**Market data**

EPIC/TKR	TRX
Price (p)	6.8
12m High (p)	12.2
12m Low (p)	6.5
Shares (m)	1,171.7
Mkt Cap (£m)	79.1
EV (£m)	66.9
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/COO	Gareth Jones
Executive Chairman	John Samuel
	+44 330 430 3052
	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

1Q'19	2018 full-year results
	Potential approval
1H'19	OrthoPureXT

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TISSUE REGENIX

2018 in review: foundations laid for osteobiologics

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). With organic growth being boosted by the acquisition of CellRight Technologies, 2017 was a dynamic year for TRX. As part of the integration, management embarked upon a revised commercial strategy to increase sales momentum and market penetration in 2018. Having already signed an agreement with Arthrex for the US, TRX has now entered a distribution agreement with Arthrex in Europe.

Strategy: To build an international regenerative medicine business with a portfolio of products using proprietary dCELL and BioRinse technology platforms, underpinned by compelling clinical outcomes. TRX is looking to expand its global distribution network, via strategic partnerships, to drive sales momentum.

HTA licence: A key goal of the CellRight integration process was to obtain a Human Tissue Authority licence to enable importation of CellRight's products into the UK (and, over time, into Europe). This was received in June 2018, allowing TRX to identify global distribution partners for its osteobiologic products.

Arthrex: Having Arthrex, Inc. (Arthrex) as its US and EU distribution partner is a significant achievement for TRX. Being a privately-owned company, little financial information about Arthrex is publicly available, and as such, it may not be on investors' radars. It has the biggest share of the Sports Medicine market, at ~33%¹.

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. The latter is, however, mitigated by the use of a hybrid sales strategy.

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 OrthoPure XT launch in the EU in 2019. Expansion of its commercial opportunities through established partners is expected to hasten the time to reach a cash-neutral position, now estimated in fiscal 2020.

Financial summary and valuation

Year-end Dec (£000)	*2016	**2016	2017	2018E	2019E	2020E
Sales	0.82	1.44	5.23	11.48	18.96	25.90
EBITDA	-9.86	-10.55	-8.98	-7.92	-2.56	1.54
Underlying EBIT	-10.11	-10.85	-9.69	-9.08	-3.73	0.33
Reported EBIT	-10.24	-11.06	-10.82	-10.08	-4.23	-0.17
Underlying PBT	-9.89	-10.74	-9.64	-9.06	-3.72	0.33
Statutory PBT	-10.03	-10.95	-10.77	-10.06	-4.22	-0.17
Underlying EPS (p)	-1.26	-1.28	-0.90	-0.71	-0.26	0.08
Statutory EPS (p)	-1.28	-1.30	-1.02	-0.79	-0.30	0.04
Net (debt)/cash	19.91	8.17	16.42	6.29	0.58	-0.05
Capital increase	19.02	0.00	37.99	0.00	0.00	0.00
P/E (x)	-	-	-	-	-	-
EV/sales (x)	-	-	12.8	5.8	3.5	2.6

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

Foundations laid for osteobiologics

Operational progress in 2018

During 2018, TRX has made steady and sustained progress towards commercialisation of its soft tissue and osteobiologic products. Acquisition of the BioRinse bone decellularisation technology platform was a key motivation behind TRX's purchase of CellRight in August 2017. Integration of the two businesses has resulted in several synergies that are expanding the growth prospects of the combined entity. Management has two key goals:

- ▶ to broaden and maximise TRX's product offering; and
- ▶ to expand the offering geographically.

TRX's technologies

BIORINSE™

dCELL™

Source: Tissue Regenix

Until the acquisition of CellRight, TRX's strategy had been to commercialise its products through a hybrid model of direct sales reps and distributors. However, CellRight's model was successfully based on a network of Original Equipment Manufacturer (OEM) partners and distributors, so management has adopted a blend of these two models with the aim to sell more products through strategic partners, both OEM and distributors, on a global basis.

In this report, we review the progress that TRX has made towards these goals in 2018, highlighting in particular its success in signing a second distribution agreement with Arthrex, a leader in the osteobiologics field. The table below acts as a reminder of the company's product offering.

Reminder: products and technology

TRX's product portfolio			
Product	Tissue source	Technology	Commercialisation stage
DermaPure	Human dermis	dCELL	Launched in 2014, sales in US
CardioPure HV	Human heart valves	dCELL	EU approval expected 2020
SurgiPure XD	Porcine dermis	dCELL	Launched in 2018, first sales in US
OrthoPure XT	Porcine tendon	dCELL	Submitted for EU approval in 2018
BioRinse portfolio	Human bone	BioRinse	Launched in US and selected export markets

Source: Hardman & Co Life Sciences Research

2018 in review: sustained operational progress

Since the CellRight acquisition in August 2017, TRX has already made significant and sustained progress in advancing the geographical availability of its expanded product offering.

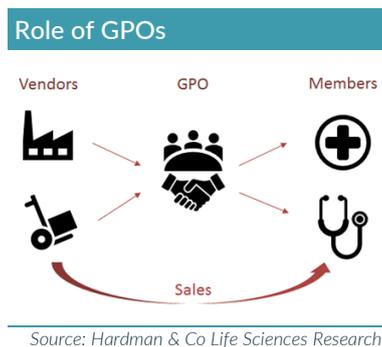
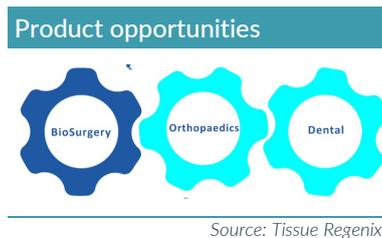
Month-by-month progress in 2018

2018	Event	Progress
January	Launch of DentalFix...	...the first BioRinse product to be launched by TRX
February	Launched BioSurgery Operating Division...	...with DermaPure its flagship product
February	ARMS Medical distribution agreement...	...accelerating DermaPure urogynaecology sales in the US
March	Arthrex US distribution agreement...	... accelerating CellRight product sales in the US
April	Tech transfer of DermaPure manufacturing to CellRight...	...increasing manufacturing capabilities ahead of schedule
May	Extended GPO agreement with Premier Inc...	...maintaining access to US in-patient population for DermaPure
June	Human Tissue Authority License for BioRinse products...	...green light for import into UK
June	Pennine Healthcare distribution agreement in UK...	...accelerating penetration of the orthopaedic spine market
November	Arthrex European distribution agreement...	... accelerating CellRight product sales across Europe

Source: Hardman & Co Life Sciences Research

Tissue regenix

Aiming to sell more products through strategic partners on a more widespread basis



Second manufacturing shift introduced in US..

...in response to increased demand for DermaPure

Strategic distribution partnerships – US

TRX is looking at more ways to maximise the opportunities for the enlarged group by broadening its product offering and through geographical expansion. To this end, management has signed two US distribution deals, with:

- ▶ ARMS Medical for urology and gynaecology;
- ▶ Arthrex in orthopaedics.

DermaPure is being used in a broadening range of indications. The expanding opportunity in urology and gynaecology led to TRX signing an exclusive agreement with the specialist uro-gyn distributor, ARMS Medical, in February 2018 to maximise the opportunity. As a multi-year agreement, hospitals and surgeons throughout the US will have access to DermaPure for use in urology and gynaecology procedures, allowing TRX's direct sales force to maintain their focus on the Wound, Plastics, Orthopaedics and General Surgery markets.

Subsequently, in March TRX signed a long-term, multi-year agreement with Arthrex for the supply and distribution of CellRight's osteobiologic products, under the OEM label Allosync, into the US sports medicine market. Arthrex is interested in repairs to all types of bone but is increasingly focusing on orthobiologics – CellRight's products for spine, foot and ankle procedures fit well within Arthrex's long-term vision. We discuss Arthrex in detail in the next section.

Group Purchasing Organisation (GPO) agreement

TRX initially focused on increasing the number of US states where DermaPure was eligible for Medicare reimbursement to maximise access in out-patient settings. This achieved, TRX has since been building relationships with GPOs in order to reach in-patients via GPO partnerships, essential for maximising the opportunity in surgical settings. In 2018, GPO agreements were strengthened further with an additional three-year contract with Premier, Inc (Premier). Key is DermaPure's health economic advantages, which were recognised by TRX receiving the 'Supplier Horizon Award' at Premier's Breakthrough conference in June 2018.

HTA licence and strategic distribution partnership - UK

TRX was successful in achieving a Human Tissue Authority (HTA) licence in June 2018, which allows it to import the BioRinse products into the UK. Over time, this will allow distribution throughout the EU. In order to commercialise these products in the UK, TRX also signed a distribution agreement with Pennine Healthcare, a specialist orthopaedic distributor based in the UK, for sales into the spine market in particular.

Manufacturing capacity

Several big steps in the successful integration of CellRight with TRX have been completed ahead of schedule, including transfer of DermaPure manufacturing from a third-party to the CellRight facility in Texas, where TRX's human-derived products are manufactured (the Group's porcine-based products are manufactured in Leeds). This gives TRX full control of the end-to-end manufacturing process and facilitates manufacture of additional products in the portfolio. Process enhancements have been achieved that have increased the shelf-life of DermaPure from two to three years.

Complementing this, TRX has introduced a second manufacturing shift in the US, adding additional capacity for global distribution. This will come into effect from January – our current sales forecasts are based on the manufacturing capacity that can be achieved with the two-shift manufacturing schedule. Should demand for DermaPure continues to rise, further investment in manufacturing may become necessary.

Multiple clinical programmes

A variety of clinical programmes are underway for both the soft-tissue portfolio and the osteobiologic products. These include pre-approval studies to support regulatory authorisation and real-world studies to collect data on the ongoing clinical and health economic improvements incurred through application of TRX's products. The programmes underway include:

- ▶ **OrthoPure XT:** analysis of the data from a two-year study is ongoing, ready for submission to TRX's Notified Body, BSI, to aid the case for CE mark accreditation. This will allow launches in the UK and, subsequently, more widely in Europe, which are expected to initiate in H1'19.
- ▶ **DermaPure in uro/gyn:** a protocol is being designed for an investigator-led study in 45 patients across three sites, with up to three years of follow up. This study will be grant funded.
- ▶ **DermaPure prospective observational study:** in planning stage awaiting final input from the Contract Research Organisation (CRO); the study involves 100 patients across four sites.
- ▶ **Cardiac:** A study of 90 paediatric patients across three centres has successfully completed. The data are being analysed ahead of submission of the results to a peer-reviewed journal.
- ▶ **DermaPure in tendon:** A protocol is being designed for a study investigating the clinical and health outcome benefits of DermaPure in tendon wrap procedures – those in which the product is placed around or over the injured tendon to accelerate the healing process.

DermaPure clinical data

New case series presented at conference

As part of the clinical validation process with respect to the use of DermaPure, case series data from six patients have been collected and were presented at the 45th annual VEITH symposium by a leading orthopaedic trauma surgeon, David Naar, in collaboration with the Cleveland Clinic in the US. The results demonstrated the substantial clinical and cost benefits associated with the use of DermaPure in acute and chronic wounds. In comparison with other options, its use was:

- ▶ more cost effective;
- ▶ prompted faster healing; and
- ▶ improved quality of life.

Patients with a range of advanced, hard to treat wounds, such as necrotising fasciitis and venous leg ulcers, were treated with DermaPure and reassessed over a number of weeks. The surface area of the wounds was measured at the outset and followed until they closed. There was a mean 65% reduction in wound size at six weeks following an average of one DermaPure application per patient. Of note, one patient had encountered a wound duration of over 10 years and had previously failed multiple graft options.

Case study

TRX and clinicians are building a strong portfolio of individual case studies demonstrating impressive patient outcomes with DermaPure. The following photographs of one such patient show the complete healing effect of DermaPure on a basal cell carcinoma excision within only five weeks.

- ▶ **Basal cell carcinoma excision (lips):** The wound was completely closed in five weeks post DermaPure application.

Clinical outcome in basal cell carcinoma



Week 0



Week 5

Source: Tissue Regenix

Being selected to present these findings at the largest vascular, endovascular, venous and wound meeting in the world is a big endorsement of DermaPure. These cases support findings from previous case studies that have shown DermaPure to successfully close chronic hard-to-heal wounds.

Distribution deals with Arthrex

In March 2018, TRX signed a multi-year distribution agreement with the orthopaedics specialist, Arthrex, for the supply and distribution of CellRight's osteobiologic products. As part of this agreement, three products were taken under the Arthrex original equipment manufacturer (OEM) brand 'Allosync' in order to increase US surgeons' access to osteobiologic products for orthopaedic, spine, and foot and ankle procedures. In 1H'18, early stocking orders from Arthrex (subsequently replenished) helped TRX to report 29% *pro forma* sales growth from its orthopaedics business unit – excellent validation of the commercialisation strategy.

TRX's relationship with Arthrex now extends to both US and Europe

Given this success, in November 2018 TRX expanded its relationship with Arthrex to include pan-European distribution. The new agreement allows Arthrex to distribute TRX's BioRinse bone portfolio throughout Europe, initially focusing on the UK, which complements TRX's existing distribution partnership with Pennine Healthcare.

Awareness of advantages of osteobiologics increasing...

Osteobiologics market potential

Orthobiologics are naturally-occurring substances that are important in the normal healing process following injury. When applied by surgeons in high concentrations, they are thought to speed up the healing process – of, for example, broken bones, injured muscles, and damaged ligaments, and to reduce the time needed for convalescence. Osteobiologics are engineered materials that act in the same way – the increasing awareness of their advantages, generated through the publication of case studies and improved clinical outcomes, is helping to drive demand for these products. The advent of innovative technologies is accelerating their use and market growth.

...but determination of market size difficult

Determination of the actual size of the osteobiologics market is difficult.

- ▶ First, it is dominated by some of the large Medtech companies, such as Zimmer Biomet, Stryker, and Medtronic, most of whom have gained market share through the acquisition of smaller specialist companies that had developed the new technologies.
- ▶ Secondly, the osteobiologic businesses are a relatively small component within these big companies, and, consequently, segmented sales data are not provided.
- ▶ Thirdly, some players remain privately-owned, e.g. Arthrex, which limits publicly available financial information.

Arthrex is ranked global #1 with an estimated 33% share of the sports medicine market...

Hardman & Co estimates that the global market for the entire range of orthopaedic products was valued at \$37.7bn in 2017, with minimal (0.4%) growth over 2016. Within this market, we believe that Arthrex was a major player, being ranked world #6 company, with ca.6% market share. However, about 40% of the market is dominated by products for large bone repair – replacement hips and knees – areas where Arthrex has no activity. In contrast, most of Arthrex's sales are in the specialist field of sports medicine, where it is ranked world #1 with around 33% of the market in 2017¹.

...and is also a leading player in the orthobiologics segment which offers growth opportunities

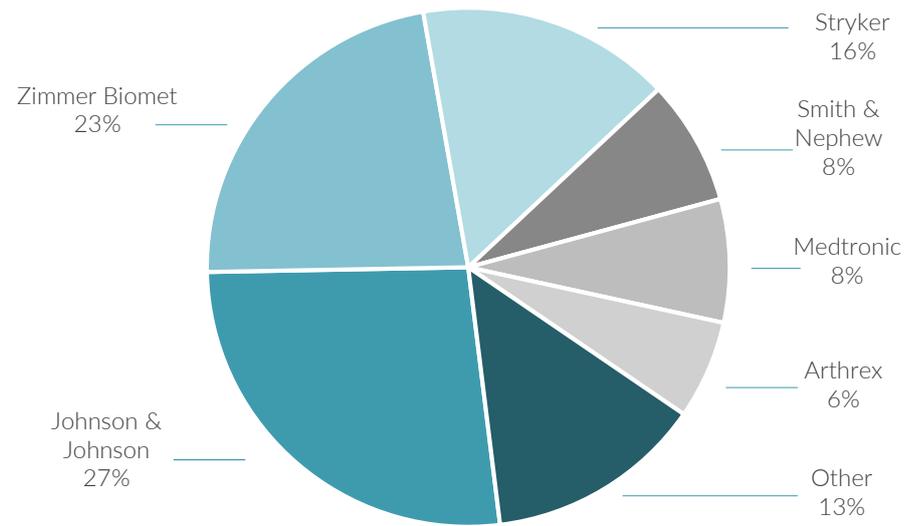
In addition, within the global orthopaedics market, we estimate the osteobiologics segment to have generated \$1.4bn-\$1.6bn of sales in 2017. Interestingly, although this is considered to be a growth segment, the rate of growth in 2017 was surprisingly low, at ca.2.5%.

1. Smith & Nephew, 2017 Annual Report

Hardman & Co estimates that the European osteobiologics market was worth around \$400m/€350m in 2017

Given that the adoption of such products is greater in the US compared with international/European markets, and assuming a current sales split of 75%:25%, we estimate that the European osteobiologics market in 2017 was worth approximately \$400m/€350m. As more products become available in Europe, for example through this distribution agreement between TRX and Arthrex, it is likely that this part of the market will grow at a faster rate than in the US in the near term.

Global orthopaedics market – 2017



Source: Hardman & Co Life Sciences Research

Arthrex is an ideal distribution partner for TRX

About Arthrex

Arthrex is a pioneer in the field of arthroscopy and sports medicine that fosters its innovative spirit to develop more than 1,000 products and procedures each year. In particular, it is a global leader in osteobiologics and arthroplasty, and although Arthrex develops most of its innovative products internally, it is not averse to buying/licensing in new technologies and products to fulfil areas of surgeon need. Therefore, TRX’s novel technology platforms fit very well with Arthrex’s global strategy.

Arthrex has an excellent reputation for both developing innovative products and commercialising them, and, in the process, helping surgeons to generate superior patient outcomes. This innovation has led Arthrex to experience a period of unprecedented demand for its products, as well as sales growth in recent years.

Being a private company, however, Arthrex’s financial information is less readily available. As a result, Arthrex’s leading position in the orthopaedics market (world #6) and, particularly, its strength in the osteobiologics market, is generally underappreciated.

With its headquarters in Florida, US and with important global divisions in Germany (Munich) and Singapore, which act as distribution hubs for Europe and SE Asia, respectively, Arthrex is uniquely positioned to deliver outstanding sales growth in ex-US markets, which we believe to be the biggest drivers of the osteobiologics market in the near to medium term. As such, Arthrex is an ideal partner for TRX in commercialising the BioRinse portfolio in the UK, and subsequently in Europe more widely, in sports medicine.

Arthrex – global operations



Source: Arthrex Inc

*Arthrex has a global distribution network,
is a leading player in global orthopaedics,
and is ranked global #1 in regenerative
sports medicine*

Conclusion

In order for TRX to enact its strategy of broadening and maximising its product offering, and to expand its offering geographically, the company needs to engage with distribution partners. Arthrex is an ideal choice for two reasons. First, it is a leading player in the global orthopaedics market with an established and strong sales network. Second, within this large market, Arthrex has a particular strength in the sub-segments of sports medicine and osteobiologics. The partnership will create the opportunity for the two companies to grow together.

Financial forecasts

- ▶ **Sales:** Forecasts are being driven by all business units, including the US, the GBM-V tissue bank in Europe, and Orthopaedics in the US and the UK from 2019.
- ▶ **Gross margin:** There will be volatility over the forecast period. On the one hand, underlying costs will initially rise because of CellRight and GBM-V, but, countering this, DermaPure margins are on a rising trend.
- ▶ **EBIT:** We forecast the EBIT loss to decrease slightly in FY'18 despite CellRight costs being included for a full 12 months in 2018. We will review forecasts once the impact of the Arthrex deal becomes clearer; current forecasts suggest that EBIT will turn positive from 2020.
- ▶ **Operating cashflow:** Forecasts suggest that operational cashflow trends towards neutral in the forecast period, 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 modest 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	11.48	18.96	25.90
COGS	-0.15	-0.73	-2.63	-5.01	-7.61	-10.22
SG&A	-7.09	-8.44	-9.61	-11.55	-11.58	-12.05
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	-9.08	-3.73	0.33
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	-10.08	-4.23	-0.17
Net interest	0.21	0.11	0.05	0.02	0.01	0.00
Underlying pre-tax profit	-9.89	-10.74	-9.64	-9.06	-3.72	0.33
Tax payable/credit	0.53	1.03	1.35	0.80	0.70	0.66
Underlying net income	-9.37	-9.71	-8.29	-8.26	-3.02	0.99
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	-0.71	-0.26	0.08
Underlying fully-dil. EPS (p)	-1.28	-1.30	-1.02	-0.79	-0.30	0.04
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	24.41	20.88	21.37
Capitalised R&D	7.45	9.24	10.21	10.45	11.59	11.92
less: Cash & deposits	19.91	8.17	16.42	6.29	0.58	-0.05
Invested capital	8.78	12.60	34.76	35.25	38.58	40.04
Cashflow						
Underlying EBIT	-10.11	-10.85	-9.69	-9.08	-3.73	0.33
Change in working capital	0.24	-0.58	-1.25	-0.22	-1.66	-1.74
Operational cashflow	-9.63	-11.13	-11.33	-8.64	-4.22	-0.20
Capital expenditure	-0.71	-0.49	-0.13	-0.50	-0.50	-0.60
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	-10.13	-5.71	-0.63
Opening net cash/(debt)	10.26	19.91	8.17	16.42	6.29	0.58
Closing net cash/(debt)	19.91	8.17	16.42	6.29	0.58	-0.05

* Year to January. **11 months to December.

Source: Hardman & Co Life Sciences Research

Notes

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