



Source: Eikon Thomson Reuters

Market data

EPIC/TKR	TRX
Price (p)	6.6
12m High (p)	12.2
12m Low (p)	5.5
Shares (m)	1,171.7
Mkt Cap (£m)	77.3
EV (£m)	69.5
Free Float*	27%
Market	AIM

*As defined by AIM Rule 26

Description

Tissue Regenix is a medical device company focused on regenerative medicine. Patented decellularisation technologies remove DNA, cells and other material from animal/human tissue and bone, leaving scaffolds that can be used to repair diseased or worn-out body parts. Its products have multiple applications.

Company information

CEO	Steve Couldwell
CFO	Gareth Jones
Chairman	John Samuel
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	www.tissuregenix.com

Key shareholders

Directors	4.3%
Invesco	29.0%
Woodford Inv. Mgt.	26.0%
IP Group	13.8%
Baillie Gifford	4.3%

Diary

1H'19	Finals
1H'19	Potential EU approval of OrthoPure XT

Analysts

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TISSUE REGENIX

Expanded GPO coverage secured

Tissue Regenix (TRX) has a broad portfolio of regenerative medicine products for the biosurgery, orthopaedics, dental and cardiac markets. It has two proprietary decellularisation technology platforms for the repair of soft tissue (dCELL) and bone (BioRinse). Following its acquisition of CellRight, management embarked on a revised commercial strategy to increase sales momentum, and it has recently secured expanded Group Purchasing Organisation (GPO) coverage in the US for DermaPure. TRX should benefit in 2019 from the US and European commercial agreements made with leading orthopaedic company, Arthrex, in 2018.

- **Strategy:** TRX is building an international regenerative medicine business with a product portfolio using proprietary dCELL and BioRinse technology platforms, underpinned by compelling clinical outcomes. It aims to expand its global distribution network, via strategic partnerships, to drive sales momentum.
- **Trading update:** In a market update, TRX announced that underlying sales growth in 2018 was just ahead of expectations, rising 47% to £11.6m (£7.9m), driven by the US performance of DermaPure. The year-end cash position, at £7.8m, was well ahead of our forecast, helped by efficient cash management.
- **EBIT upgrade:** To achieve the stated year-end cash position of £7.8m, £1.5m ahead of forecasts, TRX has managed to control operating costs or working capital. However, given that working capital was already tightly controlled, we have assumed that operating costs have reduced, and raised EBIT accordingly.
- **Risks:** TRX is exposed to many of the risks common to medical devices companies, including the regulatory hurdles particular to osteobiologics based on animal tissue, and the commercial risks of operating in a highly competitive market. A hybrid sales strategy, however, mitigates the latter.
- **Investment summary:** TRX has three value drivers: sales of BioSurgery products in the US; expansion of CellRight and TRX technologies into the orthopaedics/spine and dental markets; and preparation for the EU launch of OrthoPure XT in 2019.

Financial summary and valuation

Year-end Dec (£m)	*2016	**2016	2017	2018E	2019E	2020E
Sales	0.82	1.44	5.23	11.60	18.67	25.73
EBITDA	-9.86	-10.55	-8.98	-6.58	-1.58	2.55
Underlying EBIT	-10.11	-10.85	-9.69	-7.74	-2.76	1.34
Reported EBIT	-10.24	-11.06	-10.82	-8.74	-3.26	0.84
Underlying PBT	-9.89	-10.74	-9.64	-7.71	-2.75	1.35
Statutory PBT	-10.03	-10.95	-10.77	-8.71	-3.25	0.85
Underlying EPS (p)	-1.26	-1.28	-0.90	-0.59	-0.17	0.17
Statutory EPS (p)	-1.28	-1.30	-1.02	-0.68	-0.22	0.13
Net (debt)/cash	19.91	8.17	16.42	7.82	3.12	3.42
Capital increase	19.02	0.00	37.99	0.00	0.00	0.00
P/E (x)	-	-	-	-	-	-
EV/sales (x)	-	-	13.3	6.0	3.7	2.7

*Year to January. **11 months to December. Source: Hardman & Co Life Sciences Research

2018 trading update

- ▶ **Sales:** Underlying sales in 2018 were marginally ahead of forecasts, increasing by 47% to £11.6m vs. a revised *pro forma* figure of £7.7m for 2017, with growth across all areas of the business.
- ▶ **Biosurgery:** A key growth driver was the performance of DermaPure in the US, where sales rose 79% to \$4.5m/£3.4m from \$2.5m/£1.9m.
- ▶ **Net cash:** The period-end cash position was £1.5m ahead of expectations, at £7.8m, which was due to efficient operating cost control and/or working capital.
- ▶ **Arthrex:** Following early success with the Arthrex distribution agreement in the US, TRX announced an extension of this partnership in November 2018 to cover Europe, which should benefit 2019.

Sales – actual vs. forecasts					
Year-end Dec (£m)	2017 actual	2018 actual	Growth (CER)	2018 forecast	Delta Δ
Biosurgery	1.9	3.4	79%	3.1	+0.3
Orthopaedics/dental	*4.9	6.4	31%	6.6	-0.2
GBM-V	1.1	1.8	58%	1.8	0.0
Group sales	7.9	11.6	47%	11.5	+0.1

*pro-forma. Source: Hardman & Co Life Sciences Research

Changes to forecasts

In order to achieve the £7.8m period-end cash position stated in the trading update, which was £1.5m ahead of our forecast, TRX must have reduced its operating costs below expectations, improved working capital, or a combination of the two. However, given that the company had already tightened working capital following the acquisition of CellRight, we believe that the driver must have been improved operating costs, a stated strategy of management.

Management has been focused on the use of distribution partners, a successful sales technique of CellRight. We believe that this has limited the rise in SG&A costs for 2018 to 7% (previous forecast +20%), compared with 2017, which only reflected CellRight costs for five months. This is equivalent to a 10% reduction compared with our old forecast. As shown in the following table, this drops through the P&L and cashflow statements and was probably accompanied by a small reduction in working capital and/or capital expenditure to make up the balance.

Changes to forecasts				
Year-end Dec (£m)	----- 2018E -----		Change (%)	Delta Δ
	Old	New		
SG&A	-11.5	-10.3	+10%	+1.2
EBITDA	-7.9	-6.6		+1.3
Underlying EBIT	-9.0	-7.7	+14%	+1.3
Underlying PTP	-9.0	-7.7		+1.3
Statutory PTP	-10.0	-8.7		+1.3
Underlying EPS (p)	-0.7	-0.6	+15%	+0.1
Net cash/(debt)	6.3	7.8	+24%	+1.5

Source: Hardman & Co Life Sciences Research

Post-period: additional DermaPure coverage

This April, TRX has successfully secured approval with an undisclosed GPO for additional coverage in the US. This increases significantly the commercial opportunity for DermaPure, which is now potentially available to 95% of institutions that purchase via large GPOs.

Financial summary

- ▶ **Gross margin:** Margins are trending upwards over the forecast period. On the one hand, underlying costs will increase due to a full-year inclusion of CellRight. Countering this, DermaPure margins are on a rising trend.
- ▶ **EBIT:** The EBIT loss is now forecast to decrease further in 2018 than previously anticipated, despite CellRight costs being included for a full 12 months. We will review forecasts again when the impact of the Arthrex deals become clearer; current forecasts suggest that EBIT will turn positive from 2020.
- ▶ **Operating cashflow:** Forecasts suggest that cashflow is upwards, in line with management's aim to reach cashflow breakeven by 2020.
- ▶ **Future funding:** Forecasts simply show the effect of the cashflow statement on the cash position. At the end of fiscal 2019E, there appears to be a reasonable net cash position. If there is good sales traction, management may take on some debt to fund the working capital requirements. If progress is very rapid, additional capital for investment in manufacturing capacity will be needed.

Summary financials						
Year-end Dec (£m)	*2016	**2016	2017	2018E	2019E	2020E
Profit & Loss						
Sales	0.82	1.44	5.23	11.60	18.67	25.73
COGS	-0.15	-0.73	-2.63	-5.09	-7.63	-10.37
SG&A	-7.09	-8.44	-9.61	-10.25	-10.30	-10.71
R&D	-3.68	-3.13	-2.69	-4.00	-3.50	-3.30
Other income	0.00	0.00	0.00	0.00	0.00	0.00
Underlying EBIT	-10.11	-10.85	-9.69	-7.74	-2.76	1.34
Share-based costs	-0.14	-0.21	-0.03	-0.50	-0.50	-0.50
Exceptional items	0.00	0.00	-1.10	-0.50	0.00	0.00
Statutory EBIT	-10.24	-11.06	-10.82	-8.74	-3.26	0.84
Net interest	0.21	0.11	0.05	0.02	0.01	0.01
Underlying pre-tax profit	-9.89	-10.74	-9.64	-7.71	-2.75	1.35
Tax payable/credit	0.53	1.03	1.35	0.80	0.70	0.66
Underlying net income	-9.37	-9.71	-8.29	-6.91	-2.05	2.01
Average no. shares (m)	743.2	760.1	920.5	1,171.2	1,172.2	1,173.2
Underlying basic EPS (p)	-1.26	-1.28	-0.90	-0.59	-0.17	0.17
Underlying fully-dil. EPS (p)	-1.28	-1.30	-1.02	-0.68	-0.22	0.13
Balance sheet (@31 Dec)						
Share capital	3.80	3.80	5.86	5.86	5.86	5.87
Reserves	17.44	7.74	33.67	25.75	23.20	24.70
Capitalised R&D	7.45	9.24	10.21	10.45	11.59	11.92
less: cash & deposits	19.91	8.17	16.42	7.82	3.12	3.42
Invested capital	8.78	12.60	34.76	35.07	38.35	39.90
Cashflow						
Underlying EBIT	-10.11	-10.85	-9.69	-7.74	-2.76	1.34
Change in working capital	0.24	-0.58	-1.25	-0.74	-1.82	-2.07
Tax paid/received	0.75	0.32	1.54	1.35	0.80	0.50
Operational cashflow	-8.67	-10.70	-9.74	-6.45	-2.59	0.99
Capital expenditure	-0.71	-0.49	-0.13	-0.30	-0.30	-0.36
Acquisitions	0.00	0.00	-19.95	-1.46	-1.46	0.00
Capital increase	19.02	0.00	37.99	0.00	0.00	0.00
Change in net cash/(debt)	9.65	-11.74	8.25	-8.61	-4.70	0.30
Opening net cash/(debt)	10.26	19.91	8.17	16.42	7.82	3.12
Closing net cash/(debt)	19.91	8.17	16.42	7.82	3.12	3.42

* Year to January. ** 11 months to December.
Source: Hardman & Co Life Sciences Research

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