customer orders. Indeed, in 2023, TRX received fewer, but larger, orders from commercial partners, again highlighting their confidence in TRX's ability to provide them with good service in a timely manner. To this end, TRX has invested in Sage X3, an enterprise resource planning (ERP) system, for its US facility, which is expected to improve operating efficiency and manage financial aspects of the business.

Geographical expansion

Potential to expand into non-US markets…

As part of the opportunity to scale the business, management aimed to expand selectively on a geographical basis, starting in 2022 and then increasing the rollout in 2023. To that end, TRX signed a number of agreements for product distribution outside the US. Although the US will remain the mainstay of sales growth in the medium term, RoW sales are expected to see strong sales growth, albeit from a low base. Considerable progress was made in 2023 to scale the business; however, inventory issues in Leeds, and slow regulatory processes in Australia did restrict its progress with its novel xenograft tendon option.

Looking towards Phase 2

Phase 2 capacity has potential to add $40m p.a. of incremental sales

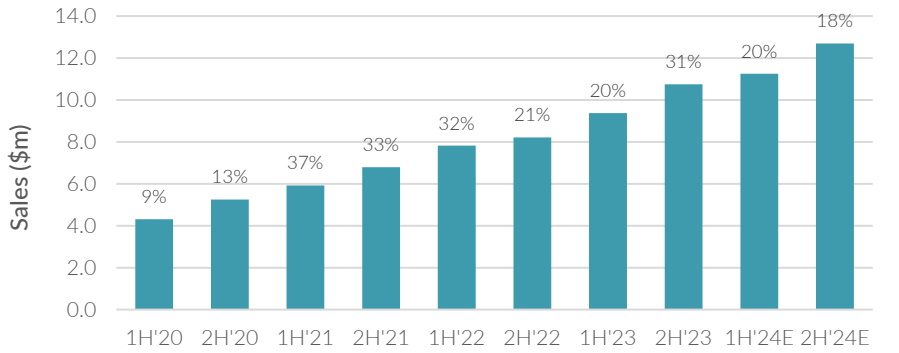
The investment in Phase 1 provided the opportunity to derive up to $40m of additional sales for the group. The increased capacity is fully operational and the increased efficiencies being derived have delayed the need to start Phase 2 of the programme to add additional clean rooms until 2025. But this is now only 12 months away and some attention to planning activities will commence in 2024, so that the company will be completely ready to push the "start button" at the appropriate time. This additional $3.6m-$3.8m investment, spread over two fiscal years, will have the potential to add up to $40m p.a. of incremental sales.

BioRinse

Continuing strong upward momentum from investment incapacity expansion

BioRinse was always expected to be the first division to benefit from Phase 1 of the investment programme to increase tissue storage and processing capacity, given its source material, diverse range of differentiated bone scaffold products and strong commercial partners. This has been borne out by results from the past six, six-month reporting periods (2021-23), with consistently high sales growth rates. TRX also reported that its top five product families – including Concelltrate, AmnioWorks and other demineralised bone matrix (DBM) products – all grew at >20% in 2023.

Half-yearly performance in BioRinse sales, 2020-24E



Source: Hardman & Co Life Sciences Research

High customer conviction about quality and supply of product

The key message at the time of the investment in capacity expansion was that "…distributors and strategic commercial partners needed to have confidence in the superior performance of BioRinse products and the ability of TRX to supply them in a timely manner…". Every set of results since completion of Phase 1 has demonstrated that TRX has convinced its strategic partners that the quality of BioRinse products leads to superior clinical outcomes, enabling them to grow their own businesses. Additionally, TRX now has the flexibility in its manufacturing processes to cope with variable order patterns from its customers such that orders can be delivered in a timely manner.

High demand suggests strong growth through forecast period

Overall, in 2023, BioRinse sales increased 25% and demand continues to be strong suggesting that above-market rates of growth will continue through the forecast period.

- Growth was led by ConCelltrate, a demineralised bone matrix, and AmnioWorks' birth tissue product families.
- The top five product families in the BioRinse portfolio all grew sales by greater than the 20% divisional average growth rate, which was considerably above the market average growth rate.
- Growth is supported by industry reputation and commercial partner confidence across all its surgical specialties – orthopaedics, sports medicine, spine, dental and trauma.
- After satisfying certain regulatory hurdles, TRX received approval for its logistics partner in the Republic of Ireland to distribute tissue in the EU. TRX also signed an agreement with SpineArt España to distribute allograft tissue into Spain.
- TRX is extremely respectful of its licence to receive and process donated human tissue in the most efficient way. Consequently, any excess inventory, is released to other tissue processors for their needs as a value-added product, once the tissue has completed a medical review.

Improving operating performance

BioRinse gross margin consistently above 50%

2023 results confirmed the strong momentum in the BioRinse business and the leverage effect on profitability from above-market-average sales growth. Since completion of the investment in capacity expansion, the gross margin for BioRinse products has recovered to be consistently above 50% and further modest gains are anticipated.

Marketing costs rise at a lower rate than sales growth

The strategy to sell products through strategic partners and distributors means that SG&A costs consistently rise at a lower rate compared with sales growth, which has a leverage effect on profitability. Note that the figures in the table below exclude the amortisation of goodwill related to the acquisition of CellRight, which was $450k in 2023.

Performance of BioRinse

Year-end Dec ($m)	2019	2020	2021	2022	2023	2024E	2025E
Sales	8.59	9.56	12.71	16.05	20.13	23.96	27.78
COGS	-3.93	-4.94	-6.86	-7.79	-9.99	-11.77	-13.38
Gross profit	**4.66**	**4.62**	**5.85**	**8.26**	**10.14**	**12.19**	**14.40**
SG&A*	-5.09	-5.66	-6.24	-6.96	-7.85	-8.80	-9.24
BioRinse EBIT	**-0.43**	**-1.04**	**-0.39**	**1.30**	**2.29**	**3.39**	**5.17**
Gross margin	*54.3%*	*48.3%*	*46.0%*	*51.5%*	*50.4%*	*50.9%*	*51.8%*
EBIT margin	***-5.0%***	***-10.9%***	***-3.1%***	***8.1%***	***11.4%***	***16.1%***	***20.4%***

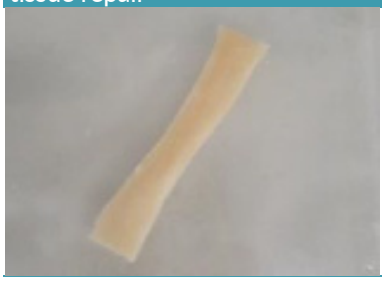
**Excludes amortisation of goodwill*
Source: Hardman & Co Life Sciences Research

Forecasts assume sales growth all down to volume…

…but any price rises would be further upside

Good growth is expected in the forecast period. Sales are anticipated to continue rising at a rate of 16%-19%, currently all due to volume. The last price rise, mostly on the BioRinse range of products, was two years ago. Any future price increases are more likely to be with BioRinse products, as the dCELL products tend to be covered by long-term contracts, albeit the introduction of line extensions may provide some flexibility.

BioRinse – Sports Medicine soft tissue repair



Source: TRX presnetation

This momentum is being derived, in part, from TRX developing new processing protocols, which are designed to extract efficiencies and minimise the effects of the tissue processing to generate high quality sterile products that have competitive advantages, and to satisfy the market. TRX is continually responding to market demand and to its strategic partners, which are the key drivers for medium term growth potential.

Leverage effect of additional sales

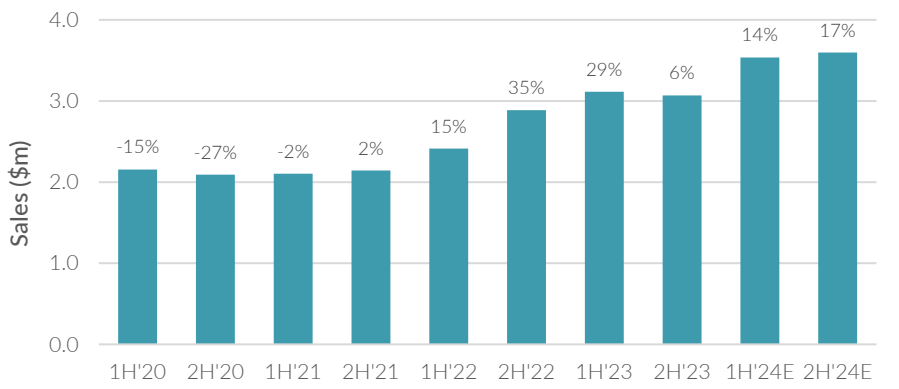
Having seen the BioRinse EBIT (excluding amortisation) rise 76% in 2023, a further ca.70% increase is expected in 2024. On a simplistic basis, the additional $4.0m (+19%) in sales equates to gross profit of $2.0m, less a 10% increase in marketing costs, generates an extra $1.6m of EBIT – i.e., 40% of additional sales drops through to the bottom line.

dCELL

Five consecutive six-month periods of growth

Over the 18 months since Phase 1 of the capacity expansion programme was completed, the underlying demand for BioRinse products and existing distribution partnerships meant that there was a natural benefit for this division. In addition, any recovery in elective surgeries following the pandemic lockdown was beyond TRX's control and, apart from the processing and manufacturing side, management took the opportunity to completely reorganise the dCELL commercial team and strategy. Taken together, this has meant that the benefits of investment have taken a little longer to emerge for this division. However, as seen with BioRinse, TRX has reported five sequential six-month periods of sales growth for dCELL. Overall, sales in 2023 grew by 17% to $6.2m with ongoing growth in the US (est. ca.14%) boosted by European sales of OrthoPure XT.

Half-yearly sales performance of dCELL, 2020-24E



Source: Hardman & Co Life Sciences Research

Attractive offering enticing more distributors

Benefits from the commercial reorganisation of the dCELL division were visible in both 2H'22 and 1H'23. Consequently, the 6% rate of growth reported for 2H'23 appears a little disappointing, especially given the new product launches. However, this should be considered with the context of the BioRinse performance, which was above expectations. One of the key advantages of the increased processing and manufacturing is that management has the flexibility to respond quickly to abnormal buying patterns from its customers; so, in 2H;'23 this benefited BioRinse to the slight detriment of dCELL. In another reporting period, the positions could be reversed. The diversity of the business and the flexibility in manufacturing provided TRX with the ability to successfully weather the pandemic and continue its growth trajectory.

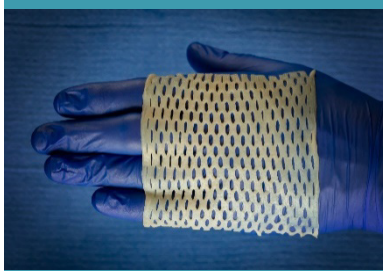
New product launches

Recent launches of products in the dCELL range are all aiming to make the life of a surgeon easier and improve patient outcomes.

OrthoPure XT

OrthoPure XT is the only non-human biological tissue graft available for certain ligament reconstruction procedures, which is being launched through distribution partners – out-licensed in the UK, Italy, Germany, China, Hong Kong and Australia. In 2022, the product was launched in Italy and Germany, with the UK added in 2023. However, the aim to launch in Australia in 2023 was hampered by delays in its regulatory approval. Additionally, inventory issues in its Leeds manufacturing site meant that launches into other selected territories were temporarily put on hold. We have little doubt that there is strong underlying demand for this product targeted at the Sports Medicine market.

DermaPure Meshed 4:6



Source: TRX presentation

VNEW

Source: TRX presentation

DermaPure Meshed 4:6

DermaPure Meshed 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. The original product in the range, DermaPure Meshed 3:1, was first introduced in June 2021. Following its success, TRX has expanded the product range with a line extension, DermaPure 4:6, that targets smaller areas, avoiding the need for surgeons to cut down the larger version to suit their needs.

VNEW® M

VNEW M is an alternative design of the existing VNEW graft, which is a pre-cut and pre-shared dermal graft, 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 is now subject to solid re-ordering after its initial launch in 2021.

dCELL has turned profitable

Reported dCELL sales growth in 2023 was 17%, with teen growth for the dCELL product range in the US boosted by strong OrthoPure XT growth, albeit from a very low base. There was good demand for dCELL products in the US, with the level of elective surgeries continuing to normalise. Sales growth would have been greater had management not taken the decision to prioritise the stronger short-term customer demand for BioRinse products, highlighting the new manufacturing flexibility. Also, sales of OrthoPure XT were held back by the inventory issues in Leeds, which restricted the further rollout of the product into more territories. Throughout the forecast period, normalisation of elective surgeries in the US is expected to boost dCELL sales, and geographical expansion of the availability of OrthoPure XT, should result in even stronger sales growth for the dCELL division.

Performance of dCELL

Year-end Dec ($m)	2019	2020	2021	2022	2023	2024E	2025E
Sales $m	5.41	4.25	4.25	5.30	6.18	7.13	8.02
COGS	-3.24	-2.37	-2.53	-3.03	-3.34	-3.63	-4.09
Gross profit	**2.17**	**1.87**	**1.72**	**2.28**	**2.84**	**3.50**	**3.93**
SG&A	-4.77	-3.42	-2.96	-3.27	-2.50	-2.62	-2.65
dCELL EBIT	**-2.60**	**-1.54**	**-1.24**	**-0.99**	**0.34**	**0.88**	**1.28**
Gross margin	*40.1%*	*44.1%*	*40.5%*	*42.9%*	*45.9%*	*49.1%*	*49.0%*
EBIT margin	***-48.0%***	***-36.3%***	***-29.1%***	***-18.8%***	***5.5%***	***12.3%***	***15.9%***

Source: Hardman & Co Life Sciences Research

Improving gross margin

For the third year running, gross margins improved in the dCELL division for two reasons. First, there were no inventory write-offs in 2023 vs. 2022. Secondly, more benefits from the manufacturing investment materialised. This was despite the inventory issues that prevented further geographical rollout of OrthoPure XT. This positive trend is expected to continue into the forecast period.

Reorganisation of the sales and marketing team in 2022 has resulted in a reduction in SG&A costs in 2023. However, this is expected to be a one-off benefit and dCELL SG&A costs are forecast to rise in order to drive sales growth.

Profitable, and margins expanding

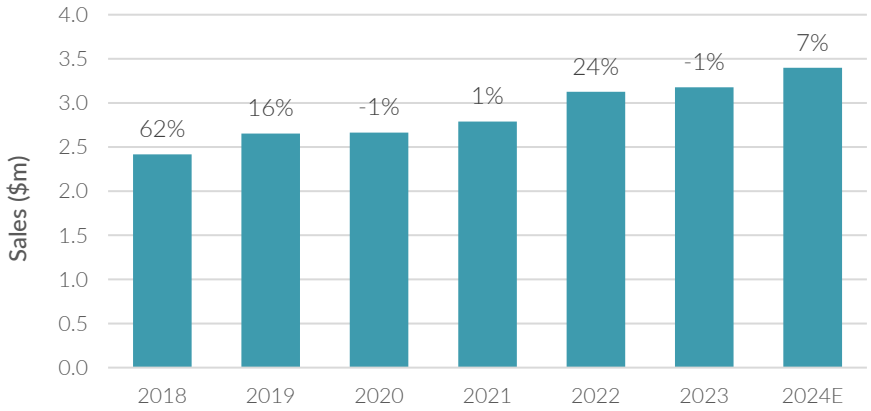
Consequently, TRX reached an important milestone in 2023, with the dCELL division turning profitable for the first time. Future sales growth is expected to have a significant leverage effect on profitability for this division, with EBIT margins rising from 5.5% in 2023 to 15.9% in 2025E.

GBM-V

Customers demand for donors with no history of COVID-19 constrained supplies

Having seen strong recovery in 2022, GBM-V had another difficult year in 2023, with underlying sales falling 1% to €2.95m/$3.18m. As seen before, the cause was largely out of TRX's control and all down to the supply of corneal tissue. Previously, customers, quite reasonably, required tissue to be sourced from donors who were free from COVID-19. However, in 2023, some customers required donors also to have no history of COVID-19 infection at all. This had a significant impact on tissue supply. Consequently, the broadly flat sales performance in local currency was very creditable, which translated into a 2% rise in reported sales. As has been observed previously, there is high demand for GBM-V products, so recovery tends to be substantial when supply constraints are removed.

Underlying sales performance of GBM-V, 2018-24E



Source: Hardman & Co Life Sciences Research

Despite the supply issues, GBM-V managed to maintain the gross margin above 50%, albeit that this was 1.1pp below the level seen in 2022. Provided the supply constraints can be overcome moving forward, gross margins are expected to make a steady improvement.

Remained profitable despite supply constraints

Administration costs were maintained broadly at 2022 levels in local currency, which, again, gave rise to a modest increase on translation. Taking all of this into account, despite having to contend with the supply constraints, GBM-V still recorded an operating profit in 2023.

Performance of GBM-V

Year-end Dec ($m)	2019	2020	2021	2022	2023	2024E	2025E
Sales €m	2.37	2.34	2.36	2.98	2.94	3.14	3.42
Sales $m	2.65	2.66	2.79	3.13	3.18	3.40	3.70
COGS	-1.79	-1.59	-1.89	-1.96	-2.12	-2.23	-2.39
Gross profit	**0.86**	**1.08**	**0.90**	**1.17**	**1.06**	**1.17**	**1.31**
SG&A	-1.27	-1.42	-1.06	-0.76	-0.84	-0.89	-0.92
GBM-V EBIT	**-0.41**	**-0.34**	**-0.15**	**0.41**	**0.22**	**0.28**	**0.39**
Gross margin	*54.3%*	*48.3%*	*46.0%*	*51.5%*	*50.4%*	*50.9%*	*51.8%*
EBIT margin	***-15.3%***	***-12.8%***	***-5.5%***	***13.1%***	***6.9%***	***8.2%***	***10.6%***

Source: Hardman & Co Life Sciences Research

Recovery could be substantial if regular supply can be sourced

Provided that GBM-V can source a regular supply of approved donor corneal tissue, sales and profits would be expected to see solid growth. Because of the natural underlying demand in the market, recovery could be quite substantial.

Financials and investment case

Income statement

- **Sales:** Strong US sales growth of 22% in fiscal 2023 drove overall group growth of 20%, which augurs well for 2024 with further expansion both of product range and geographically into selected markets.
- **COGS:** Benefits from the investment in capacity is driving manufacturing efficiencies, as evidenced by three consecutive years of gross margin expansion. Further processing efficiencies coupled with volume growth are expected to see an expansion in the gross margin moving forward.
- **SG&A:** TRX continues to invest in marketing and commercial partnerships, but at a lower rate than sales growth. This, coupled with careful control of general administration costs, has seen the group move into EBITDA-profit in 2023.
- **EBITDA:** TRX generated its first EBITDA profit in 2023 – even on a Hardman & Co basis, which includes share-based costs. The leverage effect of increased sales is forecast to expand EBITDA margins rapidly over the next two years, with the group generating its first EBIT profit in 2024.

Income statement

Year-end Dec ($m)	2020	2021	2022	2023	2024E	2025E
USD:EUR	0.877	0.846	0.952	0.925	0.925	0.925
BioRinse	9.56	12.71	16.05	20.13	23.96	27.78
dCELL	4.25	4.25	5.30	6.18	7.13	8.02
GBM-V	2.66	2.79	3.13	3.18	3.40	3.70
Sales	**16.47**	**19.75**	**24.48**	**29.49**	**34.49**	**39.50**
COGS	-8.90	-11.27	-13.22	-15.45	-17.63	-19.86
Gross profit	7.57	8.48	11.26	14.04	16.86	19.63
Gross margin	46.0%	42.9%	46.0%	47.6%	48.9%	49.7%
SG&A	-12.96	-12.46	-13.02	-14.09	-15.50	-17.05
Share-based costs	0.04	-0.11	-0.25	-0.34	-0.47	-0.47
Other income	1.10	0.00	0.00	0.00	0.00	0.00
Underlying EBITDA	**-3.20**	**-3.00**	**-0.88**	**0.58**	**1.90**	**3.18**
Depreciation	-0.32	-0.37	-0.52	-0.53	-0.55	-0.57
Amortisation	-0.73	-0.73	-0.62	-0.45	-0.47	-0.50
Underlying EBIT	**-4.26**	**-4.10**	**-2.01**	**-0.39**	**0.89**	**2.11**
Exceptional items	-8.32	-0.36	0.00	0.00	0.00	0.00
Statutory EBIT	-12.58	-4.45	-2.01	-0.39	0.89	2.11
Net interest	-0.57	-0.69	-0.82	-1.28	-0.83	-0.74
Underlying pre-tax profit	**-4.82**	**-4.79**	**-2.83**	**-1.67**	**0.06**	**1.37**
Extraordinary items	0.00	0.00	0.00	0.00	0.00	0.00
Statutory pre-tax profit	-13.15	-5.14	-2.83	-1.67	0.06	1.37
Tax payable/credit	0.68	0.16	0.23	0.01	-0.35	-0.60
Underlying net income	**-4.14**	**-4.63**	**-2.60**	**-1.66**	**-0.29**	**0.77**
Statutory net income	-12.46	-4.99	-2.60	-1.66	-0.29	0.77
Ordinary 0.1p shares:						
Period-end (m)	70.3	70.3	70.3	70.6	70.7	70.8
Weighted average (m)	44.5	70.3	70.3	70.4	70.6	70.7
Fully-diluted (m)	45.1	71.6	71.6	73.0	73.2	73.3
Underlying basic EPS (¢)	**-9.31**	**-6.58**	**-3.69**	**-2.35**	**-0.42**	**1.09**
Statutory basic EPS (¢)	-28.03	-7.09	-3.69	-2.35	-0.42	1.09
Underlying fully-dil. EPS (¢)	-9.17	-6.47	-3.63	-2.27	-0.40	1.05
Statutory fully-dil. EPS (¢)	-27.61	-6.97	-3.63	-2.27	-0.40	1.05
DPS (¢)	0.0	0.0	0.0	0.0	0.0	0.0

Source: Hardman & Co Life Sciences Research

Balance sheet

- **Inventories:** With an improved supply of higher-quality donor tissue, inventories are fairly stable. Indeed, TRX was able to release some working capital from inventories in 2023 and can now sell-on any surplus donor tissue to other processors to maximise the utilisation of this precious commodity.
- **Working capital:** TRX reduced its working capital requirement in fiscal 2023 through careful management of stocks, debtors and creditors. This has boosted TRX's financial flexibility, which has delayed the need to draw down on its increased revolving credit facility agreed earlier in the year.
- **Net cash/(debt):** At 31 December 2023, TRX had net debt of $4.75m, comprised of gross cash of $4.65m, above forecast, offset by the MidCap term loan and revolving credit facilities of $5.99m, and financial leases of $3.41m. Monthly repayments of the $2.0m term loan commenced in February 2024.
- **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 and investment needs. Additional operational efficiencies have moved the commencement of Phase 2 of the capacity expansion programme to 2025, although some of the preliminary planning activities will start in 2024.

Balance sheet						
@31 Dec ($m)	2020	2021	2022	2023	2024E	2025E
Shareholders' funds	38.27	33.39	30.40	29.36	29.06	29.83
Cumulated goodwill	0.00	0.00	0.00	0.00	0.00	0.00
Total equity	38.27	33.39	30.40	29.36	29.06	29.83
Share capital	15.95	15.95	15.95	15.95	15.95	15.95
Reserves	22.32	17.45	14.45	13.41	13.11	13.88
Provisions/liabilities	0.00	0.00	0.00	0.00	0.00	0.00
Deferred tax	0.76	0.64	0.52	0.40	0.40	0.40
Long-term leases	3.08	3.36	3.22	3.23	3.05	2.83
Short-term leases	0.35	0.12	0.13	0.18	0.18	0.18
Long-term debt	3.79	4.47	5.26	5.53	5.03	4.53
Short-term loans	0.00	0.00	1.00	0.46	0.00	0.00
less: Cash	12.97	7.71	5.95	4.65	3.46	1.15
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	**33.28**	**34.27**	**34.58**	**34.50**	**34.26**	**36.62**
Fixed assets	4.42	5.71	5.74	5.75	5.90	8.83
Intangible assets	15.30	15.06	15.06	15.14	15.14	15.14
Right-of-use assets	3.34	3.39	3.20	3.27	3.09	2.87
Goodwill	0.00	0.00	0.00	0.00	0.00	0.00
Inventories	9.60	9.72	10.88	10.36	11.51	11.86
Trade debtors	*2.42*	*2.95*	*4.20*	*3.03*	*3.94*	*4.51*
Other debtors	*1.17*	*1.16*	*0.61*	*0.70*	*0.70*	*0.70*
Tax liability/credit	*1.12*	*0.53*	*0.40*	*0.04*	*-0.35*	*-0.60*
Trade creditors	*-1.32*	*-2.57*	*-3.44*	*-1.21*	*-2.41*	*-2.90*
Other creditors	*-2.76*	*-1.67*	*-2.07*	*-2.58*	*-3.25*	*-3.80*
Debtors less creditors	0.63	0.39	-0.31	-0.01	-1.37	-2.08
Invested capital	**33.28**	**34.27**	**34.58**	**34.50**	**34.26**	**36.62**
Net cash/(debt)	**5.75**	**-0.24**	**-3.66**	**-4.75**	**-4.80**	**-6.38**
Inventory days	168	179	154	131	116	108
Debtor days	54	50	53	45	37	39
Creditor days	54	63	83	55	37	49

Source: Hardman & Co Life Sciences Research

Cashflow

- **Operational cashflow:** On a reported basis, TRX became EBITDA-positive for the full year in 2023. This is expected to continue throughout the forecast period. It should be noted that working capital outflows and certain local taxes mean that cash burn is front-loaded each year, likely to be seen at each set of interim results.
- **Working capital:** In 2023, TRX released some working capital through management of debtors and creditors. For the forecast period, to support the strong sales growth and prepare for Phase 2 of the manufacturing expansion, inventories are likely to be built up with some accompanying modest increases in trade creditors.
- **Capex:** Maintenance capex is ca.$0.4m each year. In 2024, there will be some additional costs related to initial planning activities for the Phase 2 capacity expansion in clean rooms. This is expected to cost a total approaching $4.0m spread over three years, starting in 2025.
- **Capitalised R&D:** The company continues to invest in R&D towards new product variants, but, as the core products are already approved and commercialised, this cost is being capitalised.

Cashflow						
Year-end Dec ($m)	2020	2021	2022	2023	2024E	2025E
Underlying EBIT	-4.26	-4.10	-2.01	-0.39	0.89	2.11
Depreciation	0.32	0.37	0.52	0.53	0.55	0.57
Amortisation	0.73	0.73	0.62	0.45	0.47	0.50
Share-based costs	-0.04	0.11	0.25	0.34	0.47	0.47
Inventories	*-4.12*	*-0.12*	*-1.16*	*0.52*	*-1.15*	*-0.35*
Receivables	*-0.26*	*-0.51*	*-0.70*	*1.07*	*-0.91*	*-0.57*
Payables	*0.22*	*0.16*	*1.25*	*-1.84*	*1.21*	*0.48*
Change in working capital	-4.15	-0.47	-0.62	-0.24	-0.86	-0.44
Exceptionals/provisions	-0.45	-0.36	0.00	0.00	0.00	0.00
Disposals	0.00	0.00	0.00	0.00	0.00	0.00
Other	-0.16	0.00	-0.19	0.06	0.00	0.00
Company op. cashflow	**-8.01**	**-3.72**	**-1.44**	**0.75**	**1.52**	**3.21**
Net interest	-0.32	-0.39	-0.44	-0.90	-0.27	-0.21
Lease payments	-0.24	-0.40	-0.36	-0.42	-0.46	-0.48
Tax paid/received	0.88	0.62	0.19	0.27	-0.35	-0.60
Operational cashflow	**-7.68**	**-3.89**	**-2.05**	**-0.30**	**0.44**	**1.91**
Capital expenditure	-1.57	-1.55	-0.38	-0.41	-0.70	-3.50
Capitalised R&D	-0.29	-0.50	-0.71	-0.45	-0.25	0.00
Sale of fixed assets	0.00	0.00	0.00	0.00	0.00	0.00
Free cashflow	**-9.55**	**-5.94**	**-3.14**	**-1.17**	**-0.51**	**-1.59**
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.	**-9.55**	**-5.94**	**-3.14**	**-1.17**	**-0.51**	**-1.59**
Share repurchases	0.00	0.00	0.00	0.00	0.00	0.00
Equity issues	18.67	0.00	0.01	0.07	0.00	0.00
Funding costs	-1.15	0.00	0.00	0.00	0.00	0.00
Currency effect	0.08	-0.05	-0.29	0.01	0.00	0.00
Cash/(debt) acquired	-2.43	0.00	0.00	0.00	0.00	0.00
Change in net debt	**5.63**	**-5.99**	**-3.42**	**-1.09**	**-0.51**	**-1.59**
Opening net cash/(debt)	0.12	5.75	-0.24	-3.66	-4.75	-4.80
Closing net cash/(debt)	**5.75**	**-0.24**	**-3.66**	**-4.74**	**-5.26**	**-6.38**
OCFPS (¢)	-17.27	-5.53	-2.91	-0.43	0.62	2.71

Source: Hardman & Co Life Sciences Research

Valuation

TRX plays valuable niche role for its commercial partners

Valuing a company like TRX is extremely difficult. In 2023, the company achieved a significant milestone by becoming EBITDA-positive for the full year. To get the company to where it is today, converting its technologies into commercially useful medical products and devices, 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 donor 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. We make no excuse for repeating our previously published, but updated, argument on TRX valuation.

The equivalent of 1.67p per share has been invested to get the company to where it is today and cash-generative

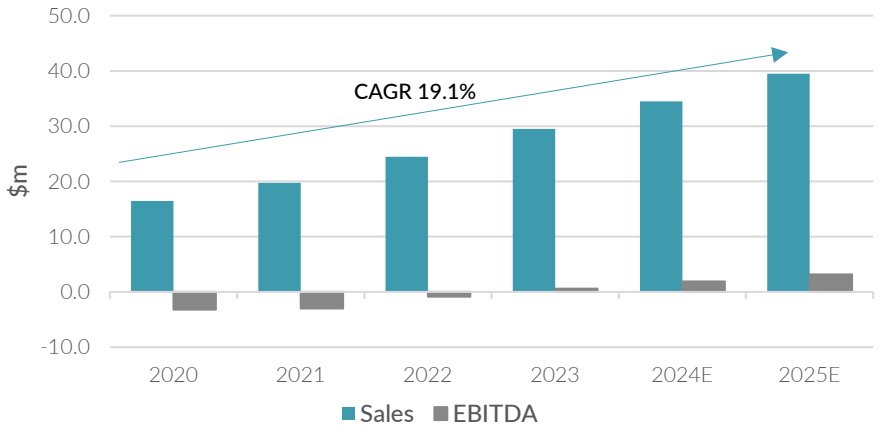
Based on the following facts, TRX, with a market capitalisation of £43.4m/$54.9m, is currently being undervalued by the market:

- To get TRX to where it is today, $150m/£118m – equivalent to 1.67p 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/£25m.
- 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 $134m/£105m.
- The administrative achievement in obtaining the relevant accreditations and licences for the harvesting and processing of human tissue is considerable.

Strong, positive momentum led TRX to become EBITDA-positive in fiscal 2023

TRX became EBITDA-profitable overall in 2023. The leverage effect of further ca.20% p.a. sales growth is expected to see this translate into becoming EBIT-positive in 2024, even allowing for the potential influence of external factors beyond the company's control.

Sales and underlying EBITDA, 2020-25E



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 relationships, are expected to drive future sales growth. Hitting the EBITDA-positive milestone in 4Q'22 and carrying this through for the full year in 2023 has provided the market with reassurance of the trend towards overall profitability. In turn, this should be reflected in upward momentum towards a market capitalisation of $158m/£125m, or 4x prospective 2025 sales, not expensive for a fast-growth, profitable, medtech.

Company matters

Registration

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Universal City
San Antonio
Texas
78148

Board of Directors

Board of Directors

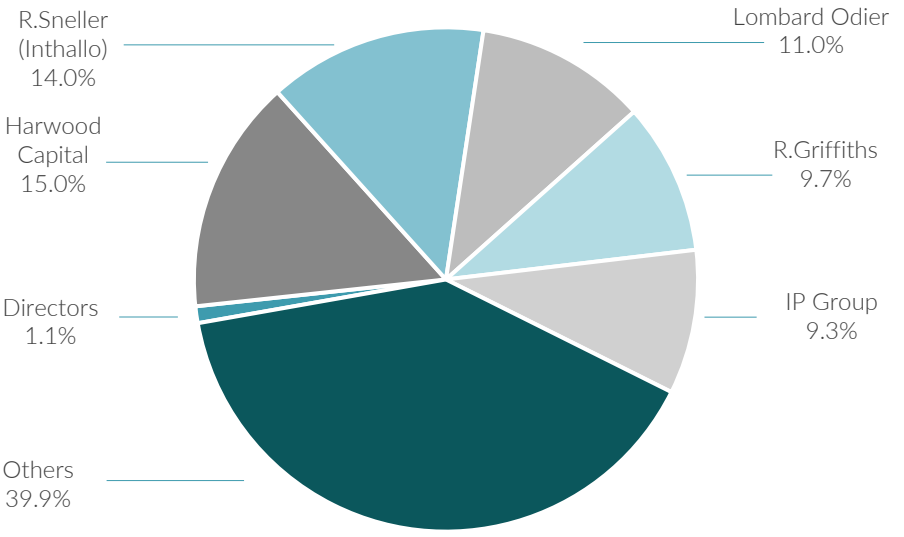
Position	Name	Remuneration	Audit
Chairman	Jonathan Glenn		M
Chief Executive Officer	Daniel Lee		
Chief Financial Officer	David Cocke		
Non-executive director	Shervanthi Homer-Vanniasinkam	M	
Non-executive director	Brian Phillips	M	C
Non-executive director	Trevor Phillips	C	M

M = member, C = chair
Source: Company reports

Share capital

On 9 April 2024, the company had 70,574,468 Ordinary shares of 10p in issue. There are also 2,585,537 options and 30,968 warrants outstanding.

Shareholders



Source: Company announcements, Hardman & Co Life Sciences Research

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Status of Hardman & Co's research under MiFID II

Some professional investors, who are subject to the new MiFID II rules from 3rd January2018, may be unclear about the status of Hardman & Co research and, specifically, whether it can be accepted without a commercial arrangement. Hardman & Co's research is paid for by the companies, legal entities and issuers about which we write and, as such, falls within the scope of 'minor non-monetary benefits', as defined in the Markets in Financial Instruments Directive II.

In particular, Article 12(3) of the Directive states: 'The following benefits shall qualify as acceptable minor non-monetary benefits only if they are: (b) 'written material from a third party that is commissioned and paid for by a corporate issuer or potential issuer to promote a new issuance by the company, or where the third party firm is contractually engaged and paid by the issuer to produce such material on an ongoing basis, provided that the relationship is clearly disclosed in the material and that the material is made available at the same time to any investment firms wishing to receive it or to the general public…'

The fact that Hardman & Co is commissioned to write the research is disclosed in the disclaimer, and the research is widely available.

The full detail is on page 26 of the full directive, which can be accessed here: http://ec.europa.eu/finance/docs/level-2-measures/mifid-delegated-regulation-2016-2031.pdf

In addition, it should be noted that MiFID II's main aim is to ensure transparency in the relationship between fund managers and brokers/suppliers, and eliminate what is termed 'inducement', whereby free research is provided to fund managers to encourage them to deal with the broker. Hardman & Co is not inducing the reader of our research to trade through us, since we do not deal in any security or legal entity.

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