

Source: Eikon Thomson Reuters

Market data

EPIC/TKR	TRX
Price (p)	11.5
12m High (p)	22.0
12m Low (p)	10.5
Shares (m) ⁺	1,161.1
Mkt Cap (£m)	133.5
EV (£m)	115.9
Free Float*	27%
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 – that can 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
	+44 330 430 3052
	www.tissueregenix.com

Key shareholders

Directors	4.9%
Invesco	29.0%
Woodford Inv. Mgmt.	25.0%
IP Group	13.9%

Diary

9 August	AIM Admission
September	Interims

Analysts

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Tissue Regenix

CellRight: Transforming US growth prospects

TRX has a broad portfolio of regenerative medicine products developed from decellularised human and porcine soft tissues for the wound care, orthopaedics, and cardiac markets. Since launch of DermaPure, the focus has been on increasing penetration of the US woundcare market to access both in- and out-patient populations, via GPOs and Medicare, respectively. To accelerate growth in the US, TRX has announced the acquisition of CellRight Technologies, which has a synergistic regenerative technology based on bone. To fund the acquisition and provide more working capital, the company has raised £40m (gross) of new capital.

- **Strategy:** To build a regenerative medicine business with a portfolio of products using the proprietary dCELL platform, underpinned by compelling clinical and economic outcomes to drive higher adoption rates, whilst retaining the strategic and corporate flexibility that the three therapeutic corporate entities provide.
- **CellRight:** TRX has announced the acquisition of CellRight Technologies in San Antonio, Texas, for \$30m/£23m, providing immediate and greater exposure to the US orthopaedic market. TRX is paying 4.4x and 12.5x prospective sales and EBITDA, respectively, for a business that has been trading profitably since 2014.
- **Capital increase:** Concomitantly, TRX has raised £40m of gross new funds via an institutional Placing and directors' Subscription @10p per share in order to make the acquisition and to fund its working capital requirements for the next 15 months.
- **FY 2016 results:** TRX has changed its accounting reference date from January to December to be in line with its international MedTech peers. Recent results were the first since the change, covering the 11 months to end-Dec'16. Sales were driven by DermaPure in the US, which grew an estimated +79% *pro forma*.
- **Investment summary:** TRX is building commercial momentum through three clear value drivers: sales of DermaPure in US; regulatory submission of OrthoPure XT in EU; and agreement of a joint venture for commercialisation of woundcare and cardiac products in Europe. *Pro forma* comparisons with and without CellRight, and likely reported numbers including CellRight, are provided.

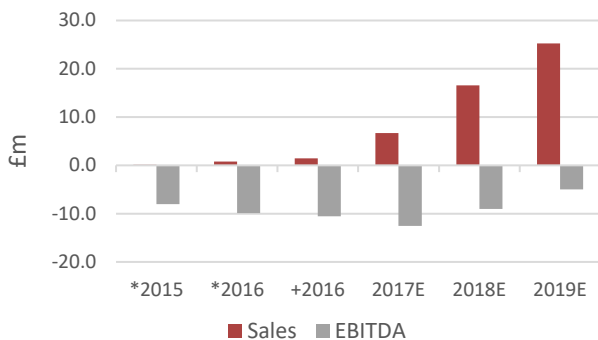
Financial summary and valuation

Fiscal year (£000)	*2015	*2016	+2016	**2017E	**2018E	**2019E
Sales	100	816	1,443	6,710	16,594	25,267
EBITDA	-8,038	-9,861	-10,549	-12,535	-9,000	-4,962
Underlying EBIT	-8,189	-10,106	-10,850	-12,948	-9,480	-5,457
Reported EBIT	-8,369	-10,242	-11,060	-13,198	-9,750	-5,747
Underlying PTP	-8,021	-9,893	-10,736	-12,875	-9,415	-5,418
Statutory PTP	-8,201	-10,029	-10,946	-13,125	-9,685	-5,708
Underlying EPS (p)	-1.2	-1.3	-1.3	-1.3	-0.7	-0.4
Statutory EPS (p)	-1.2	-1.3	-1.3	-1.3	-0.7	-0.4
Net (debt)/cash	10,257	19,907	8,173	8,591	9,752	3,593
Shares issued	5	19,019	0	35,500	12,000	0
P/E (x)	-	-	-	-	-	-
EV/sales (x)	-	-	-	17.3	7.0	4.6

*Year to January; +11-months to December; **12-months to December

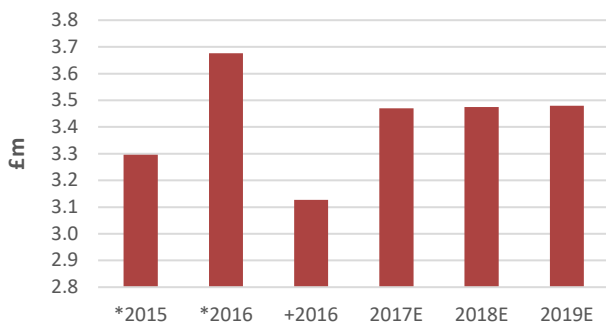
Source: Hardman & Co Life Sciences Research.

Sales and EBITDA



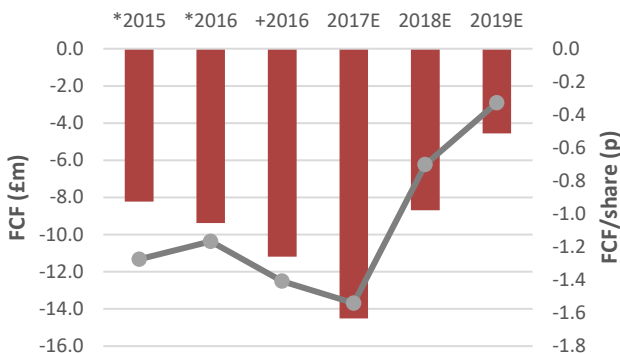
- ▶ Sales grew a reported 77% to £1.4m driven by DermaPure sales in the US and by the first GBM-V sales in Europe
- ▶ *Pro forma* sales growth of DermaPure in the US was estimated at +79% to \$2.0m (\$1.2m)
- ▶ Total sales of £6.7m are projected in 2017 due to increased US market penetration and consolidation of GBM-V sales, plus inclusion of CellRight from completion (8th August)
- ▶ EBITDA losses are expected to become larger in 2017, primarily due to considerable investment in maximising penetration of products to the market

R&D investment



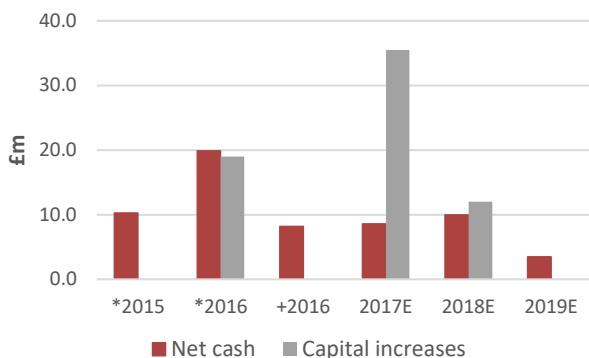
- ▶ R&D spend was -£3.1m (11 months) or -£3.4m (*pro forma*) in fiscal 2016, much lower than anticipated, due, in part, to about 15% of R&D investment being capitalised
- ▶ Capitalisation of some R&D spend on approved products is likely to continue going forward
- ▶ A total of -£12-13m R&D investment is expected over the next three years, largely on US trials of OrthoPure products

Free cashflow



- ▶ Free cashflow was -£11.2m in the 11-month period, which included modest capital expenditure
- ▶ Given that TRX continues to invest in commercialising all three segments of the business, there will be cash outflow for the forecast period
- ▶ Cashflow starts to improve significantly once sales rise to a level >£20m in 2019
- ▶ Cashflows improve following the acquisition of CellRight

Net cash & Capital increases

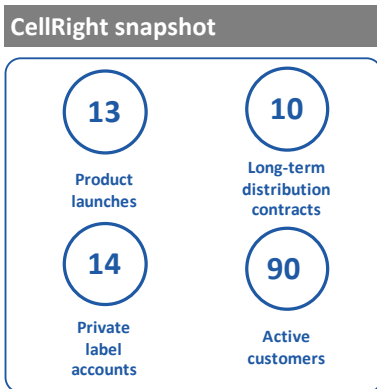


- ▶ Net cash was £8.2m on 31st December 2016, better than forecast by around +£0.7m
- ▶ Forecasts have been adjusted for the £40m cash raise to fund the CellRight acquisition and working capital needs
- ▶ With average monthly cash burn of around £1m, forecasts are assuming a further fundraise during 2H 2018
- ▶ Deferred CellRight consideration (2 x \$2.04m) affects the cash position in each of 2018 and 2019

*Year to January; *11-months to December; Source: Company data & Hardman & Co Life Sciences Research

Acquisition of CellRight Technologies

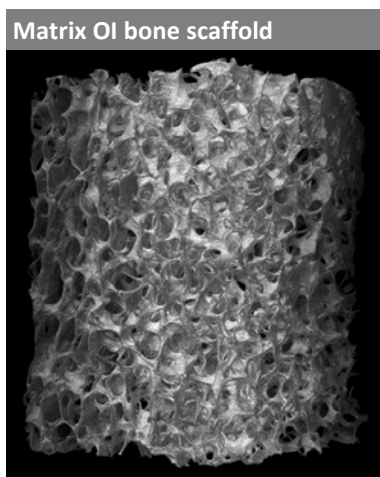
CellRight Technologies, Texas, acquired for \$30m...



Source: CellRight Technologies; Tissue Regenix

...bringing complementary tissue processing technology...

...for bone-based regenerative devices...



Source: CellRight Technologies; Tissue Regenix

...plus state-of-the-art, 13,650 sq.ft facilities

In May 2017, Tissue Regenix announced that it had engaged in discussions with the founders of CellRight Technologies Inc., regarding a combination of the two businesses. These discussions came to fruition, with TRX announcing on 20th July 2017 the conditional acquisition of CellRight for up to \$30.0m payable in cash, which was completed on 8th August following shareholder approval.

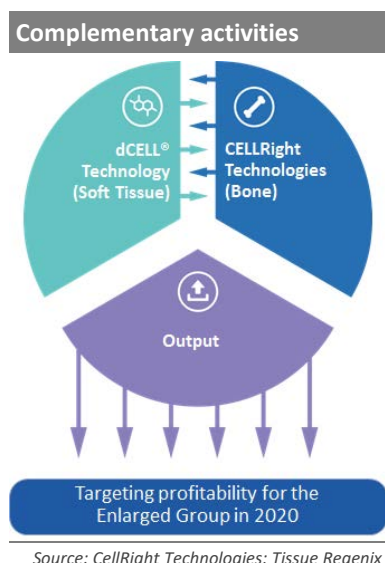
Our assessment of CellRight suggests that its strategy, expertise, and technology platform are aligned to those of TRX. CellRight is a five-year-old regenerative medicine business focused on human tissue (allograft) products, which are based on proprietary bone processing technology for use in spinal, dental and sports medicine applications. As such, it is highly complementary to the business of TRX, which is based on a similar technology, but for human and porcine soft tissues instead of bone. In its relatively short history, CellRight has successfully commercialised a number of products and the enlarged entity is expected to reduce the time and funds needed for TRX to become a fully established and profitable business in the US.

Key features

- ▶ **Synergistic technology:** CellRight’s proprietary processing technology sterilises bone without removing osteoinductive (bone forming) capacity – similar to TRX’s soft tissue dCELL process
- ▶ **Staff know-how:** CellRight is one of the industry leaders in osteoinductive matrices that preserve the natural bone growth factors: Bone Morphogenic Proteins (BNP) and Growth Factors (GF) – TRX would gain valuable expertise
- ▶ **Broader product offering:** CellRight currently markets 13 products, which would complement TRX’s proprietary products in woundcare, orthopaedic, and sports medicine markets, possibly permitting cross-selling via distributor sales. A further two product launches are expected in 2017
- ▶ **Deeper market penetration:** CellRight Technologies already sells bone scaffold-based products to the US woundcare and orthopaedic markets – TRX is likely to benefit from CellRight’s existing customer networks
- ▶ **Tissue sourcing:** CellRight’s existing relationships with tissue banks will increase the speed with which TRX can transfer manufacturing of its human tissue products
- ▶ **Regulatory progress:** CellRight is FDA¹ and AATB² accredited; all donor tissue is tested before processing and all products are processed to regulatory standards before release, a process that could be applied to DermaPure products, and to OrthoPure HT, to accelerate its route to market
- ▶ **Facilities:** CellRight Technologies owns state-of-the-art freehold facilities of 13,650 sq.ft in San Antonio, Texas together with adjacent land. There is scope to move TRX’s existing staff into the CellRight facility and close its existing San Antonio site, and to provide TRX with significant tissue processing capacity
- ▶ **Overseas:** Some CellRight products are currently available in the Middle East, South America, and South Korea; TRX sees this as an opportunity to open up further commercial channels. In addition, TRX can open up the European market for CellRight products through its GBM-V joint venture in Germany

¹ US Food & Drug Administration

² American Association of Tissue Banks



Source: CellRight Technologies; Tissue Regenix

Aim for the combined entity to reach profitability by 2020

CellRight already sells 13 products...

...in orthopaedics, spine, and general surgery



Source: CellRight Technologies; Tissue Regenix

Rationale

CellRight has been known to TRX for some years. The management teams had discussions when TRX was looking for a partner to manufacture DermaPure for the US market. Although this did not work out at the time (2012) because CellRight was in its infancy, TRX management did note the interesting technology platform of CellRight, and the relationship has been maintained over its formative years.

One notable aspect of CellRight’s technology is its similarity to dCELL technology – preservation of as many natural properties of the target organ and/or tissue as possible. However, while TRX is focused on soft tissues, CellRight is applying this to donor bone tissue, forming a scaffold that retains the five key, natural, bone growth factors and morphogenic proteins, promoting active regeneration. As such, with products targeting spine, orthopaedic, dental and general surgery, this is complementary to TRX’s orthopaedics offering, which is due to launch in the US in 2018 with OrthoPure HT.

During its short history, CellRight has successfully commercialised a number of products through distribution and private label agreements. In contrast, TRX has developed a direct salesforce for a number of targeted US hospital accounts and uses distribution partners elsewhere. Also, TRX has established a number of national contracts in the US which have the potential to benefit CellRight. There is therefore a mutual distribution benefit, with a strengthened network composed of direct and indirect relationships through which products can be commercialised. The aim is to gain sales traction and generate profitability at a faster rate, aiming for fiscal 2020.

Products

CellRight has launched 13 products since 2012 that address a multitude of clinical procedures in orthopaedics, spine and general surgery (including dentistry). Each of its products has distinctive characteristics and properties, allowing the surgeon to select the one most appropriate to a particular clinical problem. This also provides the opportunity for a number of line extensions for alternative clinical uses. Launch of new products is expected over the remaining part of 2017.

Key CellRight products					
Product	Launch	Description	O	S	GS
Matrix OI	2013	Compressible stem cell containment matrix derived from 100% allograft bone	✓	✓	✓
Matrix OI FlexIT	2013	Thin pliable osteoinductive verified cortical sheet that has the ability to be sized with scissors or a scalpel	✓		✓
MatrixCollect 100 Crunch	2015	DBM putty derived from 100 per cent. allograft bone treatment of surgically created osseous defects resulting from traumatic injury	✓	✓	✓
ConCelltrate 100	2015	Can be hydrated with saline, blood, Bone Marrow Aspirate (BMA), Platelet Rich Plasma (PRP), or other cellular components	✓	✓	✓
Matrix IQ Dermis	2014	Human derived dermal grafts	✓		✓

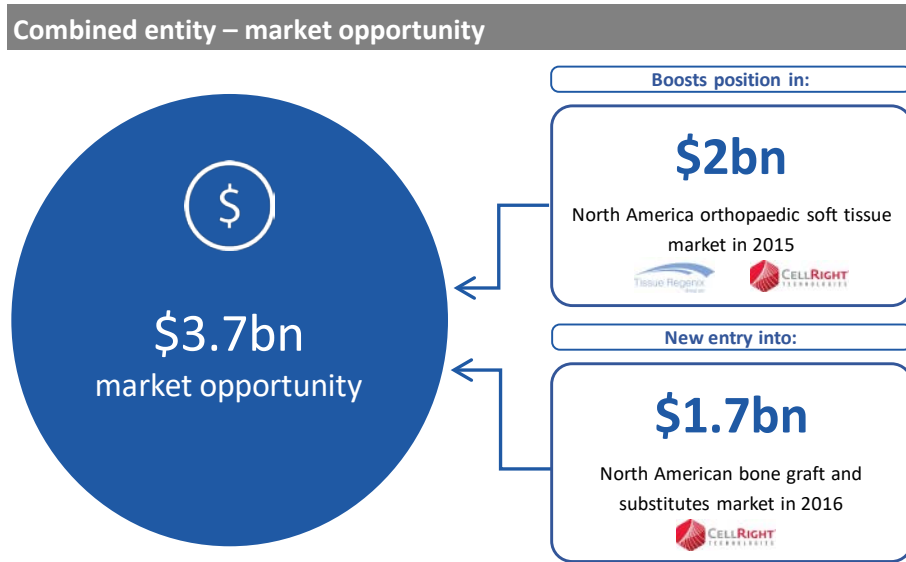
Key: ‘O’ = Orthopaedics; ‘S’ = Spine; ‘GS’ = General Surgery

Source: Acquisition announcement; Hardman & Co Life Sciences Research

\$1.7bn North American bone graft/substitutes market

Market opportunity

The acquisition of CellRight gives TRX immediate access to the \$1.7bn³ North American bone graft and substitutes market. Although the market is dominated by the large players – Medtronic, De Puy Synthes, Stryker – there is opportunity for new entrants with differentiated offerings. In addition, the existing products and commercial relationships of CellRight will pave the way for TRX’s entrance to the US orthopaedic soft tissue market, valued at \$2.0bn⁴, with OrthoPure HT in 2018.



Source: CellRight acquisition presentation

CellRight products have improved handling characteristics

Presently, the bone graft market is split between low-cost ceramics derived from cadaver bones and high-cost biosynthetic preparations. Following discussions with surgeons and KOLs, a key message is the poor ‘handling characteristics’ of many existing products – in general they are too liquid/runny to be efficiently handled. The hydration and ‘putty-like’ characteristics of CellRight’s products could add a new element and overcome some of the issues with existing products.

- ▶ Positioned to overcome some of the disadvantages of existing products by offering improved handling characteristics
- ▶ Priced between the two existing types of product, with the opportunity to take the device up the value chain

Financial performance

Sales of \$6.8m estimated for combined entity in 2017...

...based on CellRight’s strong performance

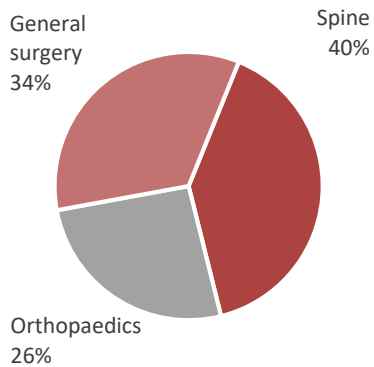
Given its relative youth, CellRight has generated an unusually strong financial performance over the last four years, which is a good indication that its products are value-added. Sales have risen at a CAGR of +61% over the last three years and have started strongly (+21%) in the first five months of trading for the current year. Based on the available information, expected product launches, and the trend for strong sales by orthopaedics companies in the final quarter of each year, Hardman estimates that sales should comfortably reach \$6.8m in fiscal 2017, potentially rising to >\$9.0m in fiscal 2018 in the event of certain synergies and cross-selling.

³ <http://www.grandviewresearch.com/industry-analysis/orthopedic-soft-tissue-repair-market>

⁴ <http://www.beckersspine.com/orthopedic-a-spine-device-a-implant-news/item/35889-medtronic-depuy-synthes-stryker-lead-north-american-bone-grafts-substitutes-market-7-observations.html>

Tissue Regenix

Sales analysis – 2016



Source: CellRight Technologies; Tissue Regenix

CellRight financial performance

Year to Dec (\$m)	*2013	*2014	**2015	**2016	+2017E
Sales	1,291	2,251	4,649	5,422	6,800
COGS			-1,817	-2,061	-2,515
Gross profit			2,832	3,361	4,285
Gross margin			60.9%	62.0%	63.0%
Overheads			-1,371	-1,778	-1,880
EBITDA	-624	102	1,461	1,583	2,405
EBITDA margin	-48.3%	4.5%	31.4%	29.2%	35.0%
EV/sales (x)	23.2x	13.3x	6.5x	5.5x	4.4x
EV/EBITDA (x)	-	-	20.5x	19.0x	12.5x

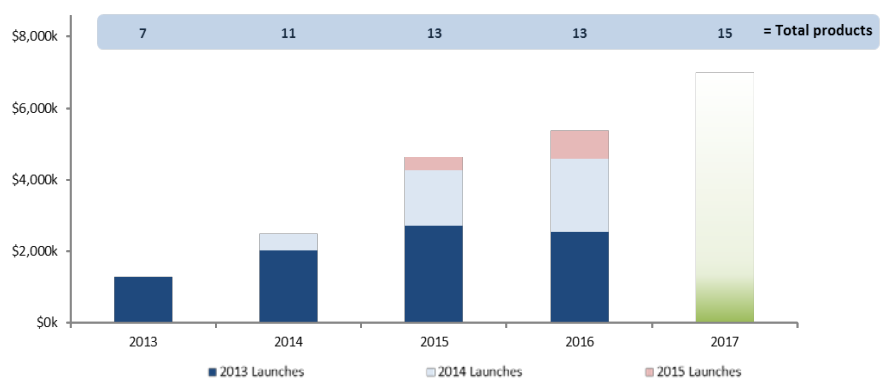
* CellRight management accounts; **Acquisition documentation; +Harman Life Sciences estimates
Source: Hardman & Co Life Sciences Research

- ▶ **Sales:** CAGR of +61% over the last three years, which would equate to +51% over four years and +47% over five years if our forecasts are met
- ▶ **Top 10 customers:** In fiscal 2016, CellRight's top 10 customers accounted for \$3.1m (57%), of which \$2.5m were to private label distributors. Both these figures were down on those for fiscal 2015
- ▶ **COGS:** The cost of sales is relatively low, and continuing the upward trend would take gross margins towards 65% in the medium term
- ▶ **Overheads:** There is less consistency surrounding the overheads. This is because the founders paid themselves a 'market wage' for the first time in 2016 and an accounting change regarding trade debtors was employed
- ▶ **EBITDA margin:** Now that the overhead changes are 'in the system' the increased sales level is expected to have a leverage effect on EBITDA margins, rising back above 33% in fiscal 2017
- ▶ **Depreciation:** Although not stated, the level of fixed assets within the consideration is reasonably high given that the property and land is freehold; therefore, the depreciation charge has been estimated at ca.\$200k p.a.

Strong record of growth during its short history...

...but readers should be aware that CellRight has been operating to a different business model to TRX

History of sales and product launches



KEY PRODUCT LAUNCHES



Source: CellRight Technologies; Tissue Regenix

*Consideration is for
\$30.0m/£23.0m in cash...*

...on a debt-free, cash-free basis

*Full consideration is equivalent to
4.4x prospective sales*



Source: CellRight Technologies website

*CellRight's CEO is remaining with
the company...*

...as TRX's Chief Scientific Officer

Consideration

Tissue Regenix is paying \$30.0m/£23.0m in cash for CellRight Technologies which will be on a debt-free, cash-free, basis. This will be split into three tranches:

- ▶ **Tranche 1:** \$25.9m/£20.0m is payable in cash on completion, which has now taken place following the GM (8th August) to approve the capital increase (see page 8) – and subject to a working capital adjustment of up to \$100k
- ▶ **Tranche 2:** Up to \$2.04m/£1.57m on a sliding scale based upon the achievement of \$6.0-7.0m sales in the first 12 months following completion
- ▶ **Tranche 3:** Up to \$2.04m/£1.57m on a sliding scale based upon the achievement of \$10.0-12.5m sales in the second 12 months following completion
- ▶ In the event that sales reach \$10m in the first 12 months following completion, \$1.0m on the second tranche can be brought forward

Based on the performance of CellRight so far in 2017, TRX management believes that it will have to pay the full amount of the earn-out consideration.

The full consideration is equivalent to 5.5x EV/sales on a historic basis, falling to 4.4x prospective sales, and to 19.0x historic EV/EBITDA, falling to 12.5x forecast EBITDA for 2017. These figures seem reasonable for a business that has demonstrated high and sustainable rates of growth and a solid level of profitability.

Facilities

CellRight was founded in 2012 and it subsequently moved into its freehold premises in Universal City, San Antonio, Texas. This state-of-the-art, 13,650 sq. ft. facility is purpose built, offers HQ and administrative facilities, and is designed with a flexible modular manufacturing unit. The facility has had several FDA inspections and has never been issued with a citation warning. It is also AATB accredited.

Given that TRX's US operations are based also in San Antonio, it is unsurprising that management intends to move its personnel into the CellRight building and to close its existing offices, thereby generating an early synergy.

The existing facility will be more than sufficient to meet the requirements of the enlarged entity for the foreseeable future. CellRight also owns approximately one acre of land adjacent to the building, providing considerable scope for expansion in the event that TRX requires more space or manufacturing capacity.

Key personnel

Jesus Hernandez – CEO

Although the vendors are receiving cash for their stake, TRX has retained the services of the Founder and CEO of CellRight, Jesus Hernandez. Jesus has many years' experience in the biologics and medical industries having held various different senior positions with medical device companies in the US. In addition, he brings extensive FDA regulatory knowledge and is an advisor to the United Network of Organ Sharing (UNOS). Following completion, Jesus will be appointed Chief Scientific Officer of Tissue Regenix.

Capital increase

*Placing and Subscription, raising
£40.0m gross funds...*

*...to fund acquisition and working
capital*

Concomitant with the announcement of the acquisition of CellRight Technologies, TRX also announced that it was undertaking a capital increase to fund the acquisition and to provide it with sufficient working capital for the next ca.15 months. The £40.0m (gross) funds raised was by way of a Placing of new Ordinary shares with institutions and a Subscription by certain directors.

- ▶ **Placing:** 395,400,000 new Ordinary shares @10p raising £39.54m gross funds
- ▶ **Subscription:** 4,600,00 Ordinary shares @10p with certain directors, raising £0.46m gross funds
- ▶ **Combined:** Issue of 400.0m new Ordinary shares, equivalent to 52.6% of the existing share capital (34.5% of enlarged share capital) to raise gross proceeds of £40.0m
- ▶ **General Meeting:** The issue was approved by shareholders at a General Meeting on 8th August 2017, with Admission to trading on AIM on 9th August 2017

Placing

*Placing raised gross funds of
£39.5m*

A total of 395.4m new Ordinary shares of 0.5p nominal value have been placed with institutions at 10p per share to raise gross funds of £39.54m. This, together with the subscription shares, represents 52.56% of the existing share capital and 34.45% of the enlarged share capital. Because of the size of the issue relative to the existing authority, the issue was conditional on approval by shareholders at a General Meeting (8th August). This had been certain, however, given that irrevocable undertakings were received from major shareholders (66.6%) and directors (6.8%), representing 73.4% of the existing share capital, or 65.2% excluding Invesco and IP Group, who were excluded from voting due to the 'whitewash' arrangement.

The Placing was very well supported by TRX's existing institutional shareholders, with Invesco, Woodford and IP Group taking up 78.6% of the Placing shares on offer and, in the cases of Invesco and Woodford, increasing their holdings. The issue needed a 'whitewash' agreement from the London Stock Exchange to waive Rule 9 of the Takeover Code, with Invesco and IP Group determined to be acting in concert and carrying more than 30% of the voting rights. These three top shareholders now control 67.8% of the enlarged share capital between them. Baillie Gifford and Jupiter participated in the Placing also, although the details of their participation were not disclosed in the Circular to shareholders and, at the time of going to press, no new disclosures had been made to the market.

Undertakings by existing shareholders					
Institution	*Existing holding	%	Placing shares	New holding	%
Invesco AM	211,328,351	27.8%	125,381,588	336,709,939	29.0%
Woodford IM	150,807,872	19.8%	139,000,000	289,807,872	25.0%
IP Group	110,837,567	14.6%	50,000,000	160,837,567	13.9%
Baillie Gifford	49,708,667	6.5%	?	49,708,667	4.3%
Jupiter AM	33,885,745	4.5%	?	33,885,745	2.9%
Directors†	51,736,716	6.8%	4,600,000	56,336,716	4.9%
Others	152,763,837	20.0%	81,018,412	233,782,249	20.1%
Total	761,068,755	100.0%	400,000,000	1,161,068,755	100.0%

**Latest disclosure prior to acquisition announcement; †see Subscription section below
Source: Circular to shareholders; Hardman & Co Life Sciences Research*

**Subscription by Directors raised
£460k**

Subscription

In the absence of an Open offer and by not being registered with a participating broker, certain directors have joined in the capital increase by way of a subscription for 4.6m new shares, also @10p per share, thereby contributing £460k to the raise, and showing strong support for the strategic decisions that have been made.

Subscription by directors					
Name	Position	Existing holding	%	New holding	%
John Samuel	Chairman	24,276,928	3.19%	26,276,928	2.26%
Alan Miller	NED	21,886,988	2.88%	22,886,988	1.97%
Antony Odell	CEO	5,572,800	0.73%	5,722,800	0.49%
Paul Devlin	CFO	0	-	300,000	0.03%
Steven Couldwell	NED	0	-	300,000	0.03%
Jonathan Glenn	NED	0	-	600,000	0.05%
Randeep Singh Grewal	NED	0	-	0	-
Shevanthi Homer-Vanniasinkam	NED	0	-	250,000	0.02%
Total Directors		51,736,716	6.80%	56,336,716	4.85%

Source: Circular to shareholders; Hardman & Co Life Sciences Research

Use of funds

Even in the absence of the CellRight acquisition, the market has been aware that TRX would need to return to the market to raise funds for working capital purposes. A capital increase has been in our forecasts, timed for 2H 2017, for over two years. The acquisition of CellRight simply increased the size of the funds needed.

Use of proceeds		
	Assumption	£m
Gross funds raised	400m @ 10p	40.0
Charges & commissions for acquisition and Placing	Est 4%	-1.6
Net funds received		38.4
Initial consideration for CellRight Technologies		-20.0
Fees & legal costs	Est 8%	-1.8
Immediate net funds for working capital purposes		16.6
First tranche of deferred consideration	Sept 2018	-1.6
Contingency for overall fees and working capital		-1.5
Working capital for next 12-18 months		13.5

Source: Circular to shareholders; Hardman & Co Life Sciences Research

Given that the enlarged group will have immediately improved infrastructure in the US, the primary use of funds will be used to support the launch of seven new products over the next two years.

**Proceeds primarily used to support
launch of seven new products...**

**...across all three business
segments**

- ▶ **Woundcare:** Integrate the portfolios of TRX and CellRight and continue to drive DermaPure growth in the US. Launch SurgiPure in the US market in 1H 2018; launch DermaPure into Europe
- ▶ **Orthopaedics:** Launch the OrthoPure portfolio into both Europe and the US following receipt of the relevant regulatory authorisations. Integrate OrthoPure within the CellRight portfolio in the US. Expand the CellRight portfolio and develop international sales and distributor networks
- ▶ **Cardiac/GBM-V:** Launch CardioPure and DermaPure to Europe following receipt of relevant regulatory authorisations, and look to expand the CellRight portfolio in Europe

FY 2016 results

*Major progress in accessing US
woundcare market*

In the 11 months to December 2016, TRX has progressed with its commercialisation strategy for its woundcare and orthopaedics products. Particular focus has been on expanding access to the US woundcare market, first via Medicare for out-patients, and now via Group Purchasing Organisations (GPOs) for the in-patient population.

Key features

Operational

- ▶ **Targeted sales:** Major US hospitals that are members of TRX's GPO agreements and that perform high numbers of procedures have been chosen as targets for DermaPure
- ▶ **US subsidiary:** Established in February 2016 for commercialisation of orthopaedic products, in advance of potential development and commercialisation of OrthoPure HT; this will be integrated into CellRight
- ▶ **Joint venture:** A European joint venture (GBM-V) was established, through which woundcare and cardiac applications will be processed. The jv will be supplemented in some countries with the use of distributors
- ▶ **EU orthopaedics:** Approval of OrthoPure XT in the EU has been slower than anticipated, in part due to recent alterations to EMA medical device directives. This makes the approval timeline hard to predict
- ▶ **US acquisition:** Discussions began for a potential acquisition of CellRight Technologies, a specialist tissue regenerative company selling human bone-based products, which complements TRX; this came to fruition post-period end

*Joint venture with a tissue bank in
Germany...*

*...for processing woundcare and
cardiac applications*

Financial

*FY 2016 sales – £1.44m – beat our
forecasts, due to consolidation of jv*

- ▶ **Sales:** Reported sales in the 11-month period were higher than our forecast at £1.44m, due to consolidation of the jv in Germany. On a 12-month *pro forma* basis, we estimate that underlying DermaPure sales in the US grew by +79%
- ▶ **Joint venture:** First sales (£121k) from the joint venture in Germany, GBM-V, were achieved in 2H'16; mainly sales of cryopreserved human corneas. Future sales contributions from this jv look set to be more significant than anticipated, given that all human tissue-derived products will be sold through it
- ▶ **COGS:** The anticipated decline in gross margin – due to lower average selling prices in the US – was greater than predicted following consolidation of GBM-V, which has gross margins approximately half those of TRX. This will recur in fiscal 2017 given that GBM-V will be consolidated for a full 12 months, but offset by higher margins at CellRight
- ▶ **R&D:** R&D spend for the 11-month period was much lower than anticipated, at -£3.1m (or -£3.4m *pro forma* 12 months to December 2016) compared to £3.7m reported for the 12 months to January 2016. Part of this was due to the modest ongoing R&D investment in woundcare products being capitalised, whereas historically all R&D has been written off. This accounting change in respect of spend related to regulatory approved products is likely to recur going forward
- ▶ **SG&A:** Considerable investment continues to be made into maximising penetration of products into the market, particularly DermaPure into both in-patient and out-patient centres in the US. This will be followed in Europe, with the expected approval and launch of OrthoPure XT

- ▶ **Underlying EBIT:** Overall operating losses were better than expected in the 11-month period at -£10.85m compared to -£11.54m forecast. One of the key influences was a lower than expected investment in R&D
- ▶ **Going concern:** Net cash at 31st December 2016 was better than forecast by about the same amount (+£0.7m), ending the period at £8.2m. With an average monthly cash burn of ca.£1.0m, TRX had sufficient cash to cover its operations until Q3 2017. The capital increase is forecast to extend the runway for the enlarged group through to 2H 2018
- ▶ **Pro forma numbers:** In order to provide a base for fiscal 2017, the table below shows our best estimate for *pro forma* results in the fiscal year ending December 2016 and 2015

Results vs forecasts				
Accounting period (£000)	11m to Dec 2016 forecast	11m to Dec 2016 actual	*12m to Dec 2015 <i>pro forma</i>	*12m to Dec 2016 <i>pro forma</i>
GBP:USD	1.340	1.347	1.529	1.354
Sales	1,300	1,443	723	1,583
COGS	-280	-354	-150	-383
Gross profit	1,020	1,089	573	1,200
Gross margin	78.5%	75.5%	79.3%	75.8%
Operating costs	-12,560	-11,939	-10,753	-13,035
Underlying EBIT	-11,540	-10,850	-10,180	-11,835
Share based costs	-276	-210	-136	-210
Reported EBIT	-11,815	-11,060	-10,316	-12,045
Net financials	122	114	213	120
Underlying PBT	-11,418	-10,736	-9,967	-11,810
Reported PBT	-11,694	-10,946	-10,103	-11,925
Weighted shares (m)	750.9	760.1		
U/lying basic EPS (p)	-1.45	-1.28		
Statutory basis EPS (p)	-1.48	-1.30		
Net cash	7,400	8,173		

**Pro forma numbers are Hardman estimates
Source: Hardman & Co Life Sciences Research*

Comparison of TRX alone and with CellRight

Sales of £5.6m for 2016 on a *pro forma* basis...

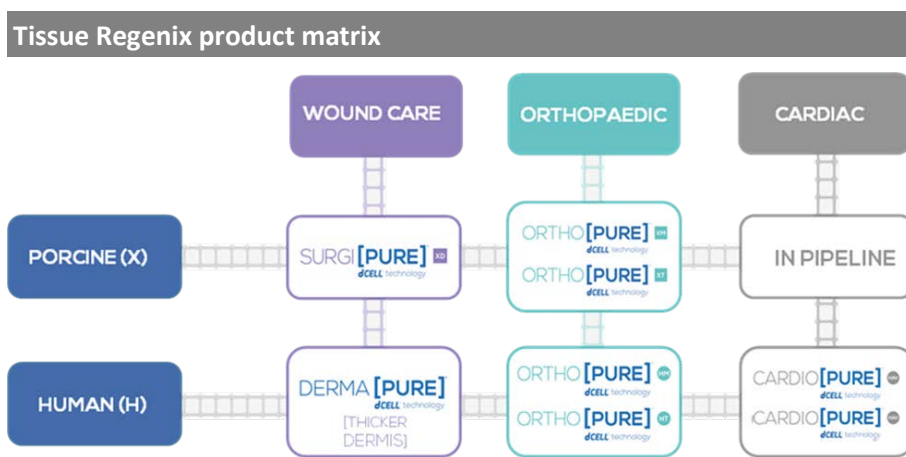
...for the combined entity (12 months)

Impact of CellRight – Pro forma				
Year to December (£000)	TRX 2016 <i>pro forma</i>	Combined 2016 <i>pro forma</i>	2017E <i>pro forma</i>	2018E
GBP:USD	1.354	1.354	1.350	1.350
Sales	1,583	5,590	9,320	16,800
COGS	-383	-1,900	-3,450	-5,880
Gross profit	1,200	3,690	5,870	10,920
Gross margin	75.8%	66.0%	63.0%	65.0%
Operating costs	-13,035	-14,390	-17,415	-19,400
Underlying EBIT	-11,835	-10,700	-11,550	-8,480
Net financials	120	250	130	80
Underlying PBT	-11,810	-10,450	-11,415	-8,400
Net income	-10,776	-9,415	-10,535	-7,425
Weighted shares (m)	750.9	1,160.1	1,161.1	1,191.1
U/lying basic EPS (p)	-1.44	-0.81	-0.91	-0.62
Net cash	8,173	8,173	9,430	10,350

**Pro forma numbers are all Hardman estimates
Source: Hardman & Co Life Sciences Research*

Operations update

There has been a substantial expansion in reimbursement coverage of the US woundcare market and progress in the commercialisation strategy for the porcine orthopaedic scaffold OrthoPure XT in EU. Launch of OrthoPure XT in Europe has been delayed further due to circumstances beyond the company’s control; clinical trial data were submitted to the regulator in November 2016 for CE Mark approval, however, there remains a bottleneck in the processing of submissions due to ongoing changes to EMA Medical Device directives.



Source: Hardman & Co Life Sciences Research

Refined sales strategy for DermaPure in US...

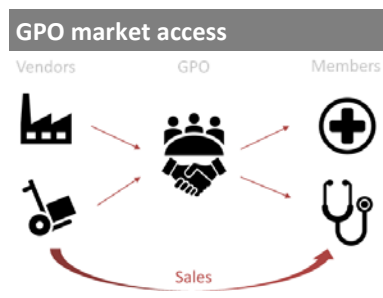
...with key hospitals targeted

Woundcare in the US

Focus has been on commercialising DermaPure in the US, where the total market for skin/dermal substitutes is estimated at \$588m (TRX Annual Report 2017). TRX has undertaken a targeted marketing exercise to identify the locations and hospitals that present biggest opportunity. The other product, SurgiPure XD, is made from porcine dermis and is used for hernia repair; although 510(k) approved, launch in the US was postponed in order to concentrate resources onto bigger commercial opportunities. This involved redeployment of staff onto commercialisation of OrthoPure XT in the EU, expected to launch in early 2018.

Expanding access

Complementing the 93% Medicare reimbursement coverage of out-patient settings, in recent months TRX has signed three Group Purchasing Organisation (GPO) agreements, including with the two largest GPOs: Premier and Vizient. GPOs expand TRX’s access to the in-patient population, the biggest target market for DermaPure, which as a single application product has the advantage of being favourably reimbursed. TRX now has 75% coverage of this market under these agreements. In addition, DermaPure was added to the Federal Supply Schedule in February 2017, allowing access to a further nine million patients, the majority of whom are veterans; veterans comprise a large segment of the woundcare market since ca.25% have diabetes. Our note published 13th March 2017, ‘Addressing woundcare in the US’, discusses TRX’s expanding US coverage in more detail. The lift in DermaPure sales resulting from the GPO agreements will be gradual, since after signing GPO agreements, individual hospitals have an internal process to demonstrate economic value, and the product needs marketing directly to clinicians.



Source: Hardman & Co Life Sciences Research

Targeted US sales

To maximise sales from the GPO network, management has refined the strategy for the direct sales team. A detailed analysis on data purchased from IMS Health in order to identify target hospitals, across four regions, that offer the highest opportunity: those that perform the highest numbers of relevant procedures and those that are members of TRX associated GPOs. The refined strategy was implemented in 1Q'17. DermaPure will be sold via distributors outside these major targets.

Orthopaedics

Delays to EU commercialisation

OrthoPure XT approval delayed due to altered EMA directives

A decellularised porcine ligament product for anterior cruciate ligament (ACL) reconstruction, OrthoPure XT, was the company's first orthopaedic product submitted for approval. Early clinical data from the single arm, multi-centre trial of OrthoPure XT in Europe (ClinicalTrials.gov identifier: NCT02540811) was submitted to the Notified Body for CE Mark in November 2016. Along with its recent financial reporting, TRX also announced that, as a consequence of ongoing alterations to EMA Medical Device directives, there would be a further delay to the regulatory approval.

First distribution partnership announced for OrthoPure XT in Europe

Signing of the first distribution agreement was also announced in 2016. A number of others have been entered into since, with initial focus on Germany, Spain & Poland. Full commercialisation is expected 18 months after approval, following successful completion of additional work such as registration in individual countries. A sales and marketing manager has been appointed in readiness for the EU launch programme.

US subsidiary established

Clinical advisory board, subsidiary, and VP North America established...

...to speed commercialisation of OrthoPure XT in US

Commercialisation of the orthopaedics products is not as advanced in the US as it is in Europe. The technology transfer of OrthoPure HT, the human tissue version of OrthoPure, can begin once a tissue bank partner has been agreed (which will now be CellRight). Ahead of this, and to aid negotiation of the complex US sports medicine market, TRX has established a subsidiary in the US with a new Clinical Advisory Board. A Vice President North America has been appointed to lead commercialisation. In terms of regulation, Tissue Regenix is in positive initial discussions with the FDA that will potentially accelerate commencement of a first-in-man clinical trial for OrthoPure XT in the US. CellRight will be able to provide its considerable experience in this area.

Joint venture

For processing of human tissue products in the EU, a joint venture multi-tissue bank, GBM-V, was successfully established in Rostock, Germany in January 2016. GBM-V can process different human tissue types at one facility, and the first sales, made in the final 8 weeks of 2016, were of human cryopreserved corneas. Further 'non-dCELL' tissue products will be distributed going forward depending on demand.

Woundcare and cardiac

TRX can pursue EU regulatory approval of its dCELL human allograft (donor organ and tissue) products now that GBM-V has been established. Commercialisation of DermaPure (via distributors) and CardioPure human heart valves (direct to hospitals) will commence in 2018. Sales levels will of course be limited by donor tissue availability.

GBM-V is being consolidated in the group's results and is expected to make a significant contribution to the sales line from fiscal 2017 (see page 14rf vg). For transparency, management intends to fully disclose the results of this joint venture as part of its 'segmental analysis' on an ongoing basis.

FY 2016 financial analysis

Divisional analysis: stand-alone TRX

TRX provides divisional disclosure on a regular basis. Notwithstanding that, in the latest set of accounts the company has increased the information within the divisional analysis, which also details the consolidation of the GBM-V joint venture.

Under SG&A, the company not only includes marketing costs, but also, unusually, R&D investment. However, analysis of the data coupled with knowledge of which products are currently being commercialised has allowed us to separate out R&D investment from marketing spend, as detailed in the table below.

Divisional analysis (ex-CellRight)						
Year end Dec (£000)	*2015	*2016	+2016	2017E	2018E	2019E
Wound Care	72	808	1,322	2,600	6,300	11,100
Orthopaedics	0	0	0	40	450	1,080
Cardiac	0	0	0	0	25	110
GBMV (jv)	0	0	121	1,640	2,460	3,200
Other	28	8	0	0	0	0
Group sales	100	816	1,443	4,280	9,235	15,490
Wound Care	-32	-154	-288	-711	-1,638	-2,700
Orthopaedics	0	0	0	-13	-139	-334
Cardiac	0	0	0	-30	-5	-28
GBMV (jv)	0	0	-66	-902	-1,402	-1,854
Group COGS	-32	-154	-354	-1,655	-3,184	-4,916
Wound Care	0	-3,956	-5,500	-6,243	-7,605	-9,267
Orthopaedics	0	-30	-61	-1,400	-1,680	-1,848
Cardiac	0	-10	-12	-364	-408	-449
GBMV jv	0	0	-308	-1,250	-1,438	-1,524
Central	0	-3,232	-3,141	-3,926	-4,005	-4,085
Group SG&A	0	-7,228	-9,022	-13,184	-15,135	-17,173
Wound Care	0	-982	0	-950	-805	-605
Orthopaedics	0	-2,352	-2,677	-2,020	-2,090	-2,300
Cardiac	0	-342	-450	-500	-580	-575
Central	0	0	0	0	0	0
Group R&D	0	-3,676	-3,127	-3,470	-3,475	-3,480
Wound Care	0	-4,284	-4,466	-5,304	-3,748	-1,472
Orthopaedics	0	-2,382	-2,738	-3,391	-3,458	-3,400
Cardiac	0	-352	-462	-894	-968	-941
GBMV (jv)	0	0	-253	-512	-380	-181
Central costs	0	-3,088	-2,931	-3,676	-3,735	-3,795
Underlying EBIT	0	-10,106	-10,850	-13,778	-12,290	-9,789

*Year to January; *11months to 31 December
Source: Hardman & Co Life Sciences Research

Corporate overhead

The *pro forma* central costs for 2016 were estimated to be £3.45m (reported £3.14m for 11 months). While there will be some increase in central costs, overall, after 2017 growth is not expected to be materially different to inflation.

Note, the cost of the new US personnel are included in the SG&A, not in central costs. This may change in the future following the acquisition of CellRight.

Changes to forecasts: stand-alone TRX

Model developed...

...to include new divisional reporting and CellRight

Sales forecasts lowered...

...to account for regulatory delays and for lead-time to GPO sales

Although the reported numbers for the 11 month period to December 2016 were similar to our forecasts, the increased breakdown described above has allowed a more sophisticated model to be built. In addition, consolidation of the jv had not been anticipated. Consequently, there are substantial changes to our forecasts:

- ▶ **Sales:** Forecasts lowered to allow for the time taken to convert in-patient GPO access in the US into utilisation, and due to regulatory delays to the approval of orthopaedic products in Europe. These declines have been offset by full consolidation of the joint venture
- ▶ **SG&A:** Continued investment in commercialisation fees to penetrate the US market. Establishment of US commercial operation in readiness for orthopaedics
- ▶ **R&D spend:** Lower R&D spend as several programmes are coming to fruition, with ca.-£12-13m expected over the next four years, compared to -£26m previously forecast. Also, ca.15% of R&D spend is now being capitalised annually
- ▶ **EPS:** Allowance had been made for a £20m equity fund raise based on the current share price – this now looks more like £12m for working capital
- ▶ **Forex sensitivity:** All forecasts are based on constant currency against *pro forma* numbers for the year to 31st December 2016. For information, a 10¢ movement in the USD alters sales for 2017 by ±£200k and EBIT losses by ±£100k

Summary of changes to forecasts (ex-CellRight)

Year end Dec (£m)		2016 PF	2017E	2018E	2019E
Sales	Old		5.56	13.12	25.06
	New	1.58	4.28	9.24	15.49
	Change		-23%	-30%	-38%
SG&A	Old		-8.91	-10.42	-12.42
	New	-9.62	-13.12	-15.13	-17.17
	Change		-47%	-45%	-38%
R&D	Old		-8.00	-8.00	-5.00
	New	-3.45	-3.47	-3.48	-3.48
	Change		+57%	+57%	+30%
EBIT (underlying)	Old		-13.94	-9.18	0.85
	New	-11.83	-13.78	-12.29	-9.79
	Change		+1%	-34%	nm
Pre-tax profit (underlying)	Old		-13.87	-9.13	0.86
	New	-11.71	-13.65	-12.15	-9.33
	Change		+2%	-32%	nm
EPS (p) (underlying basic)	Old		-1.54	-0.90	0.20
	New	-1.40	-1.42	-1.15	-0.98
	Change		+8%	-28%	nm

*Numbers may not add up exactly due to rounding
Source: Hardman & Co Life Sciences Research*

Forecasts

Profit & Loss: enlarged entity

Volatility in forecast period...

...due to impact of CellRight acquisition and consolidation of jv

- ▶ **Sales:** On a *pro forma* basis, we estimate that sales in fiscal 2017 will be about £9.3m, mostly derived from the US. Underlying sales growth of TRX products, excluding CellRight and consolidation of the jv, are forecast at +100% in 2017
- ▶ **Gross margin:** There will be volatility over the forecast period. Consolidation of CellRight and GBM-V will both have a one-off impact on the enlarged group spanning a two year period. Thereafter, margins are expected to trend upwards
- ▶ **SG&A:** Investment in commercialisation will continue to impact the numbers despite the boost that will be received from consolidating CellRight

Profit & Loss account						
Year end Dec (£000)	*2015	*2016	+2016	2017E	2018E	2019E
GBP:USD		1.523	1.347	1.350	1.350	1.350
Sales	100	816	1,443	6,710	16,594	25,267
COGS	-32	-154	-354	-2,507	-5,870	-8,436
Gross profit	68	662	1,089	4,203	10,724	16,832
Gross margin		81.1%	75.5%	62.6%	64.6%	66.6%
SG&A	-1,766	-7,092	-8,812	-13,682	-16,729	-18,809
R&D	-3,296	-3,676	-3,127	-3,470	-3,475	-3,480
Underlying EBITDA	-8,038	-9,861	-10,549	-12,535	-9,000	-4,962
Depreciation	-151	-245	-301	-414	-480	-494
Amortisation	0	0	0	0	0	0
Other income	0	0	0	0	0	0
Underlying EBIT	-8,189	-10,106	-10,850	-12,948	-9,480	-5,457
Share based costs	-180	-136	-210	-250	-270	-290
Exceptional items	0	0	0	0	0	0
Statutory operating profit	-8,369	-10,242	-11,060	-13,198	-9,750	-5,747
Net interest	168	213	114	73	64	39
Pre-tax profit	-8,021	-9,893	-10,736	-12,875	-9,415	-5,418
Exceptional items	0	0	0	0	0	0
Reported pre-tax	-8,201	-10,029	-10,946	-13,125	-9,685	-5,708
Tax payable/credit	620	527	1,034	880	976	977
Underlying net income	-7,401	-9,366	-9,702	-11,996	-8,440	-4,440
Statutory net income	-7,581	-9,502	-9,912	-12,246	-8,710	-4,730
Ordinary shares:						
Period-end (m)	654	760.1	760.1	1,161.1	1,221.1	1,221.1
Weighted average (m)	637	743.2	760.1	919.4	1,176.1	1,221.1
Fully diluted (m)	676	784.7	805.1	964.4	1,221.1	1,266.1
Underlying basic EPS (p)	-1.16	-1.26	-1.28	-1.30	-0.72	-0.36
Statutory basic EPS (p)	-1.19	-1.28	-1.30	-1.33	-0.74	-0.39
U/I Fully-diluted EPS (p)	-1.10	-1.19	-1.21	-1.24	-0.69	-0.35
Stat. Fully-diluted EPS (p)	-1.12	-1.21	-1.23	-1.27	-0.71	-0.37
DPS (p)	0.0	0.0	0.0	0.0	0.0	0.0

*Year to January; *11months to 31 December
Source: Hardman & Co Life Sciences Research

Balance sheet

- ▶ **Net cash:** The net cash position was £8.2m at 31st December 2016. With a cash burn rate approaching £1m per month, this cash injection was very much needed. By the end of fiscal 2017, forecasts suggest that TRX will have net cash of about £8.5m. Based on our forecast cash burn of just over £1.0m per month, the company has sufficient working capital until the end of 3Q 2018
- ▶ **R&D:** In a slight change of accounting policy, all continuing R&D investment in products that have received regulatory approval is being capitalised and included in intangible assets, which are then to be amortised in line with IAS38 once the product is launched
- ▶ **Capitalised R&D:** Our stated capitalised R&D in the balance sheet is to allow for the calculation of ROIC which is based on NOPLAT divided by invested capital, both of which require written-off R&D to be added back and amortised
- ▶ **Capital increase:** Our forecasts assume that the company will raise a further £12m of new working capital towards the end of fiscal 2018, which will be sufficient to take the business through to profitability by the end of fiscal 2020

Balance sheet						
@31st Dec (£000)	*2015	*2016	2016	2017E	2018E	2019E
Shareholders' funds	11,578	21,239	11,536	34,790	38,081	33,350
Cumulated goodwill	0	0	0	0	0	0
Total equity	11,578	21,239	11,536	34,790	38,081	33,350
Share capital	3,271	3,801	3,801	5,805	6,105	6,105
Reserves	8,307	17,438	7,735	28,985	31,976	27,245
Capitalised R&D	7,450	9,239	10,206	10,701	11,049	11,397
Long-term debt	0	0	0	0	0	0
Short-term loans	0	0	0	0	0	0
less: Cash	10,257	19,907	8,173	8,591	9,752	3,593
Invested capital	8,771	10,571	13,569	36,900	39,378	41,154
Fixed assets	435	901	1,087	3,333	3,292	3,347
Intangible assets	0	0	550	15,935	17,504	19,073
Capitalised R&D	7,450	9,239	10,206	10,701	11,049	11,397
Inventories	34	64	661	2,714	3,664	4,039
Trade debtors	40	398	427	1,611	1,984	2,521
Other debtors	1,907	1,927	2,703	2,203	1,703	1,203
Tax liability/credit	-73	-72	-147	0	0	0
Trade creditors	-312	-501	-618	-711	-853	-1,023
Other creditors	-710	-1,385	-1,300	1,114	1,034	597
Debtors less creditors	852	367	1,065	4,218	3,869	3,298
Invested capital	8,771	10,571	13,569	36,900	39,378	41,154
Net cash/(debt)	10,257	19,907	8,173	8,591	9,752	3,593

*@31st January

Source: Hardman & Co Life Sciences Research

Cashflow

TRX's cashburn is in the region of £1m per month...

...suggesting that a further fundraise (ca.£12m) is needed later in calendar 2018

- ▶ **Cashburn:** Even though cashflow will be boosted by CellRight, TRX remains in an investment phase to commercialise its opportunity, with an average monthly cash burn in the order of £1m per month
- ▶ **Working capital:** There will be a short-term increase in working capital requirement following the acquisition of CellRight, from increased inventories and trade debtors
- ▶ **R&D:** Much of the R&D investment has already been made and we are forecasting that it will remain steady at £3.0-3.5m per annum. The next key trials will be for OrthoPure XT in the US, expected to commence late 2018
- ▶ **Amortisation:** An adjustment to amortisation will be required once the goodwill element of CellRight is known and over how many years it will be amortised
- ▶ **Capital increase:** As stated earlier, our forecasts have always assumed a capital raise in 2017. Although the cash raised was double our forecast, most of it was needed to fund the acquisition, leaving a lower than expected level (ca.£13.5m) for working capital purposes, which will last TRX through to 2H 2018, when we are forecasting a further raise of about £12.0m

Cashflow						
Year end Dec (£000)	*2015	*2016	+2016	2017E	2018E	2019E
Underlying EBIT	-8,189	-10,106	-10,850	-12,948	-9,480	-5,457
Depreciation	151	245	301	414	480	494
Amortisation	0	0	0	0	0	0
<i>Inventories</i>	-34	-30	-597	-2,053	-950	-375
<i>Receivables</i>	0	-596	-90	-584	227	263
<i>Payables</i>	0	862	106	-93	308	379
Change in working cap.	-213	236	-581	-2,730	-415	267
Other	0	0	0	0	0	0
Company op cashflow	-8,285	-9,625	-11,130	-15,265	-9,415	-4,695
Net interest	168	213	114	73	64	39
Tax paid/received	0	745	319	1,034	880	976
Operational cashflow	-8,117	-8,667	-10,697	-14,158	-8,471	-3,680
Capital expenditure	-114	-711	-487	-352	-440	-549
Sale of fixed assets	0	0	0	0	0	0
Free cashflow	-8,231	-9,378	-11,184	-14,509	-8,911	-4,230
Dividends	0	0	0	0	0	0
Acquisitions	0	0	-550	-20,078	-1,581	-1,581
Other investments	0	0	0	-495	-347	-348
Cashflow after invests.	-8,231	-9,378	-11,734	-35,082	-10,840	-6,159
Share repurchases	0	0	0	0	0	0
Share issues	5	19,019	0	35,500	12,000	0
Change in net debt	-8,226	9,650	-11,734	418	1,160	-6,159
Opening net cash	18,483	10,257	19,907	8,173	8,591	9,752
Closing net cash	10,257	19,907	8,173	8,591	9,752	3,593
Hardman FCF/share (p)	-1.3	-1.2	-1.4	-1.5	-0.7	-0.3

*Year to January; *11 months to 31 December
Source: Hardman & Co Life Sciences Research

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