

**Market data**

EPIC/TKR	TRX
Price (p)	18.0
12m High (p)	22.5
12m Low (p)	15.0
Shares (m)	760.1
Mkt Cap (£m)	136.8
EV (£m)	123.3
Free Float*	34%
Market	AIM

*As defined by AIM Rule 26

Description

TRX is a medical device company in regenerative medicine. Its patented dCELL technology removes DNA, cells & other material from animal/human tissue leaving an acellular tissue scaffold, not rejected by the body, which can then be used to repair diseased or worn out body parts. Its products have multiple applications.

Company information

CEO	Antony Odell
CFO	Paul Devlin
Chairman	John Samuel
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	www.tissueregenix.com

Key shareholders

Directors	6.9%
Invesco	27.8%
Woodford IM	18.3%
Techtran Group	13.6%
Baillie Gifford	7.0%

Diary

9 Dec 2016	Hardman report
1H-17	CE Mark OrthoPure XT
May-17	Finals

Analysts

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Tissue Regenix**Addressing woundcare in the US**

TRX has a broad portfolio of regenerative medicine products developed from decellularised human and porcine tissues for the wound care, orthopaedics, and cardiac markets. Sales of DermaPure have continued to gain traction in the US following launch in 2014 – growth in 1H 2016 was +128%. Since launch, the focus has been on expanding Medicare coverage, but recent news has been about increasing access into both in- and out-patient populations through GPOs and the Veterans Association. This further strengthens DermaPure's commercial position, in line with the company's strategy, and underpins our forecasts for fiscal 2017.

- **Strategy:** To build a regenerative medicine business with a portfolio of products using the dCELL platform, underpinned by compelling clinical and economic outcomes designed to drive higher adoption rates, whilst retaining the strategic and corporate flexibility that the three therapeutic corporate entities provide.
- **Patient coverage:** Over the last 12 months, TRX has been increasing steadily the number of US states where DermaPure is eligible for Medicare reimbursement: it is covered in 47 states, representing 93% of traditional Medicare out-patient beneficiaries. Now, DermaPure is also reaching in-patients via GPO contracts.
- **US Federal Supply Schedule:** Recently, DermaPure has been added to the US Department of Veteran Affairs Federal Supply Schedule (FSS), via the Veteran's Health Medical Supply with whom it has a distribution agreement. Veterans comprise a large segment of the wound care market – ca.25% have diabetes – and the FSS covers almost nine million people.
- **Innovative Technology Contract:** Availability of DermaPure has also been enhanced through the award of an Innovation Technology contract from Vizient, the largest member-owned healthcare company in the US. Such awards are reserved for new technologies that are proven to improve clinical outcomes.
- **Conclusion:** Recent news has all been positive for DermaPure. The last 12 months has been characterised by maximising availability of the product in the US market, initially targeting Medicare coverage, which now stands at 93%. Latterly, further expansion to in- and out-patient populations has been accompanied by technology awards. DermaPure enters fiscal 2017 on a very strong footing.

Financial summary and valuation

Fiscal year (£000)	*2014	*2015	*2016	+2016E	++2017E	++2018E
Sales	6	100	816	1,300	5,567	13,124
R&D	-3,356	-3,296	-3,676	-5,270	-8,000	-8,000
Underlying EBIT	-6,483	-8,189	-10,106	-11,540	-13,940	-9,184
Reported EBIT	-6,577	-8,369	-10,242	-11,815	-14,236	-9,500
Underlying PBP	-6,209	-8,021	-9,893	-11,418	-13,866	-9,129
Statutory PBT	-6,303	-8,201	-10,029	-11,694	-14,162	-9,445
Underlying EPS (p)	-0.9	-1.2	-1.3	-1.45	-1.7	-1.0
Statutory EPS (p)	-0.9	-1.2	-1.3	-1.48	-1.7	-1.1
Net cash/(debt)	18,483	10,257	19,907	7,600	11,942	1,682
Capital increases	8	5	19,019	0	20,000	0
P/E (x)	-	-	-	-	-	-
EV/sales (x)	-	-	-	-	23.1	9.8

*Year to January; + 11-months to December (current); ++Year to December

Source: Hardman & Co Life Sciences Research

DermaPure: US market access grows

Wound care



Source: Tissue Regenix

DermaPure HD is TRX’s most commercially advanced wound care product, the other being SurgiPure XD, but launch of the latter is ‘on hold’ to allow all the marketing investment to be concentrated on DermaPure. DermaPure is a human allograft product made from human dermis using TRX’s proprietary dCELL technology platform. Its target market is advanced care of acute and chronic wounds, such as the severe hard-to-heal ulcers that occur in diabetic patients.

The company is, at present, totally focused on selling DermaPure in the US, where the reimbursement environment is favourable for medical devices in comparison to Europe. The US market for advanced wound care is estimated to be \$3.2bn, and is growing, in part, due to the increasing prevalence of obesity.

Market strategy

Tissue Regenix has an advocacy and adoption strategy. With a hybrid sales model, DermaPure is reaching end-users via direct sales and also distributors covering three regions of the country (east, west, central). It is certified for reimbursement for out-patient use in Medicare and Medicaid beneficiaries, and is currently accessible to 93% of all Medicare patients. There is now only one jurisdiction outstanding. Concomitantly, sales of DermaPure have increased steadily since launch in 2014 as additional distributors have been appointed and contracts approved.

Group Purchasing Organisations (GPOs)

TRX is also engaging with GPOs, which are central to providing access to integrated healthcare systems (IHS) in the US. GPOs negotiate contracts and pricing with vendors (manufacturers or distributors) on behalf of their member organisations (hospitals, nursing homes, community clinics, etc).

TRX contracts with GPOs will provide access to the large in-patient market, particularly essential for advanced wound care products for surgical use, resulting in accelerated sales growth and simplification of the US sales process. TRX is targeting GPOs with the greatest coverage: the first contract was achieved in July 2016 and the second in December 2016 with Premier Inc, the GPO ranked number two by number of hospital beds covered¹.



Source: Hardman & Co Life Sciences Research

Top 8 GPOs by hospital beds			
Rank	GPO	US hospitals covered	# Beds
1	Vizient	>3,300	>575k
2	Premier Inc	3,750	>350k
3	Intalere	3,734	>273k
4	Cardinal Health	70%	>212k
5	McKesson Pharmaceutical		>197k
6	AmerisourceBergen		>182k
7	HealthTrust Purchasing Group	1,600	>168k
8	Department of Veterans Affairs	152	>39k

Source: Definitive Healthcare; Hardman and Co Life Sciences Research

¹ Definitive Healthcare: <http://www.definitivehc.com/top-10-lists/top-10-gpos-by-member-hospital-beds>

The company’s news this year to date has been dominated by announcement of further GPO contracts.

The FSS services the largest integrated healthcare system in the US

Federal Supply Schedule

The company announced in February that DermaPure is now included on the United States Department of Veteran Affairs (VA) Federal Supply Schedule (FSS) as a result of the FSS’ distribution agreement with Veteran’s Health Medical Supply (VHMS). In addition to its 800 community outpatient clinics, the VA is ranked 8th by hospital beds and the FSS services the largest IHS in the US, covering around nine million people, many of whom are veterans. Wound care is extremely important in this patient group: it is estimated that 25% of veterans have diabetes compared to 9% in the general population. VHMS is a veteran-owned small business that distributes and assists with the sales of medical supplies and equipment to US government agencies; it’s contract with the FSS was approved in 2014.

Technology awards

DermaPure secured its aforementioned GPO contract with Premier under a ‘Breakthrough Technology Agreement’ following an extensive four-step review process which concluded that the product offers unique attributes compared to other treatment options. This important milestone increased penetration of the in-patient market, and independently advocated dCELL technology.

DermaPure ‘offers...incremental benefit over other products’

Increasing access to the in-patient market even further, DermaPure was awarded an Innovative Technology Contract by Vizient, Inc., the largest member-owned health care company in the US. These contracts are awarded to technologies that either enhance clinical care for patients, or that improve care delivery and business models. DermaPure was recommended for the award by a panel of hospital representatives with expertise in wound care on the basis that it:

*‘offers unique and incremental benefit over other products on the market’
Vizient, Inc. Director of Procurement*

Vizient was given a ‘World’s Most Ethical Company’ designation in 2016 by Ethisphere Institute – a strong foundation for its relationship with member organisations, who are not-for-profits that seek to deliver cost-effective care.

Conclusion

Over the last six months, TRX has made a number of announcements that individually represent small, but significant, increments to the accessible number of patients for DermaPure. When viewed together, DermaPure is accessible now to both in-patient and out-patient populations, through the well-supported Veterans Association with its relatively high population of diabetics, and to 93% of eligible Medicare patients. This means that DermaPure enters calendar/fiscal 2017 on a very strong footing, which we expect to be reflected in the company’s financial results.

DermaPure access summary			
Patient type	Group	Beds	Lives
Out-patients	Medicare	-	55.3m
In-patients	GPOs (e.g. Premier, Vizient)	>1.0m	
Mixed	Veteran Affairs	>39k	9.0m
Diabetics	Total in US		ca.30.0m
	Aged over 65 years		ca.12.0m

Source: Multiple sources compiled by Hardman and Co Life Sciences Research

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