27 September 2022

TISSUE REGENIX

Operating leverage

Tissue Regenix (TRX) is focused on the development and commercialisation of two proprietary processing technologies for the repair of soft tissue (dCELL) and bone (BioRinse). It has a broad portfolio of regenerative medicine products for the biosurgery, orthopaedics and dental markets. 1H'22 results provided further evidence of the benefits of TRX's strategic activities over the past two years, with the combination of sales growth and operating efficiencies driving the company rapidly towards EBITDA- and cashflow-breakeven. Additional efficiencies identified in San Antonio's capacity expansion give greater flexibility to the start of Phase 2.

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

- **Interim results:** 1H'22 results were marginally better than forecast, which benefited from the trading update provided in July. Underlying sales rose 27%, to \$11.84m (\$9.43m), and the EDITDA loss was reduced greatly, by 59%, to \$0.65m (\$1.61m). Gross cash at the period-end was \$6.17m.

- **Outlook:** Strong sales growth was seen in all three divisions, and is expected to continue through 2H'22. With increased operating efficiencies and close control of corporate costs, the sales growth is providing leverage towards profitability, and TRX is now expected to become EBITDA-positive during 4Q'22.

- **Risks:** To some degree, forecasts are dependent on the continued recovery in elective surgeries in the US – so we are mindful of a potential outbreak of winter COVID. Also, in the current economic climate, labour shortages within partners and healthcare institutions, and supply chain challenges, may constrain growth.

- **Investment summary:** TRX has a broad portfolio of innovative regenerative products that are in demand from surgeons. Completion of Phase 1 of its capacity expansion programme and reorganisation of the whole facility have led to operating efficiencies and comfort of supply to distribution partners. In our opinion, TRX is well-positioned to deliver persistently strong sales growth, which will drive margin expansion and highlight the low rating of the shares. An EV/sales multiple of 4x 2023E sales generates a valuation of \$122m/£110m.

Financial summary and valuation

Year-end Dec ($m)	2019	2020	2021	2022E	2023E	2024E
Sales	16.66	16.47	19.75	24.30	30.40	36.71
EBITDA	-8.17	-3.20	-3.00	-0.78	1.36	4.53
Underlying EBIT	-9.22	-4.26	-4.10	-1.98	0.06	2.37
Statutory EBIT	-9.24	-12.58	-4.45	-1.98	0.06	2.37
Underlying PBT	-9.68	-4.82	-4.79	-2.69	-0.63	1.74
Statutory PBT	-9.70	-13.15	-5.14	-2.69	-0.63	1.74
Underlying EPS (¢)	-0.78	-0.09	-0.07	-0.04	-0.01	0.02
Statutory EPS (¢)	-0.78	-0.28	-0.07	-0.04	-0.01	0.02
Net cash/(debt)	0.12	5.75	-0.24	-2.49	-3.10	-2.89
Equity issues	0.00	18.67	0.00	0.00	0.00	0.00
EV/sales (x)	2.4	2.4	2.0	1.6	1.3	1.1
EV/EBITDA (x)	-	-	-13.1	-50.5	28.9	8.7

Source: Hardman & Co Life Sciences Research

Pharmaceuticals & Biotechnology

Source: Refinitiv

Market data

EPIC/TKR	TRX
Price (p)	0.49
12m high (p)	0.73
12m low (p)	0.34
Shares (m)	7,036
Mkt cap (£m)	34.5
EV (£m)	36.7
Free float*	53%
Reporting currency	USD
Country of listing	UK
Market	AIM

**As defined by AIM Rule 26*

Description

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

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

Key shareholders

Directors	1.0%
Harwood Capital	16.1%
R. Griffiths	11.3%
Lombard Odier	10.2%
IP Group	9.6%
R.Sneller (Inhallo)	8.6%

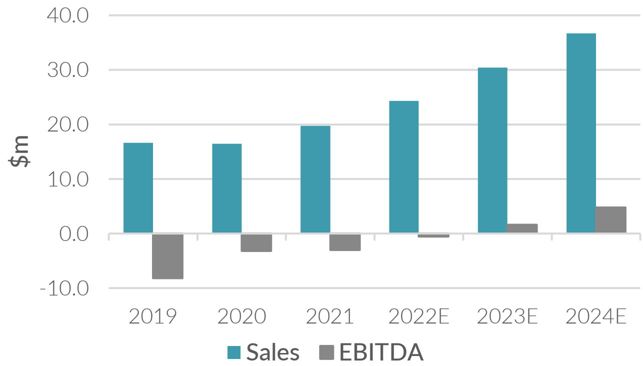
Diary

Mar'23	Final results

Analyst

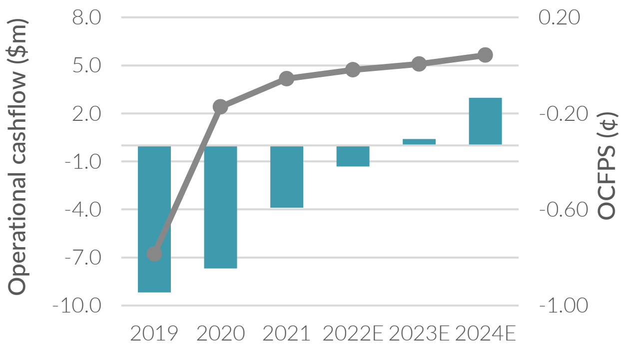
Martin Hall +44 (0)203 693 7075
mh@hardmanandco.com

Sales and EBITDA



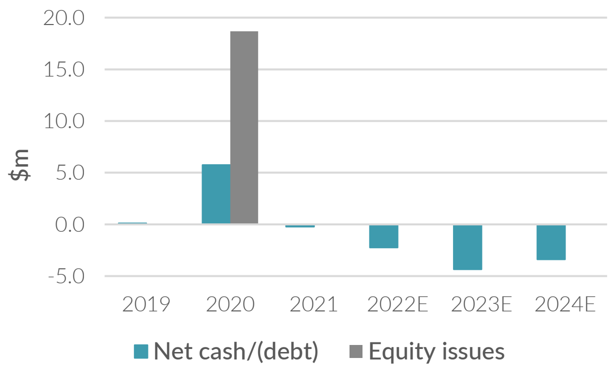
- Increased manufacturing capacity and strong demand from strategic distribution partners are driving BioRinse growth.
- dCELL product sales have benefited from reorganisation of the commercial sales team and management structure.
- Sales expansion has a leverage effect on margins, such that EBITDA and EBIT are trending towards profitability in 2022 and 2023, respectively.
- Forecasts have been prepared on a conservative basis, mindful of the potential effect of winter COVID on elective surgeries.

Operational cashflow and OCFPS (rhs)



- There has been a positive trend in the rate of cash burn over the past three years.
- Inventory levels appear stable, but with high sales growth, the trend in inventory days is in a downward direction.
- Reducing working capital needs is expected to have a positive effect on operational cashflow.
- The return of elective surgeries to pre-pandemic levels would have a leverage effect on cashflows, but is dependent on labour and supply chain challenges and winter COVID levels.

Net cash/(debt) and equity issues



- TRX has raised $134m/£103m from investors since inception, the latest being $18.7m/£14.6m gross capital in 2020 to invest in capacity expansion.
- Gross cash at 30 June 2022 was $6.2m, which is supported by a revolving credit facility of $5.0m.
- Conservative forecasts suggest that TRX has sufficient cash to reach cashflow-breakeven.
- This position would be improved significantly if there were to be a faster recovery in elective surgeries.

Source: Company data, Hardman & Co Life Sciences Research

Interim results summary

As a general comment, this is the third successive six-month period that this management team has delivered a great performance ahead of market expectations. With products in demand and strong commercial partners, in our opinion, the high rate of growth looks set to continue.

Operational and commercial features

34% increase in shipments to customers

- **Shipments:** Continuing the theme seen in 2H'21, product diversity has been beneficial to growth and minimised TRX's reliance on any single sector or strategic partner. Overall, unit product shipments in the US increased 34% in 1H'22.
- **Commercial:** TRX reorganised the dCELL commercial team to position it for a recovery in elective surgeries, which resulted in a return to sales growth.
- **Increased efficiencies:** Compared with expectations used to justify the capacity expansion programme, increased efficiencies in donor processing have raised the additional sales potential by 33%, to $40m, giving management more flexibility on the commencement of Phase 2 of the programme.

Financial features

- **Sales:** TRX had already provided the market with underlying sales growth of 27%, to $11.8m, in a recent trading update. However, while strong growth (32%) had been expected, solid growth (14%) in dCELL and exceptional recovery (+24%) in GBM-v were above forecasts, which augurs well for the future.
- **COGS:** Although the gross margin was broadly the same in 1H'22, at 45.8%, compared with 45.7% in 1H'21, it was well above the nadir (40.4%) reached in 2H'21. We believe this is due to manufacturing efficiencies from Phase 1 of the capacity expansion, coupled with price increases in 1Q'22 on the BioRinse range.
- **SG&A:** Benefits from reorganising the marketing team and good management of general costs were evident in the marked reduction in SG&A, from 68% of sales in 1H'21 to 56% of sales in 1H'22. This highlights the leverage effect of sales growth on the rapid trend towards profitability.

59% reduction in EBITDA loss

- **EBITDA:** Even including much higher share-based costs, there was a 59% reduction in EDITDA losses, at $0.65m ($1.61m). Excluding these costs, as TRX does, the reduction was even more marked, at 67%.
- **Net cash/(debt):** TRX ended the period with gross cash of $6.17m, but net debt of -$2.39m (including lease liabilities). Both these figures were better than our forecasts prior to the release of the July trading statement.

Interim results summary – actual vs. expectations

Half-year-end Jun ($m)	1H'21 actual	1H'22 actual	Change CER	1H'22 *forecast	Delta Δ
BioRinse	5.92	7.90	+33%	7.80	+0.10
dCELL	2.10	2.40	+14%	2.10	+0.30
GBM-V	1.42	1.50	+24%	1.40	+0.10
Group sales	**9.44**	**11.84**	**+27%**	**11.30**	**+0.50**
COGS	-5.12	-6.42	+25%	-6.44	+0.02
SG&A	-6.45	-6.60	-7%	-7.24	+0.64
Share-based costs	-0.02	-0.11	-	0.00	-0.11
Underlying EBITDA	-1.61	-0.65	+59%	-1.75	+1.10
Underlying EBIT	**-2.16**	**-1.29**	**+40%**	**-2.35**	**+1.06**
Gross cash	9.06	6.17	-	5.45	+0.72
Net cash/(debt)	**-0.24**	**-2.39**	**-**	**-3.42**	**+1.03**

**Prior to release of trading update on 19 July 2022*
Note: numbers may not add up exactly due to rounding
Source: Hardman & Co Life Sciences Research

Analysing the strong performance

Sales

All three segments contributed to strong underlying sales growth

TRX had already informed the market that underlying sales in 1H'22 had seen strong growth of 27% (+25% on a reported basis), to $11.84m. This was credited to a recovery in healthcare markets in the US to near pre-pandemic levels and the benefits being seen from the company's investment in capacity expansion. However, while the market had anticipated that most of this growth was likely ascribed to the BioRinse segment, continuing on from 2H'21, it had not anticipated the return to growth in both of TRX's other divisions, dCELL and GBM-v. We highlighted this in a recent report[1], *Strong 1H'22 sales suggest upside potential*, published on 19 July 2022, especially as it was against an exceptionally strong comparator in 1H'21, which was showing recovery from the very difficult trading environment seen during 2020. What we did not know in July was the leverage effect that such sales growth would have on profitability.

1H'22 sales performance

Half-year end-Jun ($m)	1H'21 actual	1H'22 actual	CER growth	1H'22 *forecast	Δ
BioRinse	5.92	7.83	+32%	7.80	+0.03
dCELL	2.10	2.41	+15%	2.10	+0.31
GBM-v	1.42	1.60	+24%	1.40	+0.20
Group sales	**9.44**	**11.84**	**+27%**	**11.30**	**+0.54**

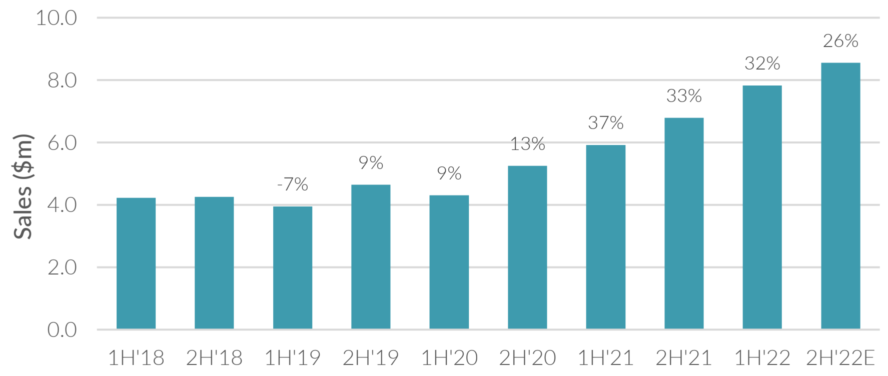
**Prior to release of trading update on 19 July 2022*
Source: Hardman & Co Life Sciences Research

BioRinse

Three consecutive six-month periods of >30% sales growth

The BioRinse segment continued its very strong upward trend, with sales rising 32% in 1H'22. Given the strong commercial relationships that have been developed over the past two to three years, plus demand for its diverse range of differentiated bone scaffold products, which are applicable to a number of specialities (foot/ankle, spine, dental, orthopaedics), the BioRinse segment was always expected to be the first to benefit from the capacity expansion programme. This has now resulted in three consecutive six-month periods where sales growth has been above 30%.

Half-yearly performance in BioRinse sales



Source: Hardman & Co Life Sciences Research

Distributors and strategic commercial partners clearly have confidence in the ability of TRX to deliver products in a timely manner, which is resulting in a consistent flow of orders, albeit there is variability in customer demands, meaning that TRX needs to remain flexible and proactive in responding to the needs of these customers.

[1] https://hardmanandco.com/research/corporate-research/strong-1h22-sales-suggest-upside-potential/

While the outlook remains positive, the healthcare sector is not immune to the challenges facing global markets in terms of labour shortages and supply chain issues. However, we remain confident that TRX is well-placed to assist partners in facing these challenges and to maintain strong growth. For the full year, we are forecasting sales growth of 29%; 2022 is benefiting from the single-digit price rises that were adopted from 2Q'22. This equates to 2H'22 growth also of 26%.

dCELL

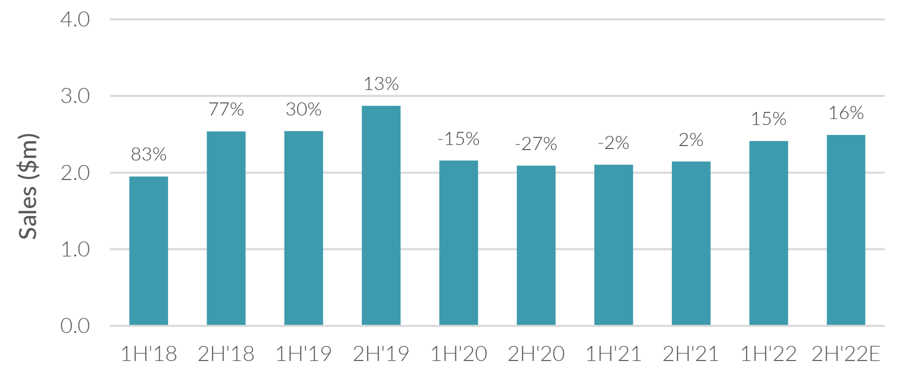
Evidence of some return towards normality of elective surgeries…

…contributing to 15% sales growth

The dCELL segment covers decellularised soft tissue products used in a number of specialities – wound care, hernia repair, urogynaecology and sports medicine. It is liked by surgeons because it is flexible, easy to handle and is readily accepted and incorporated into surrounding tissue. The trading statement in July alluded to the fact that there had been some more recovery in elective surgeries during 1H'22, which caused us to raise our growth rate estimate from a low-single-digit level to 14%. The actual outcome for dCELL sales was 15% growth.

The dCELL range is particularly dependent on elective surgeries. As part of a programme to position products for a recovery in sales, which were severely dented during the pandemic lockdown, management reorganised the commercial team and strategy during 1H'22, and sales growth has recovered, although it remains 16% below the level seen in 2H'19, showing that there is more upside potential.

Half-yearly performance in dCELL sales



Source: Hardman & Co Life Sciences Research

During the period, over 30 new distributors were hired and trained, and the previous three layers of management have been compressed to a single layer, allowing the flattened structure to get closer to customers and sales channel partners.

Strong contribution form sales to Arms Medical

Of note was the sales performance with strategic urogynaecology partner, Arms Medical, where stocking-up sales rose 21% from 1H'21.

In Europe, TRX is continuing to prepare for the reintroduction of OrthoPure XT, the only commercially available xenograft for sports medicine indications. The company has signed an exclusive licence with Geistlich Biomaterials Italia for the Italian market.

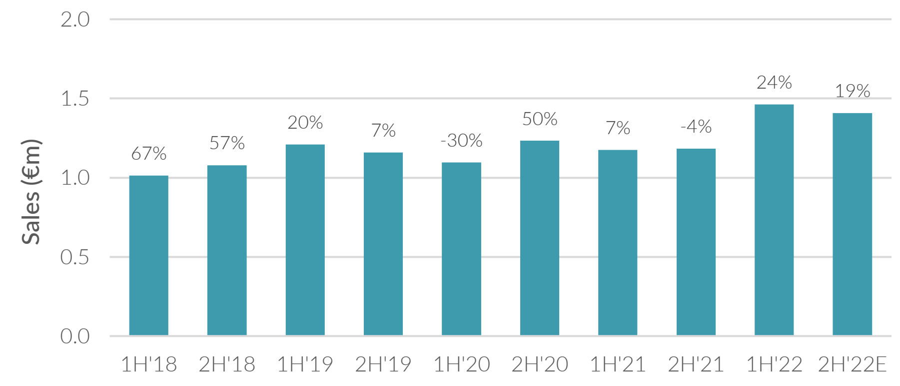
In our opinion, while mindful of the risk of winter COVID affecting elective surgeries, we have increased our sales growth rate for the dCELL segment for 2H'22 closer to the growth rate seen in 1H'22. This results in an increase in our sales forecast for dCELL for the full year, from $4.6m to $4.9m. There remains considerable upside potential when the level of elective surgeries recovers fully.

GBM-v

Unexpected recovery in underlying growth at GBM-v…

From the July trading statement, by default, we had established that there had been good recovery in sales from TRX's JV, GBM-v, in Germany. However, we still underestimated the strength of that recovery. Identification of additional sources of tissue resulted in robust underlying growth of 24%, to €2.9m, with forex hitting the reported number severely, to $1.6m (+13%).

Half-yearly performance in GBM-v sales



Source: Hardman & Co Life Sciences Research

…knocked back at reported level by weak EUR

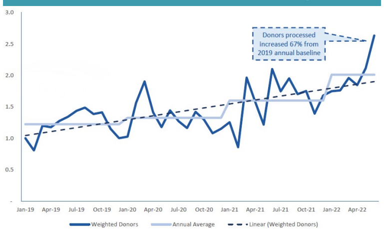
For the full year, we have increased the forecast growth rate to 19%, closer to the exceptional 24% sales growth seen in 1H'22. However, the recent further weakening of the EUR against the USD will reduce this to $2.9m on a reported basis, which is the same as previously forecast – i.e. much higher underlying growth than expected previously, reduced by much weaker currency on translation. However, all the costs will be lower, for the same reason.

Positive trends from the four "S" strategy

Our previous three reports on TRX have highlighted how, over the past two years, the new management team has continued to develop the commercial strategy, reorganising the operations to service more efficiently the underlying product demand, and investing in manufacturing capacity at its US facilities. A combination of these factors has contributed to the following, all of which have seen further progress during 1H'22:

- Built an even stronger relationship with tissue banks that are governed in the US by the National Organ Transplant Act (NOTA) to ensure adequate supplies of high-quality human tissue – such as bone, soft tissue and birth tissue.
- Built a strong product base with the addition of two new products – allograft (human-derived) and xenograft (animal-derived) – which preserve the inherent properties of tissue that has been processed gently to retain biological activity.
- Strengthened customer relationships, particularly with some of the leading global orthopaedic companies, and added more than 30 new distributors over the past nine months in the dCELL segment, following reorganisation of the commercial team.
- Greatly increased tissue processing activity – e.g. a doubling in BioRinse processing during the past 12 months, with the new capacity on stream.

Increased donor processing



Source: TRX presentation

All of these outcomes fit well with the management strategy to focus on the four "Ss", with the progress and objectives described in the following graphic.

Progress with the four "Ss"

	SUPPLY	SALES REVENUE	SUSTAINABILITY	SCALE
H1 2022 *Accomplishments*	• Phase One of expansion at San Antonio has created more capacity than originally anticipated • Created **revenue potential over c.33% more** than previously stated • Signed **two new donor supply contracts** for BioRinse®	• More agile than before, **executing projects twice as fast** in turn growing sales • Commercial reorganisation of dCELL® division has begun to show benefits with **renewed sales growth**	• **Adjusted EBITDA loss decreased 67%** to $0.5m (H1 2021 loss: $1.5m) • Increased capacity from Phase One expansion **allows Phase Two capital expenditure to be pushed out** • **Cash position supports current business plan**	• Identified and are in the process **of establishing a third-party logistics provider** to provide distribution services to the European Union and the UK
2022 & beyond *Future objectives*	• Construction of Phase 2 expansion has been pushed to 2025 as a result of the capacity created by Phase 1 • Phase 2 will include an additional ten clean rooms	• Continue double-digit growth, following the same trajectory as the Company's other USA business	• 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

Source: TRX presentation

TRX has been positioning itself to meet the demand for its products and to overcome the surgical backlog caused by the pandemic. The addition of new white-label and proprietary products, coupled with the increased processing and manufacturing capacity to service customer demand, has resulted in strong sales growth in the past 12 months. Sales growth of a similar order of magnitude (+25% underlying, +23% on reported basis) during 2H'22 can be reasonably expected, and, together with the leverage effect on profitability, this should see TRX become EBITDA-positive during 4Q'22.

Conclusion

Robust sales performances in 2H'21 and 1H'22 augur well for future

The robust sales performances reported for 2H'21 and 1H'22 augur well for the future. The better-than-expected performance at dCELL has had a modest knock-on effect on our full-year 2022 sales forecasts. The exceptional performance at GBM-v is being lost on translation, due to the weakening of the EUR against the USD. As seen in the 1H'22 numbers, even a small beneficial change in sales has a leverage effect towards profitability.

At this stage, we are continuing to adopt a conservative basis for our forecasts, mindful of the challenges associated with labour shortages, which are affecting the constraining elective surgeries and the potential winter COVID risk. Despite this approach, we believe that TRX is still on track to become EDITDA-positive in 4Q'22 and much closer to EBITDA-breakeven for the full year.

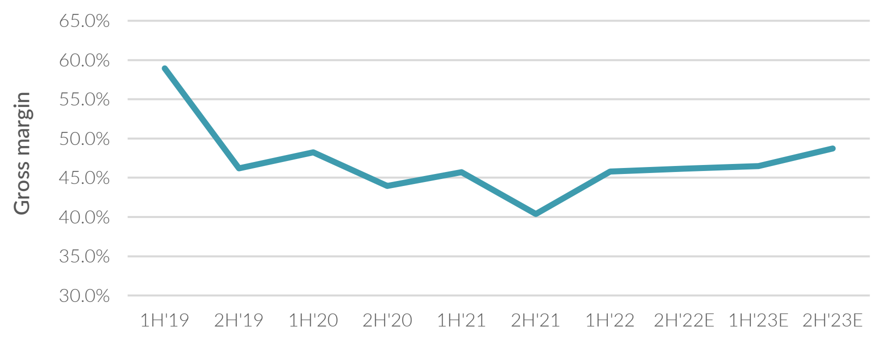
Cost analysis

Gross margin

From 2H'21 nadir, gross margins are on upward trend through more efficient tissue processing

From the pre-pandemic highs when there was strong demand for TRX's products, there has been a downward trend in the gross margin, reaching a nadir of 40.4% in 2H'21. However, the increase in donor processing, together with greater flexibility in manufacturing derived from the capacity expansion and reorganisation of San Antonio, are starting to reap benefits. These increased efficiencies, coupled with a price increase on the BioRinse range in 1Q'22, generated a rise in the gross margin in 1H'22, compared with 2H'21, to 45.8%, albeit that this is broadly the same as the level of 45.7% reached in 1H'21. As the benefits continue, we expect the gross margin to continue to rise.

Trend in gross margin



Source: Hardman & Co Life Sciences Research

Underlying SG&A

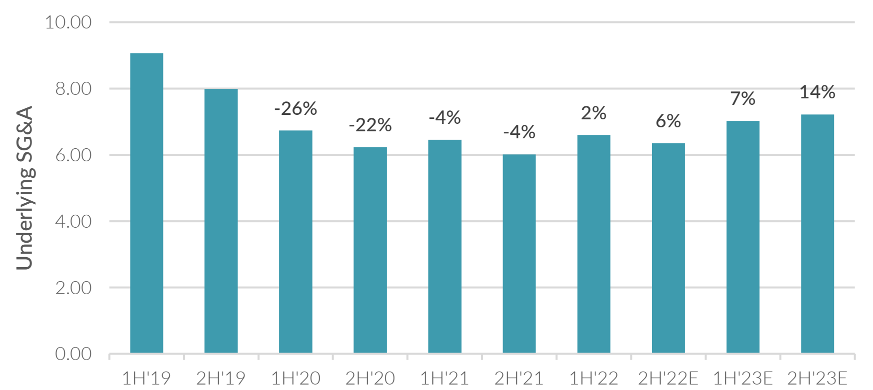
Absolute SG&A spend has been flattish for two and half years...

The absolute spend on underlying marketing and general administrative spend has remained fairly constant in each of the past five six-month trading periods, as can be seen in the following graphic. Given that sales have been rising over recent periods, the leverage of sales increases towards profitability is very clear.

...providing leverage effect to strong sales growth

In 2H'22, we are expecting this trend to continue. However, 2023 is a more difficult to forecast, given the current global economic situation. While management will continue to maintain tight cost control, it seems prudent to expect SG&A to rise ca.10% over the course of next year. However, this will still be well down on the absolute spend in 2019.

Trend in underlying SG&A



Source: Hardman & Co Life Sciences Research

Forecast summary

As a reminder, from 2021, TRX is reporting results in USD, as the vast majority of its business is derived in the US. Prior years have been restated to reflect this.

- **Sales:** Strong 1H'22 sales augur well for 2H'22. However, we remain mindful of the general economic environment affecting TRX's customers and healthcare providers to impact elective surgeries; so our forecasts remain conservative.
- **COGS:** The trend line suggests that the gross margin reached a nadir in 2H'21. The benefits of increased plant capacity and streamlining were evident in 1H'22 results, and we expect this to continue moving forward.
- **SG&A:** Although TRX continues to invest in marketing and commercial partnerships, the general administration costs are not expected to rise substantially – although we are keeping an eye on global inflation.
- **Gross cash:** The cash position at 30 June was $6.17m. Management maintains that this will be sufficient to support its current growth plans.

Financial summary

Year-end Dec ($m)	2019	2020	2021	2022E	2023E	2024E
GBP:EUR	0.893	0.877	0.846	0.960	0.960	0.960
Income statement						
Sales	**16.66**	**16.47**	**19.75**	**24.30**	**30.40**	**36.71**
COGS	-8.96	-8.90	-11.27	-13.13	-15.89	-19.19
SG&A	-17.05	-12.96	-12.46	-12.95	-14.25	-14.96
Share-based costs	0.15	0.04	-0.11	-0.20	-0.20	-0.20
Underlying EBIT	**-9.22**	**-4.26**	**-4.10**	**-1.98**	**0.06**	**2.37**
Exceptional items	-0.02	-8.32	-0.36	0.00	0.00	0.00
Statutory EBIT	-9.24	-12.58	-4.45	-1.98	0.06	2.37
Net interest	-0.46	-0.57	-0.69	-0.72	-0.69	-0.63
Underlying pre-tax profit	**-9.68**	**-4.82**	**-4.79**	**-2.69**	**-0.63**	**1.74**
Tax payable/credit	0.55	0.68	0.16	0.10	0.03	-0.09
Underlying net income	-9.12	-4.14	-4.63	-2.59	-0.60	1.65
Average no. shares (m)	1,171.9	4,447.7	7,033.1	7,036.3	7,037.3	7,038.3
Underlying basic EPS (¢)	**-0.78**	**-0.09**	**-0.07**	**-0.04**	**-0.01**	**0.02**
Statutory basic EPS (¢)	-0.78	-0.28	-0.07	-0.04	-0.01	0.02
Balance sheet (@31 Dec)						
Share capital	7.74	15.95	15.95	15.95	15.95	15.95
Reserves	24.75	22.32	17.45	14.85	14.25	15.90
Inventories	5.53	9.60	9.72	10.05	10.56	10.96
Working capital	0.61	0.63	0.39	-0.20	-0.67	0.37
Leases	0.00	3.43	3.48	3.27	2.96	1.79
Debt	3.02	3.79	4.47	4.47	4.47	4.47
less: Cash	3.14	12.97	7.71	5.24	4.32	3.36
Invested capital	**33.03**	**33.28**	**34.27**	**33.83**	**33.74**	**35.08**
Cashflow						
Underlying EBIT	-9.22	-4.26	-4.10	-1.98	0.06	2.37
Change in working capital	-2.35	-4.15	-0.47	-0.58	-0.52	-0.24
Tax paid/received	0.65	0.88	0.62	0.53	0.10	0.03
Operational cashflow	**-9.18**	**-7.68**	**-3.89**	**-1.55**	**0.14**	**2.71**
Capital expenditure	-0.44	-1.57	-1.55	-0.50	-0.75	-2.50
Acquisitions	0.00	0.00	0.00	0.00	0.00	0.00
Equity issues	0.00	18.67	0.00	0.00	0.00	0.00
Change in net debt	**-9.86**	**5.63**	**-5.99**	**-2.25**	**-0.61**	**0.21**
Opening net cash/(debt)	9.98	0.12	5.75	-0.24	-2.49	-3.10
Closing net cash/(debt)	**0.12**	**5.75**	**-0.24**	**-2.49**	**-3.10**	**-2.89**

Source: Hardman & Co Life Sciences Research

Company matters

Registration

Incorporated in the UK with company registration number 05969271.

UK operations:

Unit 3
Phoenix Court
Lotherton Way
Garforth
Leeds
LS25 2GYT

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

US operations:

1808 Universal City Boulevard
Universal City
San Antonio
Texas
78148

Board of Directors

Board of Directors

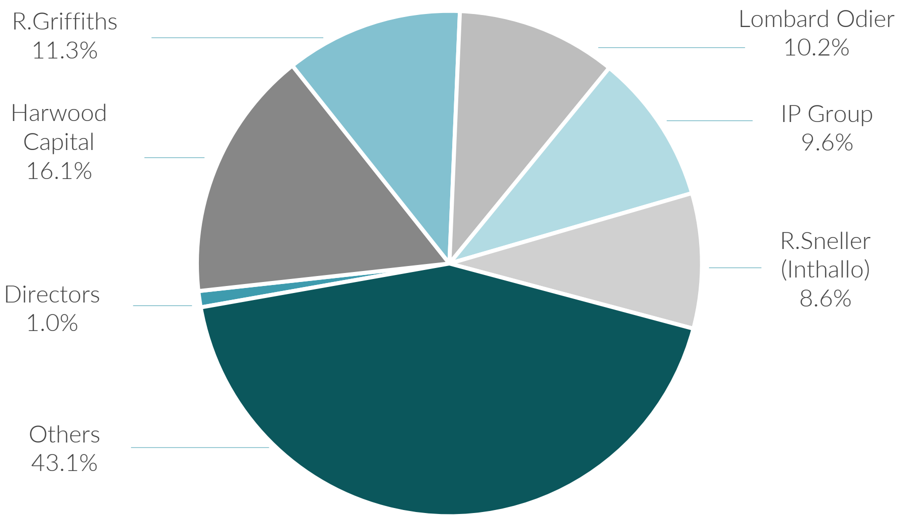
Position	Name	Remuneration	Audit
Chairman	Jonathan Glenn		M
Chief Executive Officer	Daniel Lee		
Chief Financial Officer	David Cocke		
Non-executive director	Shervanthi Homer-Vanniasinkam	M	
Non-executive director	Brian Phillips	M	C
Non-executive director	Trevor Phillips	C	M

M = member, C = chair
Source: Company reports

Share capital

On 12 September 2022, the company had 7,035,794,890 Ordinary shares of 0.1p in issue. There are also 171.89m options and 3.10m warrants outstanding.

Shareholders



Source: Company announcements, Hardman & Co Life Sciences Research

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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

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research@hardmanandco.com

1 Frederick's Place
London
EC2R 8AE

+44 (0)203 693 7075

www.hardmanandco.com