TISSUE REGENIX

Maiden pre-tax profit

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 seven consecutive reporting periods of strong growth, with TRX becoming profitable in 1H'24. TRX is about to invest in Phase 2 of its capacity expansion programme, which has the potential to take group sales up to $100m. TRX deserves to be re-rated, in our view.

- **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 is being used to expand capacity further with Phase 2.
- **Interims:** In 1H'24, TRX reported double-digit (16.3%) sales growth for the seventh consecutive reporting period, generating sales of $16.4m ($14.1m). Growth was observed in all three divisions. EBITDA increased more than three-fold to $1.15m ($0.35m) and TRX generated its maiden PBT of $0.13m.
- **Phase 2 capacity investment:** TRX has started Phase 2 of its capacity expansion programme to significantly increase the number of clean rooms, providing greater flexibility to satisfy changing demand and take group sales up to $100m. This programme is fully funded and expected to be completed by the end of 2025.
- **Forecasts:** TRX has a diverse set of products, which are sold directly or through strong partners. Unexpected headwinds affected the BioRinse range (+12% in 1H'24), but its processing flexibility was switched to dCELL (+34%). Higher gross margins in 1H'24 have been carried through to the full year, and 2025.
- **Investment summary:** 2023 was a milestone year when TRX was fully EDITDA-positive and cash-generative in 2H'23. Further growth in 1H'24 has seen the group become EBIT- and PBT-profitable. Cash generation is being used to expand processing and manufacturing further through Phase 2 of its capacity investment programme in 2025. This is a quality operation with very strong partners. An EV/sales multiple of 4x 2025E sales generates a valuation of $159m/£120m.

Financial summary and valuation

Year-end Dec ($m)	2020	2021	2022	2023	2024E	2025E
Sales	16.47	19.75	24.48	29.49	34.40	39.70
Underlying EBITDA	-3.20	-3.00	-0.88	0.58	2.25	3.54
Underlying EBIT	-4.26	-4.10	-2.01	-0.39	1.19	2.43
Statutory EBIT	-12.58	-4.45	-2.01	-0.39	1.19	2.43
Underlying PBT	-4.82	-4.79	-2.83	-1.67	0.38	1.34
Statutory PBT	-13.15	-5.14	-2.83	-1.67	0.38	1.34
Underlying EPS (¢)	-9.31	-6.58	-3.69	-2.35	-0.46	0.73
Statutory EPS (¢)	-28.03	-7.09	-3.69	-2.35	-0.46	0.73
Net cash/(debt)	5.75	-0.24	-3.66	-4.75	-5.30	-7.32
Equity issues	18.67	0.00	0.01	0.07	0.15	0.00
EV/sales (x)	3.9	3.3	2.7	2.1	1.8	1.6
EV/EBITDA (x)	-	-	-	108.3	28.0	17.8

Source: Hardman & Co Life Sciences Research

Pharmaceuticals & Biotechnology

Source: LSEG, 2024

Market data

EPIC/TKR	**TRX**
Price (p)	**60.0**
12m high (p)	73.0
12m low (p)	48.0
Shares (m)	71.40
Mkt cap (£m)	42.8
EV (£m)	48.2
Free float*	60%
Country of listing	UK
Reporting currency	USD
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
Chairman	Jonathan Glenn

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Key shareholders

Directors	1.1%
Harwood Capital	14.8%
R. Sneller (Inthallo)	14.0%
Lombard Odier	12.1%
R. Griffiths	9.6%
IP Group	9.2%

Diary

Jan'25	Trading update
Mar'25	2024 final results

Analyst

Martin Hall mh@hardmanandco.com

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1H'24 results

Operational highlights

- **BioRinse:** BioRinse sales were below expectations due to some product lines being impacted by various headwinds, including the reimbursement landscape for wound care products, but still grew 12.2% to \$10.5m (\$9.4m). Higher-margin demineralised bone matrix products (DBM) still grew an impressive 26%.
- **dCELL:** Highlighting the company's manufacturing flexibility, sales from the dCELL range greatly exceeded expectations, growing 34.0% to \$4.2m (\$3.1m). Strong underlying performance from DermaPure in the US was boosted by the recent launches of OrthoPure XT in Europe.
- **GBM-V:** Resolution of tissue supply in Germany has seen a return to growth for the retinal products of GBM-V, with sales rising 6.2% to €1.58m/\$1.71m (€1.49m/\$1.61m).

Financial highlights

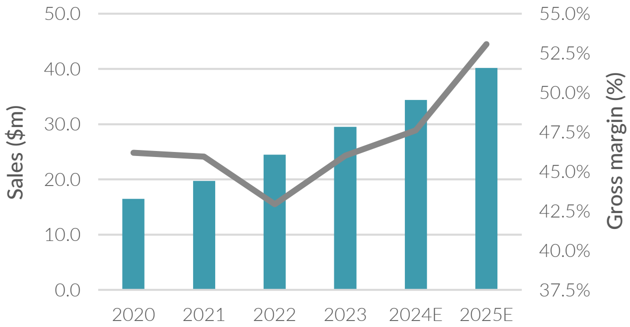
- **Sales:** Although the make-up was not as expected, group sales overall were \$0.2m better than forecast, rising 16.3% to \$16.4m. This highlights the increased operational flexibility derived from TRX's investment in Phase 1 of its capacity expansion, tissue storage and tissue processing programme.
- **COGS:** Improved gross margins were reported in all three divisions in 1H'24. The overall group gross margin increased from 49.1% to 52.5% through a combination of greater manufacturing efficiencies and improved product mix.
- **SG&A:** Underlying (excluding share-based costs) SG&A costs increased 13.3% to \$8.0m (\$7.1m) in 1H'24, a slower rate than sales growth. This scenario is expected to continue highlighting the leverage effect of the sales growth.
- **Profitability:** Having reported an EBITDA-positive result in both 1H'23 and for the full year, TRX has reported its maiden EBIT and profit before tax in 1H'24.
- **Net cash/(debt):** At 30 June, TRX had gross cash of \$3.5m against debt and operating leases of \$10.5m. Just before the period-end, TRX completed the freehold acquisition of its facility in San Antonio, which was achieved at an equivalent annual cost to the company. This change resulted in the movement of long-term operating leasing into long-term debt, with minimal change to the net debt position.

Interim results summary – actual vs. expectations

Year-end Dec (\$m)	1H'23 actual	1H'24 actual	Growth CER	1H'24 *forecast	Delta Δ
BioRinse	9.37	10.52	+12.2%	11.06	-0.54
dCELL	3.11	4.17	+34.0%	3.58	+0.59
GBM-V	1.61	1.71	+6.2%	1.58	+0.13
Group sales	**14.10**	**16.40**	**+16.3%**	**16.22**	**+0.18**
COGS	-7.17	-7.78	+8.0%	-18.55	+0.32
SG&A	-7.05	-7.99	+13.3%	-0.44	-0.14
Share-based costs	-0.11	-0.10	nm	-0.65	-0.10
Underlying EBITDA	0.25	1.02	+315%	0.76	+0.26
Underlying EBIT	**-0.23**	**0.52**	**n/m**	**0.24**	**+0.28**
Gross cash	4.06	3.46	-0.76	3.90	-0.44
Net cash/(debt)	**-5.43**	**-7.01**	**-1.58**	**-6.20**	**-0.81**

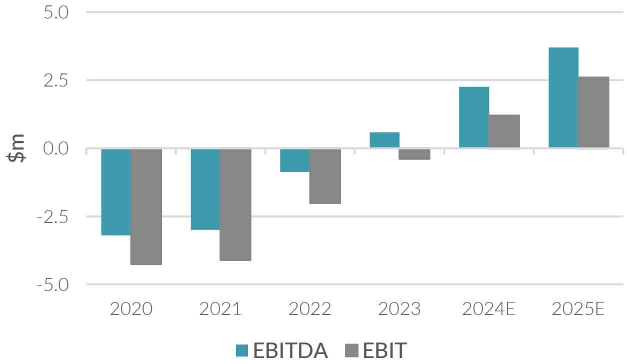
**Prior to release of business update statement on 16 July*
Note: numbers may not add up exactly due to rounding
Source: Hardman & Co Life Sciences Research

Sales and gross margin



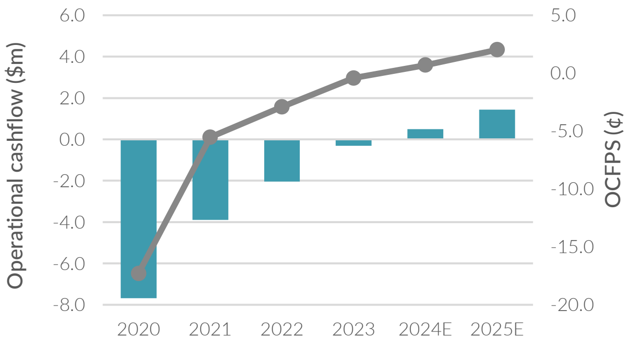
- Sales: 20.2% CAGR 2020-25. High-margin divisions are driving performance offset by the lower-growth JV in Germany.
- Strong US sales growth from diversified customer base boosted by new market entry, line extensions and geographical expansion.
- Gross margin is on a strong upward trend as the full benefits of the capacity investment continue to materialise.

EBITDA and underlying EBIT



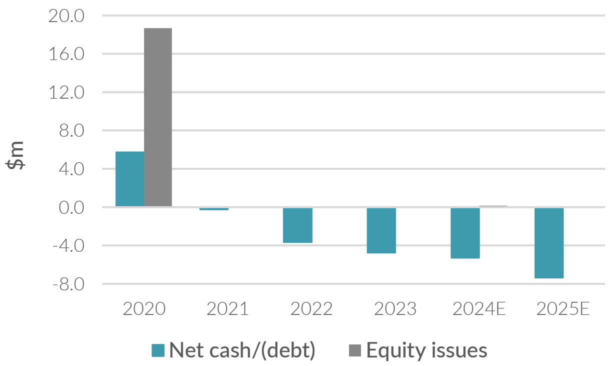
- TRX initially turned EBITDA-positive in 4Q'22 but was overall EBITDA-positive in fiscal 2023.
- Leverage effect of strong sales growth is expected to see EBITDA rise rapidly throughout the forecast period.
- All three divisions have been profitable since 2023 and the group as a whole turned profitable in 1H'24.
- The leverage effect of increased sales is expected to be very apparent over the next three years, with strong EBIT growth.

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 debt facilities, 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 30 June 2024, was $3.5m, replicating the traditional cash outflow in the first-half of year. This 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

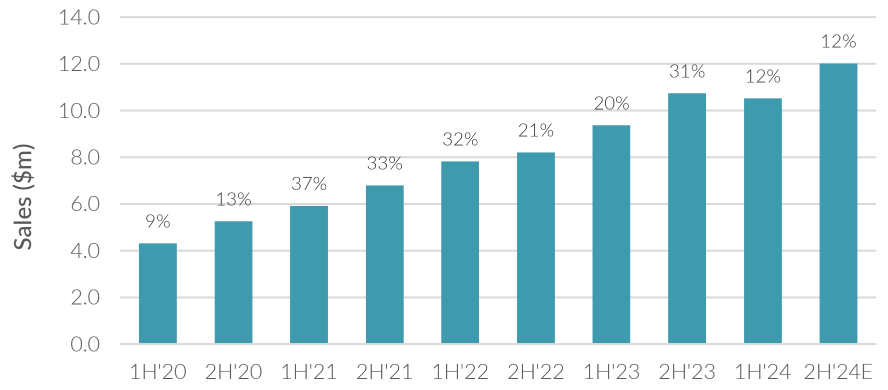
BioRinse

Diverse range of differentiated bone scaffold products…

… with strong underlying demand

Our two previous reports both highlighted the expectation that the BioRinse division would benefit from the Phase 1 capacity expansion programme, because of its 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. Therefore, a reduction in the growth rate to 12% in 1H'24 has come as something of a surprise – in our fiscal 2023 report[1], we were expecting growth of 20%. However, as mentioned earlier, there have been some regulatory headwinds and a few customers have been affected by the reimbursement landscape and spooked by the MAC proposals regarding reimbursement of certain medical products, notably wound management, which has altered the demand patterns. While a slight concern for the BioRinse division (see below), TRX's diverse product portfolio and flexible processing and manufacturing has benefited the dCELL division in 1H'24.

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



Source: Hardman & Co Life Sciences Research

Strong underlying DBM sales growth in 1H'24 held back by headwinds faced by some third-party products and donor tissue sales…

Further analysis of comments made in the interim statement indicate to us that the third-party products affected represent a relatively small proportion of total BioRinse sales and attract lower margins. In contrast, the vast majority of sales are for higher-added-value DBM products – including Concelltrate, AmnioWorks and spinal products – and these were reported to have sales growth of 26%, consistent with >20% seen in several recent reporting periods.

… but these "other sales" will be insignificant after 2024

With the high value-added DBM, spine and sports medicine products growing at a fast rate, certainly above the divisional average, the contribution and significance of birth tissue products and sales of surplus donor tissue has greatly diminished. We expect a similar pattern for the remainder of 2024. Although the headwinds are likely to continue for the remainder of 2024, once accounted for, any further downside risk is extremely limited, such that the growth rate for the BioRinse division, as a whole, should revert back towards the 20% level in 2025.

There appear to be three main factors behind the headwinds that affected the BioRinse growth rate observed in 1H'24:

- Ongoing supply chain issues, regulatory review delays, reimbursement challenges and personnel shortages that have affected the whole US healthcare market over the past 18 months, including TRX's partners.
- Dynamic changes in the wound care market caused by proposed changes to Medicare reimbursement (see details below).

[1] *Six consecutive periods of >20% growth* – 10 April 2024

- Slower-than-expected regulatory approvals process has extended the entry timetable for new non-US markets for donor tissue and tissue products.

However, despite these challenges, the core higher-added-value DBM and related products were largely unaffected by these headwinds.

Changes to Medicare reimbursement

MAC reimbursement proposals hit some wound care products…

… but TRX products largely unaffected by proposals

Questions as to how medtech companies might be affected by the Medicare Administrative Contractors (MAC) reimbursement proposals for outpatient wound care has been a significant topic of conversation over the past six months. But the latest iteration has attracted considerable attention. With companies reporting 2Q/1H numbers recently, focus has been on products and companies most likely to be affected. Our understanding is that there is a coordinated proposal to eliminate coverage for ca.90% of certain product categories, notably skin substitute products for diabetic foot ulcers/venous leg ulcers. However, other categories are also affected. The bottom line is that the outlook for reimbursement going forward has been challenged for products that lack specific acceptance criteria, to include robust clinical evidence from a randomised clinical trial. Fortunately, most of TRX's products do not come under this category and should be largely unaffected.

Improving operating performance

Leverage effect of strong top line falls through to EBIT

The BioRinse business has seen strong sales momentum over the past two years, which has had a positive leverage effect on profitability. Although the sales growth was slightly lower than anticipated in 1H'24, it was derived from higher-value-added products, which attract higher margins. This pattern is expected to continue in 2H'24 and into the future. 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	22.55	26.00
COGS	-3.93	-4.94	-6.86	-7.79	-9.99	-10.05	-11.35
Gross profit	**4.66**	**4.62**	**5.85**	**8.26**	**10.14**	**12.50**	**14.64**
SG&A*	-5.09	-5.66	-6.24	-6.96	-7.85	-9.30	-10.42
BioRinse EBIT	**-0.43**	**-1.04**	**-0.39**	**1.30**	**2.29**	**3.20**	**4.23**
Gross margin	*54.3%*	*48.3%*	*46.0%*	*51.5%*	*50.4%*	*55.4%*	*56.3%*
EBIT margin	***-5.0%***	***-10.9%***	***-3.1%***	***8.1%***	***11.4%***	***16.3%***	***18.2%***

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

Changes to forecasts

Reduction in BioRinse sales forecasts offset by similar rise in dCELL sales

Our BioRinse sales forecast has been reduced by ca.$1.5m for both 2024 and 2025, effectively replicating the >50% decline seen in "other" in 1H'24 into 2H'24 and beyond. However, this has been accompanied by an increase in the margin, reflecting the higher-value-added nature of the DBM products, so the reduction in EBIT is much more modest.

Conclusion

Above-market-average growth of value-added DBM products

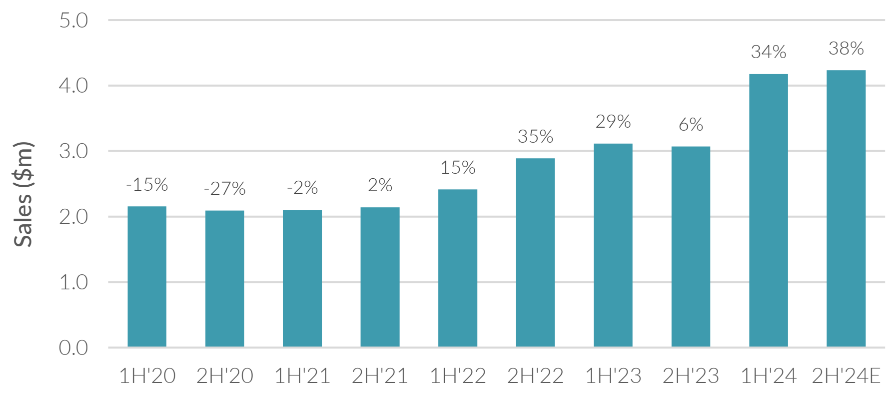
Readers should not be overawed by the headwinds seen in 1H'24, because they are affecting only a small part of this business and the headline sales growth rate. The core high-value-added DBM products continue to grow well above the market average and improve the divisional margin and profitability. They are reinforced by strong and supportive partners such as Arthrex.

dCELL

Flexibility in processing led to exceptional 1H'24 dCELL performance

Investment in Phase 1 of the capacity expansion programme and reorganisation of manufacturing facilities has provided TRX with far greater processing and production flexibility. The was supremely demonstrated in 1H'24 when those aforementioned headwinds started to affect demand for some BioRinse products. Management was able to reallocate its resources on to dCELL products, which were experiencing very strong demand in surgical indications. Consequently, sales growth in 1H'24 far exceeded expectations (6%), at 34%, generating sales of $4.2m. Overall, 17% more units were shipped with a higher sales value – notably the premium priced mesh products, which reduce wastage, save surgeons' time and have improved clinical outcomes. The exceptional growth in the US was boosted by recent launches of OrthoPure XT in Europe.

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



Source: Hardman & Co Life Sciences Research

Expansion of profitability

Leverage effect of sales driving big rise in margins and EBIT

On the back of solid (17%) sales growth in 2023, the dCELL division turned profitable for the first time. Normalisation in the level of elective surgeries, recent product launches – notably DermaPure Meshed – and resolution of inventory issues in Leeds resulted in increased demand for dCELL products, which was satisfied by the production switch away from BioRinse. On the back of 34% sales growth in 1H'24, the dCELL EBIT increased almost six-fold to $0.69m. All of the positive characteristics seen in 1H'24 are expected to continue throughout 2H'24, further increasing the positive contribution that dCELL will be making to the group.

Performance of dCELL

Year-end Dec ($m)	2019	2020	2021	2022	2023	2024E	2025E
Sales	5.41	4.25	4.25	5.30	6.18	8.41	10.10
COGS	-3.24	-2.37	-2.53	-3.03	-3.34	-3.89	-4.66
Gross profit	**2.17**	**1.87**	**1.72**	**2.28**	**2.84**	**4.51**	**5.45**
SG&A	-4.77	-3.42	-2.96	-3.27	-2.50	-3.00	-3.60
BioRinse EBIT	**-2.60**	**-1.54**	**-1.24**	**-0.99**	**0.34**	**1.52**	**1.85**
Gross margin	*40.1%*	*44.1%*	*40.5%*	*42.9%*	*45.9%*	*53.7%*	*53.9%*
EBIT margin	***-48.0%***	***-36.3%***	***-29.1%***	***-18.8%***	***5.5%***	***18.0%***	***18.3%***

Source: Hardman & Co Life Sciences Research

Moving forward, further geographical expansion of OrthoPure XT, the only non-human biologic option for particular anterior cruciate ligament reconstruction procedures, is expected to boost the underlying US strength of the dCELL division and further expand profitability.

Changes to forecasts

Although the 2024 sales dCELL sales forecast has only risen $1.3m, this has a significant leverage effect on profitability, which can be seen in the following table.

Changes to dCELL forecasts

Year-end Dec	2023		2024E			2025E	
($m)	actual	Old	New	Δ	Old	New	Δ
Sales	6.18	7.13	8.41	+18%	8.02	10.10	+26%
COGS	-3.34	-3.63	-3.89		-4.09	-4.66	
Gross profit	**2.84**	**3.50**	**4.51**	+29%	**3.93**	**5.45**	+39%
SG&A	-2.50	-2.62	-3.00		-2.65	-3.60	
BioRinse EBIT	**0.34**	**0.88**	**1.52**	+73%	**1.28**	**1.85**	+45%
Gross margin	*45.9%*	*49.1%*	*53.7%*	+4.6pp	*49.0%*	*53.9%*	+4.9pp
EBIT margin	*5.5%*	*12.3%*	*18.0%*	+5.7pp	*15.9%*	*18.3%*	+0.3pp

Source: Hardman & Co Life Sciences Research

Conclusion

dCELL forecasts increased following strong 1H'24 performance

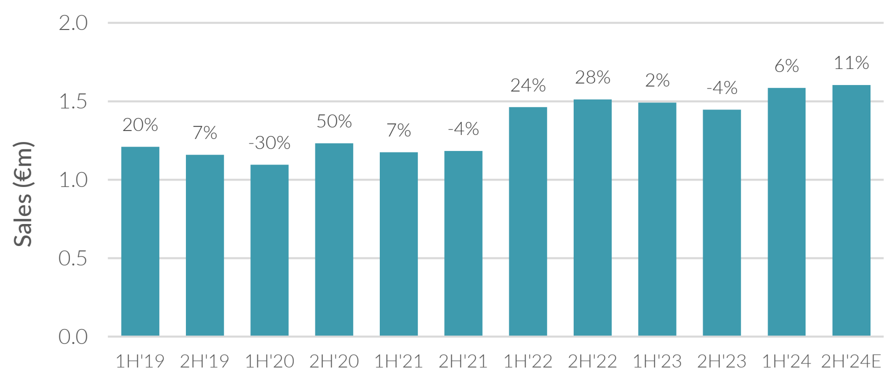
In our *previous report on TRX*, we highlighted how the BioRinse division had benefited in fiscal 2023 from the newfound processing and manufacturing flexibility to the detriment of dCELL growth. We also suggested that, in another reporting period, these roles could be reversed as demand changes. Little did we realise that this would happen so quickly. This flexibility was exemplified by the exceptional performance of dCELL in 1H'24. Given that there remains considerable uncertainty over the MAC reimbursement proposals for wound repair products, we expect this situation to continue for the remainder of 2024 and into 2025. dCELL is forecast to make a substantial and growing contribution to group profitability in the forecast period and beyond.

GBM-V

GBM-V is a stable and modest contributor, as dictated by the JV arrangement

Over the past several reporting periods, the sales performance of GBM-V has been fairly stable. Alterations in the sales growth rates are largely caused by tissue supply issues that are largely out of GBM-V's control. What has never been in doubt is the solid demand for its corneal-derived products. In 1H'24, there has been a reasonable recovery from the difficulties encountered in 2023, which were affected by the ability to source adequate supplies of corneal tissue from donors known to have a history of being totally free from COVID-19 infection. The outcome in 1H'24 suggests that the tissue supply has stabilised.

Half-yearly performance in GBM-V sales, 2020-24E



Source: Hardman & Co Life Sciences Research

The gross margin at GBM-V fluctuates along with its sourcing and tissue suitability issues for corneal tissue. In difficult times, it drops to ca.33%; and in a better environment, the gross margin can rise to as high as 40%. Our forecasts assume that there will be continued improvement now that there appears to be a steady source of tissue. In 1H'24, it rose to 35.0% and further improvements are expected as the year progresses.

Administration costs are also fairly stable in local currency with fluctuations often attributable to translation into US$. Overall, we anticipate GBM-V contributing about $0.4m to EBIT in 2024, with an EBIT margin of 11.6%.

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	3.19	3.33
Sales $m	2.65	2.66	2.79	3.13	3.18	3.45	3.60
COGS	-1.79	-1.59	-1.89	-1.96	-2.12	-2.21	-2.27
Gross profit	**0.86**	**1.08**	**0.90**	**1.17**	**1.06**	**1.24**	**1.33**
SG&A	-1.27	-1.42	-1.06	-0.76	-0.84	-0.84	-0.89
GBM-V EBIT	**-0.41**	**-0.34**	**-0.15**	**0.41**	**0.22**	**0.40**	**0.44**
Gross margin	*32.4%*	*40.4%*	*32.4%*	*37.5%*	*33.4%*	*36.0%*	*37.0%*
EBIT margin	***-15.3%***	***-12.8%***	***-5.5%***	***13.1%***	***6.9%***	***11.6%***	***12.3%***

Source: Hardman & Co Life Sciences Research

Changes to forecasts

Slight increase in GBM-V expectations after improved 1H'24 outcome

There has been a very small increase in sales for our 2024 forecast to reflect the slightly better-than-expected performance in 1H'24. Improvements in both the gross and net margins for 1H'24 have also been carried through to the full year, such that the EBIT has increased from $0.28m to $0.40m.

Phase 2 capacity investment

Purchase of freehold an integral part of long-term strategy

In June 2024, management made the important long-term decision to take the opportunity to purchase the freehold for one of its manufacturing facilities at 1740 Universal City Boulevard, San Antonio – the company already owns the other building. In 2019, TRX signed a lease for this new 21,000 sq.ft. building, which is adjacent to the group's existing manufacturing facility and integral to its capacity expansion plans. At that point in time, the need for the full building was still to be determined, the company did not have a strong enough balance sheet, nor the operating income, to support a financing plan to purchase the building, so management negotiated a lease with an option to buy at a pre-agreed fixed price. With TRX entering profitability on the back of strong operating growth, attractive fixed-rate financing with no cash down-payment was readily available to exercise the purchase option. This does not materially alter the overall short-term financial cost and has the potential to generate long-term savings, as the lease had standard annual increases. This acquisition is important as it coincides with Phase 2 of the capacity expansion investment.

Original plan

Phase 1

As a reminder, Phase 1 involved complete reorganisation of the activities undertaken in the two buildings, which resulted in:

- increasing the donor tissue storage capacity three-fold with new, modern freezers;
- having a dedicated, centralised and efficient distribution function for finished products;
- providing additional office space for finance, human resources, donor services and senior management; and
- undertaking the first three activities in order to free up space in the existing building to add two additional clean rooms, bringing the total to seven.

This work was completed on budget ($2.7m) and on time, in 2021, and was expected to provide sufficient capacity to increase annual sales to a maximum of $30m.

Phase 2

As the Phase 1 capacity neared full utilisation, and when the company was suitably resourced, the original plan was to add a further 10 clean rooms, greatly increasing production capacity, with the aim of adding up to $35m of additional annual sales. Phase 2 in the original plan was expected to cost a total of $4.5m-$5.5m and be completed by the end of 2025.

Capacity expansion plan update

Within the first six months from completion of Phase 1, management was already starting to see a greater level of efficiencies than had been anticipated at the outset. There has been a recurring theme within the announcement of each set of six-month results. Even today, there is recognition that further improvements can be made in processing and scheduling.

Capacity increase from Phase 2 expected to support sales of $100m

In the original plan, all of the current capacity was expected to have been used up by now. However, the continual identification and implementation of efficiencies means that the current capacity will last through 2025. Even though the plan has evolved, TRX still expects the new clean rooms to be completed during 2025, meaning that Phase 2 dovetails nicely with the Phase 1 capacity becoming more stretched. The ever-increasing efficiencies mean that management now expects the enlarged capacity to be sufficient to support group sales of up to $100m.

Some infrastructure work done while optimising Phase 1

During the build process for Phase 1, certain optimisations were identified – notably the Phase 2 mechanical infrastructure work for electrical, plumbing and some air conditioning – which could be more efficiently undertaken as part of the Phase 1 construction work. Consequently, these elements of the expansion programme were brought forward, as they reduced the capital outlay and lowered the subsequent impact on operations later in the project.

Phase 2 planning and logistics already started

During 2H'24, TRX is undertaking all of the planning and logistics work in preparation for Phase 2, then construction will start is earnest in 1H'25. Given the key element of the infrastructural work has already been done, implementation of Phase 2 through the additional clean rooms will be relatively fast and it is expected to be completed, commissioned and validated during 2H'25. The bulk of the remaining cost – now estimated to be $3.6m-$3.8m – will be incurred in 2025.

Measuring increased efficiency – donor processing

Donor processing KPIs important measure of efficiency

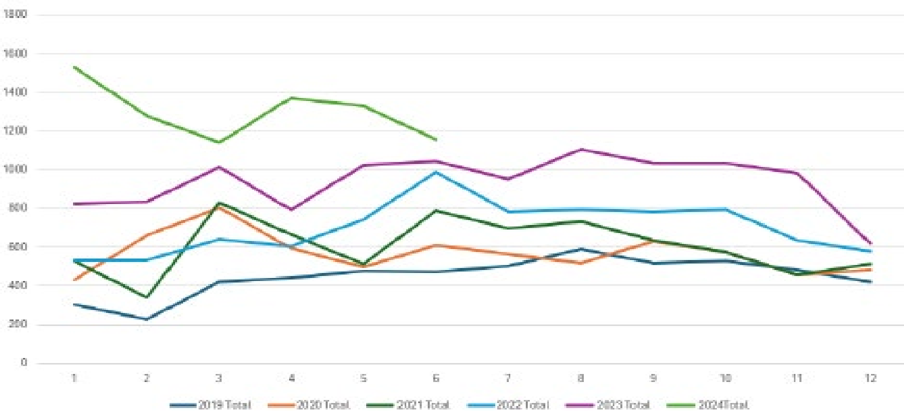
Apart from the fact that TRX has been able to generate sales that are well above those anticipated to be achievable at the beginning of the capacity expansion programme, and at higher margins, one of the KPIs by which management assesses increased efficiency is through the monitoring of donor processing. Using 2019 as the base point – i.e. prior to Phase 1 – there has been a steady increase in the number of donors processed per FTE, which has almost doubled.

Donors processed – FTE weighted by donor type

Source: Tissue Regenix 1H'24 presentation

Additionally, over the same period, the number of donors processed per month (weighted donor hours) has increased every year, with 2024, to date, far exceeding the data for 2023.

Donors processed – by month (weighted donor hours)



Source: Tissue Regenix 1H'24 presentation

In 1H'24, management stated that there had been a 29% increase in tissue processing to support the growing sales demand. However, this figure hides the processing flexibility that TRX now has. In response to the headwinds discussed in BioRinse and the opportunities within dCELL, resources were shifted towards musculoskeletal processing and, overall, there was a 52% increase in total processing during 1H'24. Further benefits are anticipated in the future.

Donor tissue

Ahead of the capacity expansion programme, a key goal of TRX management was to develop much stronger relationships with tissue banks that are governed in the US by the National Organ Transplant Act (NOTA) to ensure an adequate supply of high-quality human tissue – such as bone, soft tissue and birth tissue. As the company is expanding further, this remains a priority.

Two more tissue donor partners added in 1H'24

Maintaining the supply of donor tissue for normal operational needs continues to be a key focus, enabling TRX to be flexible in meeting its processing needs. This was exemplified through the dynamic demand cycles in 1H'24. It is a significant challenge to maintaining this balance when there are rapid shifts in market segments. In an attempt to overcome these challenges and manage donor relationships and tissue inventories, TRX added two additional recovery partners. Conscious of the sensitivities associated with donor tissue and respectful of the need to maximise the gift, TRX adds value (part processed) to the surplus tissue and makes it available to other national and international tissue processing companies.

Financials and investment case

Income statement

- **Sales:** TRX's diversified portfolio is expected to see mid-to-high teen sales growth in coming periods, although the divisional contributions might fluctuate due to dynamic changes in some markets. BioRinse and dCELL will remain the core drivers, supported by solid underlying demand at GBM-V.
- **COGS:** Management continues to identify additional cost efficiencies in its tissue processing and manufacturing facility. In addition, improvement in the product mix to higher-value-added products continues to boost gross margins.
- **SG&A:** Marketing spend will continue to rise, but at a slower rate than sales growth, highlighting the leverage effect of increased sales. Central costs are under control and will also rise at a slower rate than sales growth.
- **Profitability:** In 1H'24, TRX hit a major milestone, turning profitable at both the EBIT and PBT level. Profitability will rise rapidly with sales rising faster than costs, helped by strong underlying markets. Addition of more production capacity in 2025 will further boost profitability.

Income statement

Year-end Dec ($m)	2020	2021	2022	2023	2024E	2025E
$:€	0.877	0.846	0.952	0.925	0.925	0.925
BioRinse	9.56	12.71	16.05	20.13	22.55	26.00
dCELL	4.25	4.25	5.30	6.18	8.41	10.10
GBM-V	2.66	2.79	3.13	3.18	3.45	3.60
Sales	**16.47**	**19.75**	**24.48**	**29.49**	**34.40**	**39.70**
COGS	-8.90	-11.27	-13.22	-15.45	-16.15	-18.28
Gross profit	7.57	8.48	11.26	14.04	18.26	21.43
Gross margin	46.0%	42.9%	46.0%	47.6%	53.1%	54.0%
SG&A	-12.96	-12.46	-13.02	-14.09	-16.77	-18.70
Share-based costs	0.04	-0.11	-0.25	-0.34	-0.30	-0.30
Other income	1.10	0.00	0.00	0.00	0.00	0.00
Underlying EBITDA	**-3.20**	**-3.00**	**-0.88**	**0.58**	**2.25**	**3.54**
Depreciation	-0.32	-0.37	-0.52	-0.53	-0.59	-0.61
Amortisation	-0.73	-0.73	-0.62	-0.45	-0.47	-0.50
Underlying EBIT	**-4.26**	**-4.10**	**-2.01**	**-0.39**	**1.19**	**2.43**
Exceptional items	-8.32	-0.36	0.00	0.00	0.00	0.00
Statutory EBIT	-12.58	-4.45	-2.01	-0.39	1.19	2.43
Net interest	-0.57	-0.69	-0.82	-1.28	-0.82	-1.09
Underlying pre-tax profit	**-4.82**	**-4.79**	**-2.83**	**-1.67**	**0.38**	**1.34**
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	0.38	1.34
Tax payable/credit	0.68	0.16	0.23	0.01	-0.50	-0.60
Underlying net income	**-4.14**	**-4.63**	**-2.60**	**-1.66**	**-0.12**	**0.74**
Statutory net income	-12.46	-4.99	-2.60	-1.66	-0.12	0.74
Ordinary 0.1p shares:						
Period-end (m)	70.3	70.3	70.3	70.6	71.4	71.5
Weighted average (m)	44.5	70.3	70.3	70.4	71.0	71.4
Fully diluted (m)	45.1	71.6	72.4	73.0	73.6	74.0
Underlying basic EPS (¢)	**-9.31**	**-6.58**	**-3.69**	**-2.35**	**-0.46**	**0.73**
Statutory basic EPS (¢)	-28.03	-7.09	-3.69	-2.35	-0.46	0.73
Underlying fully dil. EPS (¢)	-9.17	-6.47	-3.59	-2.27	-0.44	0.71
Statutory fully dil. EPS (¢)	-27.61	-6.97	-3.59	-2.27	-0.44	0.71
DPS (¢)	0.0	0.0	0.0	0.0	0.0	0.0

Source: Hardman & Co Life Sciences Research

Balance sheet

Conversion of the premises from a long-term lease to freehold has resulted in significant movements between financial leases (debt) and fixed assets, although the financial leases have effectively been replaced by a mortgage. The overall balance sheet changes are summarised in the table below.

Purchase of premises freehold

($m)	@31 Dec 2023	@30 Jun 2024	Δ
Property, plant and equipment	5.75	8.75	+3.01
Right-of-use assets	3.27	0.23	-3.04
Intangible assets	15.14	15.21	+0.07
Total long-term assets	**24.15**	**24.19**	**+0.04**
Long-term leases	3.23	0.14	+3.08
Short-term leases	0.18	0.08	+0.10
Long-term debt	5.53	9.70	-4.18
Bank overdraft	0.46	0.54	-0.09
Total financial liabilities	**9.40**	**10.47**	**-1.08**

Source: Hardman & Co Life Sciences Research

- **Inventories:** Inventories rose in 1H'24 because of the change in business mix caused by dynamic changes in the market. Production of some line extensions were undertaken in anticipation of regulatory approvals, which have taken longer than expected.

Balance sheet

@31 Dec ($m)	2020	2021	2022	2023	2024E	2025E
Shareholders' funds	38.27	33.39	30.40	29.36	29.38	30.13
Cumulated goodwill	0.00	0.00	0.00	0.00	0.00	0.00
Total equity	38.27	33.39	30.40	29.36	29.38	30.13
Share capital	15.95	15.95	15.95	15.95	15.95	15.95
Reserves	22.32	17.45	14.45	13.41	13.43	14.18
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	0.14	-0.08
Short-term leases	0.35	0.12	0.13	0.18	0.08	0.08
Long-term debt	3.79	4.47	5.26	5.53	9.70	9.20
Short-term loans	0.00	0.00	1.00	0.46	0.54	0.00
less: Cash	12.97	7.71	5.95	4.65	5.17	1.89
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**	**35.08**	**37.84**
Fixed assets	4.42	5.71	5.74	5.75	8.75	11.64
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	0.23	0.01
Goodwill	0.00	0.00	0.00	0.00	0.00	0.00
Inventories	9.60	9.72	10.88	10.36	11.48	11.92
Trade debtors	*2.42*	*2.95*	*4.20*	*3.03*	*3.93*	*4.54*
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*	*-2.39*	*-2.61*
Debtors less creditors	0.63	0.39	-0.31	-0.01	-0.51	-0.87
Invested capital	**33.28**	**34.27**	**34.58**	**34.50**	**35.08**	**37.84**
Net cash/(debt)	**5.75**	**-0.24**	**-3.66**	**-4.75**	**-5.30**	**-7.32**
Inventory days	168	179	154	131	116	108
Debtor days	54	50	53	45	37	39
Creditor days	54	63	83	55	41	52

Source: Hardman & Co Life Sciences Research

Cashflow

- **Operational cashflow:** Having become EBITDA-positive in 2023, TRX has built upon this in 1H'24 and also become profitable at both EBIT and PBT levels.
- **Working capital:** It should be noted that working capital outflows and certain local taxes mean that cash burn is front-loaded each year. This was seen again in 1H'24, and there was an additional impact from the rise in inventories ahead of anticipated regulatory approvals.
- **Tax:** TRX has used up all of its carry-forward losses in the US. Consequently, there is a tax liability/payment for profits generated on US operations. There are specific overseas offsets, notably R&D tax credits in the UK.
- **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. In 1H'24, $0.31m was capitalised.

Cashflow

Year-end Dec ($m)	2020	2021	2022	2023	2024E	2025E
Underlying EBIT	-4.26	-4.10	-2.01	-0.39	1.19	2.43
Depreciation	0.32	0.37	0.52	0.53	0.59	0.61
Amortisation	0.73	0.73	0.62	0.45	0.47	0.50
Share-based costs	-0.04	0.11	0.25	0.34	0.30	0.30
Inventories	*-4.12*	*-0.12*	*-1.16*	*0.52*	*-1.12*	*-0.44*
Receivables	*-0.26*	*-0.51*	*-0.70*	*1.07*	*-0.90*	*-0.61*
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	-0.82	-0.57
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	0.10	0.00
Company op. cashflow	**-8.01**	**-3.72**	**-1.44**	**0.75**	**1.83**	**3.27**
Net interest	-0.32	-0.39	-0.44	-0.90	-0.69	-0.85
Lease payments	-0.24	-0.40	-0.36	-0.42	-0.30	-0.34
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**	**0.49**	**1.48**
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	-0.50	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**	**-0.71**	**-2.02**
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**	**-0.71**	**-2.02**
Share repurchases	0.00	0.00	0.00	0.00	0.00	0.00
Equity issues	18.67	0.00	0.01	0.07	0.15	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**	**-0.56**	**-2.02**
Opening net cash/(debt)	0.12	5.75	-0.24	-3.66	-4.75	-5.30
Closing net cash/(debt)	**5.75**	**-0.24**	**-3.66**	**-4.74**	**-5.30**	**-7.32**
OCFPS (¢)	-17.27	-5.53	-2.91	-0.43	0.69	2.07

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 1H'24, the company achieved a significant milestone by becoming profitable overall, and this is expected to expand in the full-year and beyond. To get the company to where it is today, converting its technologies into commercially useful medical products and devices, TRX has invested ca.$123m plus the additional $30m cash consideration for the 2017 acquisition of CellRight. 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 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 166p 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 £42.8m/$56.9m, is currently being undervalued by the market, in our view:

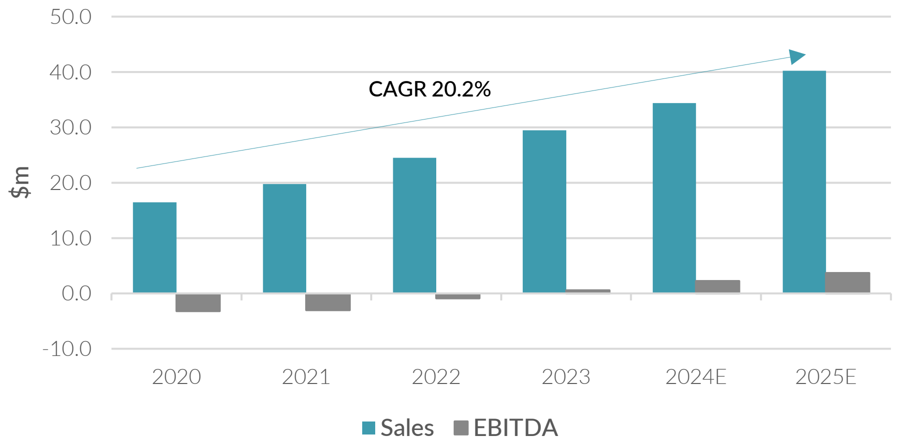
- To get TRX to where it is today, $153m/£117m – equivalent to 166p per share – has been invested into the company.
- The R&D investment by TRX to obtain marketing authorisations for a number of products, excluding all the investment made by CellRight, has been $33m/£25m.
- The marketing and administrative 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 ca.$120m/£91m.
- 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…

… and profitable overall in 1H'24

TRX has been EBITDA-positive since 2023 and became EBIT and PBT profitable in 1H'24. The leverage effect of an additional $1.0m of sales would translate into an extra ca.$0.5m (+42%) profit. It is generating sufficient cash from operations to undertake Phase 2 of its capacity expansion programme with the potential to add up to $50m to sales, bringing the total sales potential to $100m.

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 are expected to continue driving sales growth. The market has still not accepted that TRX is cash-generative and profitable. This should be reflected in upward momentum towards a market capitalisation of $159m/£120m, or 4x prospective 2025 sales, not expensive for a fast-growth, profitable, medtech.

Company matters

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Board of Directors

Board of Directors

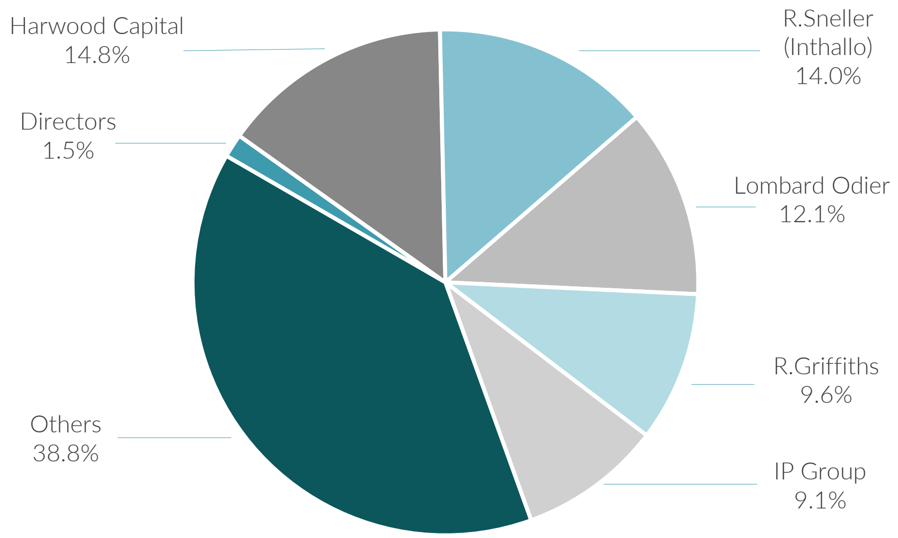
Position	Name	Remuneration	Audit
Chairman	Jonathan Glenn		M
Chief Executive Officer	Daniel Lee		
Chief Financial Officer	David Cocke		
Non-executive director	Shervanthi Homer-Vanniasinkam	M	
Non-executive director	Brian Phillips	M	C
Non-executive director	Trevor Phillips	C	M

M = member, C = chair
Source: Company reports

Share capital

On 20 September 2024, the company had 71,395,635 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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