hardman&co

Pharmaceuticals & Biotech

Source: Eikon Thomson Reuters

Market data

EPIC/TKR	TRX
Price (p)	18.3
12m High (p)	22.5
12m Low (p)	12.7
Shares (m)	759.7
Mkt Cap (£m)	138.7
EV (£m)	118.8
Free Float*	33%
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	Ian Jefferson
Chairman	John Samuel

+44 (0)330 430 305
www.tissueregenix.com

Key shareholders

Directors	6.9%
Invesco	27.8%
Woodford IM	18.0%
Techtran Group	13.6%
Baillie Gifford	7.2%
Jupiter AM	4.6%

Events

Oct-16	Interim results
2H-16	SurgiPure XD US launch
2H-16	OrthoPure XT CE Mark
May-17	Final results

Analysts

Martin Hall 020 7148 1433
mh@hardmanandco.com
Gregoire Pave 020 7148 1434
gp@hardmanandco.com

Tissue Regenix

Major progress towards orthopaedics approvals

Tissue Regenix is now in the commercialisation phase having validated its dCELL® technology to produce 'like-for-like' tissue specific, structure-preserving scaffolds for use in multiple clinical settings. DermaPure has started well in the US for treating chronic wounds and traction will increase now that it is widely reimbursed by Medicare providers. But newsflow in the next 12 months is likely to be dominated by the approval and launch of the orthopaedics products for meniscal and tendon repairs. Despite short term monthly cashburn of c.£1m, TRX is building long term value, evidenced by 32p NPV driven by three core product areas.

- **Strategy**: To build and commercialise a portfolio of products using its proprietary dCELL technology platform thereby creating a leading regenerative medicine business. Potential applications of dCELL are diverse and address a number of unmet medical needs in wound care, orthopaedics and cardiology.

- **OrthoPure:** Early confidence from EU trials indicate that TRX is making rapid progress with OrthoPure XT (porcine/tendon) suggesting that CE Mark is achievable by the end of 2016, six months earlier than forecast. OrthoPure XM (porcine/meniscus) was shown to be integrated into the patient's own tissue.

- **Regulation:** As a consequence, the US regulatory strategy has been revised. The route to market for OrthoPure XM will be via a 510(k) rather than the far more expensive and time consuming PMA process. OrthoPure XT will require a PMA, but TRX is reviewing a plan with the FDA by which this process can be expedited.

- **Risks:** Clinical and regulatory (three ongoing clinical trials in order to achieve approvals), financial (further funding for OrthoPure US trial costs but these could be through partnerships), and commercial (roll out of DermaPure, SurgiPure and OrthoPure) but mitigated by use of a hybrid sales strategy.

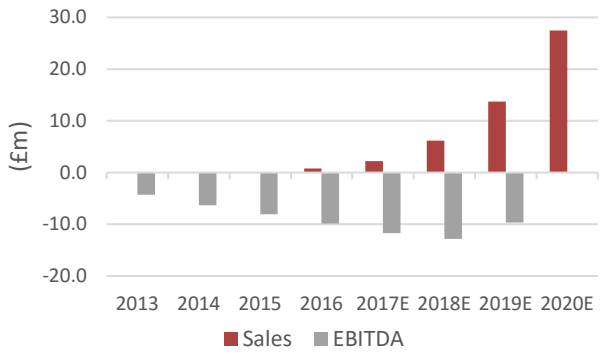
- **Investment summary:** TRX is building commercial momentum through three clear value drivers: Good early sales of DermaPure (chronic wounds), launch of SurgiPure (hernia repair) and earlier CE Mark for the OrthoPure XT, tendon product. This is de-risking the business for investors, but also drawing the attention of potential acquirors. Our DCF valuation is 32p per share, heavily influenced by near-term R&D and marketing investment.

Financial summary and valuation

Year end Jan (£000)	2014	2015	2016	2017E	2018E	2019E
Sales	6	100	816	2,217	6,166	13,708
R&D	-3,356	-3,296	-3,676	-6,000	-8,000	-8,000
Underlying EBIT	-6,483	-8,189	-10,106	-11,980	-13,088	-9,977
Reported EBIT	-6,577	-8,369	-10,242	-12,156	-13,284	-10,193
Underlying PTP	-6,209	-8,021	-9,893	-11,821	-13,027	-9,865
Statutory PTP	-6,303	-8,201	-10,029	-11,997	-13,223	-10,081
Underlying EPS (p)	-0.9	-1.2	-1.3	-1.5	-1.6	-1.1
Statutory EPS (p)	-0.9	-1.2	-1.3	-1.5	-1.6	-1.1
Net cash/(debt)	18,483	10,257	19,907	7,673	14,064	3,271
Capital increases	8	5	19,019	0	20,000	0
P/E (x)	-	-	-	-	-	-
EV/sales (x)	-	-	-	-	19.3	8.7

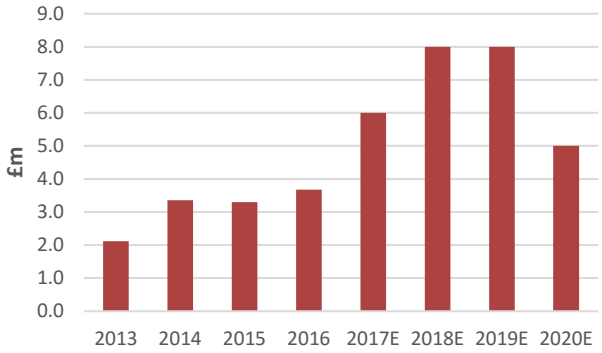
Source: Hardman & Co Life Sciences Research

Sales & EBITDA



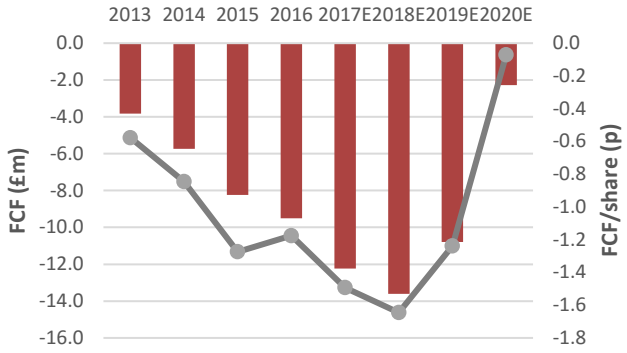
- DermaPure launched in US in 2014 for the in-patient hospital market segment for acute and chronic wounds
- SurgiPure XD 510(k) approval in the US (9th March) was a significant regulatory milestone
- European launch of OrthoPure XT through distributor model in 2017 and OrthoPure HM/HT in the US in 2017
- CardioPure HV European launch expected in 2017 through distributor model

R&D investment



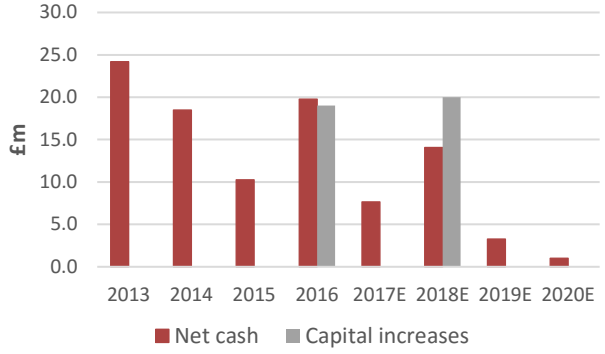
- Cumulative investment in R&D since 2006 has been ca.£19.7m
- R&D spend is forecast to rise following March 2015 Placing to secure CE Mark for OrthoPure XM/XT in Europe
- Funds will be used to complete processes to achieve clearance for human versions of OrthoPure HM/HT for meniscus and ligament repair in the US
- Costs of PMA/510(k) studies for porcine meniscus and ligament products commencing 2018 included in model

Free cashflow



- Despite cash burn increasing through 2018, the investment is creating long term value in the business
- Investment to date has demonstrated the application of dCELL process to multiple clinical settings
- Clinical applications are all in areas of high unmet medical/clinical need; namely chronic and acute/complex wounds, sports medicine and cardiac valves
- Cashflow significantly improve once sales reach £20m

Net cash & Capital increases



- Since AIM admission in 2010, £47.2m (£49.5m gross) has been raised to fund the business
- £19m (£20m gross) was raised in January 2015 to commercialise DermaPure in US, to launch SurgiPure XD (porcine hernia patch in US), and to fund the development and working capital requirements for human meniscus and ligament products (OrthoPure HM and HT) in the US
- Forecasts assume a further raise of £20m to expand commercial opportunities in the US and EU

Source: Company data; Hardman & Co Life Sciences Research

Orthopaedics update

The orthopaedics pipeline, targeted at tissue repair within the Sports Medicine market, consists of four products – two each derived from human and porcine (xenografts) – focused on meniscus tears and tendon repairs. The aim is to offer surgeons a readily available and reliable 'off the shelf' graft, stored at room temperature, that requires minimal preparatory work prior to implantation.

Orthopaedics portfolio

Product	Origin	Indication
OrthoPure HM	Human	Meniscus
OrthoPure XM	Porcine	Meniscus
OrthoPure HT	Human	Tendon (ACL)
OrthoPure XT	Porcine	Tendon (ACL)

Source: Tissue Regenix; Hardman & Co Life Sciences Research

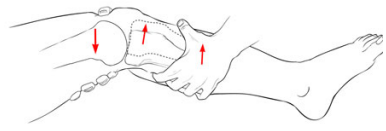
While the OrthoPure products derived from human tissue will be reviewed in the US under the HCT/P 361 regulatory process (see page 7), those derived from porcine tissue are undergoing clinical trials. Tissue Regenix update the market recently (11th July 2016) on progress in these EU trials and their impact on the regulatory process.

- **OrthoPure XT** – Confidence that the encouraging clinical data will result in CE mark earlier than expected at the end of calendar 2016
- **OrthoPure XM** – Positive trial data and establishment of a cheaper and faster route to the US market

This note highlights the recent events and updates the market on the regulatory processes needed for US and EU commercialisation.

OrthoPure XT

Lachman test



Source: www.orthoinfo.org

OrthoPure XT is a decellularised xenograft tendon being developed as a regenerative scaffold for the treatment and repair of anterior cruciate ligaments (ACL). Currently tendon repairs are made using autografts which are derived from a patient's own tendon which are associated with significant co-morbidity, and allografts derived from human cadaver for which there is an inadequate supply.

Clinical update

In late 2015, TRX commenced a single arm, multi-centre clinical trial with OrthoPure XT in Europe (ClinicalTrials.gov identifier: NCT02540811). The non-comparative clinical investigation had a target of 40 patients with either a partial or complete ACL tear/rupture. Following surgical implantation with OrthoPure XT the primary end-point had two objectives:

- **Performance** – Lachman[1], Pivot Shift[2] and Arthrometer readings (side-to-side difference in mm) of knee joint stability compared to that of the un-operated knee
- **Safety** – frequency and seriousness of any potential adverse events

[1] The Lachman test is a passive accessory movement test of the knee performed to identify the integrity of the anterior cruciate ligament (ACL)

[2] The pivot shift test is the most specific clinical test as it is able to accurately indicate an anterior cruciate ligament (ACL) rupture.

The secondary end-point assesses

- **Improvement** – subjective score of the patient about functional improvement in terms of symptoms, sport activity and ability to function in a 24 months' timeframe
- **Integration** – MRI scan evidence of integration of the implant into the patient's own tissue

OrthoPure XT clinical trial	
	Comment
Patients	40 patients, 9 sites in UK, Poland and Spain
Primary objective	Safety and performance (side to side knee movement)
Secondary objective	Improvement in knee function
Outcomes	Measured at 3, 6, 12 and 24 months: Lachman and pivot shift test, VAS, IKDC, KOOS and LYSHOLM at 0, 3, 12, and 24 months MRI follow-up at 3, 12 and 24 months Arthrometer readings at 0, 3, 6, 12 and 24 months
Inclusion criteria	Partial or complete ACL tear 18 to 60 years Normal ACL on contralateral knee ICS classification Grade I or II
Exclusion criteria	No previous ACL surgery on target knee No surgical intervention on target knee in prior 3 months Current ACL injury on contralateral knee Meniscal repairs on target knee requiring >33% meniscectomy

Source: www.clinicaltrial.gov; Tissue Regenix

Earlier CE Mark – 4Q 2016

Tissue Regenix has been encouraged by very positive preliminary data from this on-going trial in Europe. As a consequence, the company is planning to file via its Notified Body for CE mark earlier than previously expected and is now anticipating approval for commercialisation before the end of 2016, about six months earlier than previously forecast.

US strategy

Data from the EU trial have encouraged management to open discussions with the FDA about a process whereby OrthoPure XT can obtain US regulatory approval. The company is planning, in coming months, to apply for permission to start a pilot clinical study for OrthoPure XT.

This represents a significant milestone and a successful outcome would pave the way for a larger clinical study that would be the foundation for an application for Pre-Marketing Approval (PMA) in the US. Historically, around 300 patients were required for PMA for a Class III medical device, which was time consuming and costly. However, in recent years there have been several examples of successful PMA applications for Class III medical devices following 1 x 120 patient multi-centre trial or 2 x 75 patient trials.

Agreement with the FDA for a small pilot study would likely expedite the pivotal study. Such a study could be funded by TRX alone or in collaboration with a commercial partner. This decision will become clearer once the European CE Mark trials have been completed. Although this is all very positive for a US launch, such an event is unlikely before 2020.

OrthoPure XM

OrthoPure XM is a decellularised porcine meniscus being developed as a regenerative scaffold for the meniscal tear market. The current standard-of-care is repair the meniscus wherever and whenever possible and, if not, a partial meniscectomy. During the partial meniscectomy of damaged tissue, the goal is to use OrthoPure XM to replace any removed tissue. The recent announcement also updated the market on trial progress and regulatory approach for OrthoPure XM.

Clinical trial

In March 2015, TRX commenced an open non-comparative clinical study (ClinicalTrial.gov Identifier: NCT02270905) assessing the safety and efficacy of OrthoPure XM in patients with chronic pain, following a previously failed meniscal repair or partial meniscectomy.

The primary objective of the interventional study is to generate sufficient data to obtain approval in Europe in the form of CE Mark. The aim of the investigation is:

- **Primary end-point** – To assess the pain relief obtained from the implant measured by Visual Analog Scale (VAS)
- **Secondary end-point** – To measure functional improvement in the knee using patient questionnaires

MRI scans will also be performed to assess the integration of the dCELL meniscus within that of the recipient's remaining meniscus.

OrthoPure XM – clinical trial

	Comment
Patients	60 patients, 9 sites in UK, Poland and Spain
Primary objective	Safety and performance in improving pain
Secondary objective	Improvement in knee function
Outcomes	Measured at 3, 6, 12 and 24 months: VAS, IKDC, KOOS and LYSHOLM at 0, 3, 12, and 24 months MRI follow-up at 3, 12 and 24 months
Inclusion criteria	Irreparable medial or lateral meniscus tear or loss with intact rim 18 to 55 years Stable knee joint ICRS (International Cartilage Repair Society) Grade I or II No more than 3 surgeries on involved meniscus
Major exclusion criteria	Total meniscal loss Significant malalignment of knee Advanced osteoarthritis Concomitant surgery required

VAS – Visual Analogue Scale, IKDC – International Knee Documentation Committee Score; KOOS – Knee injury and Osteoarthritis Outcome Score; LYSHOLM – Lysholm knee score
Source: www.clinicaltrial.gov; Tissue Regenix

Provisional results and implant update

Preliminary results as observed on MRI scans indicate that the OrthoPure XM implant is biocompatible and has become integrated in the patient's own tissue. Moreover, surgeons involved in the study suggested some revisions to the product that will result in a single product format. From a long-term commercial perspective, a single commercial format will have obvious advantages. Therefore, TRX announced its intention to commence a second EU clinical trial to supersede the initial study.

Those patients currently enrolled in the initial clinical trial will still be monitored. However, any future recruits/studies will use the newer version of the product.

Consequently, when CE Mark is eventually received, TRX will have a simpler commercial offering. The market update indicated that the application to begin a new trial using the revised implant will be made in 4Q 2016. If all goes according to plan, OrthoPure XM is expected to be launched in Europe during 2018.

Change to US regulatory process

At the time of publication of our initiation report on TRX (January 2016), there was no predicate device on the US market against which OrthoPure XM could be compared. This meant that the company would need to embark on the costly and time consuming PMA process in order to obtain approval for commercialisation from the FDA. However, Tissue Regenix has identified a route to market via a 510(k) market clearance pathway, which is a much easier and less costly process.

In order to gain the 510(k) market clearance, some preliminary pre-clinical work is needed, followed by a small clinical trial. A clinical study will then complement this initial work. This would suggest approval shortly after 2020.

Regulatory summary

A summary of the different regulatory processes involved is on the following page. From the perspective of Tissue Regenix the following table summarises the different regulatory pathways which the company must comply with in core geographic territories, in order to gain clearance and approval to market for its orthopaedic pipeline.

Orthopaedic regulatory pathway

	US		Europe	
Product	**Pathway**	**Clearance/ Approval**	**Pathway**	**Clearance/ Approval**
OrthoPure HM	HCT/P 361	2017	n/a	n/a
OrthoPure HT	HCT/P 361	2017	n/a	n/a
OrthoPure XM	510(k)	2020+	CE Mark	2018
OrthoPure XT	PMA	2020+	CE Mark	2017

Source: Company reports; Hardman & Co Life Sciences Research

Regulation – route to market

The following represents a short summary of the regulatory processes mentioned in this report for approval of products in the US and Europe, such as TRX's orthopaedic implants for tissue repair.

US

The route to market is dependent on the origin of the tissue and existence of predicates. For non-human tissue, the FDA recognises three classes of medical devices: Class I, II, and III. TRX is developing Class II and III devices for which an application for Pre-Market Approval (PMA) or 510(k) must be made.

Pre-market Approval (PMA)

PMA submissions are required for Class III implantable medical devices for which there is no predicate device, e.g. OrthoPure XT. The standard is high and requires formal clinical studies to demonstrate both safety and efficacy to support the claims made for the device. Such studies require a higher number of patients and possibly longer trials. This is a costly option but brings a 'first-in-class' position, which commands higher margins.

510(k) Clearance

The 510(k) process can be used, even for Class III medical devices, where a predicate device for the same indication is already approved and available. Under a 510(k) submission, the company must provide evidence that its device is substantially equivalent to the predicate device. The FDA typically takes 90 days to clear the device, ask questions, or reject the application.

HCT/P 361

Products using human donor are subject to a different regulatory pathway – namely HCT/P. Human cells or tissue intended for implantation, transplantation, infusion, or transfer into a human recipient is regulated by the US Center for Biologics Evaluation and Research (CBER). Where the product is minimally manipulated, intended for homologous use only, not combined with another article and has no systemic effect (except in certain situations) then the product is further classified under section 361.

Europe

CE Mark

The process for obtaining regulatory approval for Class III (highest risk) medical devices in Europe is much simpler. After a company has demonstrated in clinical trials that its device is safe, non-toxic and efficacious, all documentation is verified by an approved Notified Body in readiness for an application for CE Mark. This ensures that the device and its intended use and meets all regulatory requirements of the Medical Devices Directive. Once all processes and documentation is verified by the Notified Body, CE Mark usually takes about 60 days.

EU Tissue & Cells Directive

These directives were established to harmonise the approach to regulation of human tissues and cells across Europe. They set a benchmark for standards that must be met when carrying out any activity involving tissues and cells for human application (patient treatment). The Directives also require that systems are in place to ensure that all tissues/cells used in human application are traceable from donor to recipient.

Financial update

- **Sales** – Although 2016 sales were about double our forecast, we have left expectations for 2017 and 2018 broadly unchanged until we see evidence of greater traction
- **OrthoPure XT** – Sales forecasts may need to be adjusted upwards given the increased probability that OrthPure XT will receive CE Mark in late 2016
- **Costs** – Significant infrastructure costs associated with commercialisation of the products are expected to be incurred in each of the next three years

Profit & Loss account

Year end Jan (£000)	2013	2014	2015	2016	2017E	2018E	2019E	2020E
Sales	**49**	**6**	**100**	**816**	**2,217**	**6,166**	**13,708**	**27,484**
COGS	0	0	-32	-154	-580	-1,557	-3,576	-7,206
Gross Profit	**49**	**6**	**68**	**662**	**1,637**	**4,609**	**10,132**	**20,278**
Gross margin				81.1%	73.8%	74.8%	73.9%	73.8%
SG&A	-2,257	-3,133	-1,766	-3,672	-7,372	-9,427	-11,826	-15,268
R&D	-2,122	-3,356	-3,296	-3,676	-6,000	-8,000	-8,000	-5,000
Underlying EBITDA	**-4,256**	**-6,359**	**-8,038**	**-9,861**	**-11,735**	**-12,818**	**-9,694**	**10**
Deprec & Amortis	-74	-124	-151	-245	-245	-270	-284	-298
Licensing/Royalties	0	0	0	0	0	0	0	0
Other income	0	0	0	0	0	0	0	0
Underlying EBIT	**-4,330**	**-6,483**	**-8,189**	**-10,106**	**-11,980**	**-13,088**	**-9,977**	**-288**
Share based costs	-82	-94	-180	-136	-176	-196	-216	-236
Exceptional items	0	0	0	0	0	0	0	0
Statutory Operating profit	-4,412	-6,577	-8,369	-10,242	-12,156	-13,284	-10,193	-524
Net financial income	440	274	168	213	159	61	113	26
Pre-tax profit	**-3,890**	**-6,209**	**-8,021**	**-9,893**	**-11,821**	**-13,027**	**-9,865**	**-261**
Exceptional items	0	0	0	0	0	0	0	0
Reported pre-tax	-3,972	-6,303	-8,201	-10,029	-11,997	-13,223	-10,081	-497
Reported taxation	474	710	620	527	735	1,200	1,600	1,600
Underlying net income	**-3,416**	**-5,499**	**-7,401**	**-9,366**	**-11,085**	**-11,827**	**-8,265**	**1,339**
Statutory net income	-3,498	-5,593	-7,581	-9,502	-11,261	-12,023	-8,481	1,103
Period-end shares (m)	653	653	654	760.1	760.1	760.1	760.1	760.1
Weighted average shares (m)	635	636	637	748.2	748.2	748.2	748.2	748.2
Fully diluted shares (m)	653	673	676	789.7	801	801.1	801.1	801.1
Underlying Basic EPS (p)	**-0.54**	**-0.87**	**-1.16**	**-1.25**	**-1.46**	**-1.56**	**-1.09**	**0.18**
Statutory Basic EPS (p)	-0.55	-0.88	-1.19	-1.27	-1.48	-1.58	-1.12	0.15
U/l Fully-diluted EPS (p)	**-0.52**	**-0.82**	**-1.10**	**-1.19**	**-1.38**	**-1.48**	**-1.03**	**0.17**
Stat. Fully-diluted EPS (p)	-0.54	-0.83	-1.12	-1.20	-1.41	-1.50	-1.06	0.14
DPS (p)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Growth								
Sales	n/a	-88%	1567%	716%	172%	178%	122%	100%
Operating ratios								
Cost of goods	0.0%	0.0%	32.0%	18.9%	26.2%	25.2%	26.1%	26.2%
Gross margin	n/a	n/a	n/a	81.1%	73.8%	74.8%	73.9%	73.8%
SG&A	n/a	n/a	n/a	450%	332%	153%	86%	56%
R&D	n/a	n/a	n/a	450%	271%	130%	58%	18%

Source: Hardman & Co Life Sciences Research

Balance sheet

- **Net cash** – TRX ended FY2016 with net cash of £19.9m, having just raised net proceeds of £19m (January 2016). Our forecasts indicate that net cash will be £7.7m at the end of fiscal 2017
- **Investment** – Our forecasts assume that TRX continues to invest behind its pipeline of products which include appropriate PMA/510(k) studies with OrthoPure XM and XT in the US which will cost around $15m (£11m)
- **Fund raise** – Based on current expectations, we would anticipate a further fund raise during fiscal 2018 for further investment in the clinical programmes for regulatory approval and working capital for commercialisation. Alternatively, this could come potentially from a licensing deal

Balance sheet

@31st Jan (£000)	2013	2014	2015	2016	2017E	2018E	2019E	2020E
Shareholders' funds	24,466	18,978	11,578	21,239	9,978	17,955	9,474	10,577
Cumulated goodwill	0	0	0	0	0	0	0	0
Total equity	24,466	18,978	11,578	21,239	9,978	17,955	9,474	10,577
Share capital	3,264	3,267	3,271	3,801	3,801	3,801	3,801	3,801
Reserves	21,202	15,711	8,307	17,438	6,177	14,154	5,673	6,776
Capitalised R&D	3,355	5,632	7,450	9,239	12,720	17,254	20,870	20,997
Long-term loans	0	0	0	0	0	0	0	0
Short-term loans	0	0	0	0	0	0	0	0
less: Cash & securities	24,206	18,483	10,257	19,907	7,673	14,064	3,271	991
Invested capital	**3,615**	**6,127**	**8,771**	**10,571**	**15,024**	**21,145**	**27,073**	**30,582**
Fixed assets	238	472	435	901	1,533	2,373	3,478	4,916
Intangible assets	0	0	0	0	0	0	0	0
Capitalised R&D	3,355	5,632	7,450	9,239	12,720	17,254	20,870	20,997
Inventories	0	0	34	64	249	632	1,361	2,821
Trade debtors	*2*	*0*	*40*	*398*	*207*	*574*	*1,361*	*2,821*
Other debtors	*705*	*1,127*	*1,907*	*1,927*	*1,927*	*1,927*	*1,927*	*1,927*
Trade creditors	*-205*	*-368*	*-312*	*-501*	*-186*	*-459*	*-953*	*-1,693*
Tax liability	*-54*	*-55*	*-73*	*-72*	*0*	*0*	*0*	*0*
Other creditors	*-426*	*-681*	*-710*	*-1,385*	*1,948*	*2,042*	*2,335*	*3,056*
Debtors less creditors	22	23	852	367	523	886	1,363	1,848
Invested capital	**3,615**	**6,127**	**8,771**	**10,571**	**15,024**	**21,145**	**27,073**	**30,582**

Source: Hardman & Co Life Sciences Research

Key mtrics

@31st Jan (£000)	2013	2014	2015	2016	2017E	2018E	2019E	2020E
Net cash/(debt)	24,206	18,483	10,257	19,907	7,673	14,064	3,271	991
Net debt/equity (%)	98.9%	97.4%	88.6%	93.7%	76.9%	78.3%	34.5%	9.4%
After-tax ROIC	-94.5%	-89.8%	-84.4%	-88.6%	-73.8%	-55.9%	-30.5%	4.4%
Interest cover (x)	-	-	-	0.0	0.0	0.0	0.0	0.0
Dividend cover (x)	-	-	-	0.0	0.0	0.0	0.0	0.0
Cap-ex/depreciation (x)	2.1	2.9	0.8	2.9	3.5	4.1	4.9	5.8
Cap-ex/sales (%)	316.3%	5966.7%	114.0%	87.1%	40.1%	18.0%	10.1%	6.3%
Net asset value/share (p)	3.9	3.0	1.8	2.8	1.3	2.4	1.2	1.4
Stock days	-	-	-	29	60	55	50	50
Debtor days	-	-	-	178	50	50	50	50
Creditor days	-	-	-	1,187	45	40	35	30

Source: Hardman & Co Life Sciences Research

Cashflow

- TRX has utilised increasing levels of cash over each of the last four years as it has ramped up both marketing and development capabilities across a broad pipeline of product families
- The incremental increase (ca.£9-10m estimate) in R&D investment in 2017 and 2018 is to fund clinical studies for OrthoPure XM/XT in the US, which drops straight through the cashflow statement
- Free cash outflows are forecast to continue to rise, peaking in FY2018 at ca.£13-14mm after which DermaPure becomes sufficiently well established to begin to offset the underlying burn
- Our forecasts do not assume any revenues from OrthoPure XM/XT in the US. In the event that TRX markets OrthoPure XM/XT on its own in the US, there would likely to an increase in investment and working capital towards the end of the decade. In contrast, a decision to out-license or partner the product could result in an up-front milestone receipt.

Cashflow

Year end Jan (£000)	2013	2014	2015	2016	2017E	2018E	2019E	2020E
Operating profit/(loss)	-4,412	-6,577	-8,369	-10,242	-12,156	-13,284	-10,193	-524
Depreciation	74	124	151	245	257	270	284	298
Amortisation	0	0	0	0	0	0	0	0
Inventories	0	0	-34	-30	-185	-383	-730	-1,460
Working capital	-86	238	-213	266	-124	-94	-294	-720
Share based payment	82	94	180	136	176	196	216	236
Company op cashflow	**-4,342**	**-6,121**	**-8,285**	**-9,625**	**-12,031**	**-13,295**	**-10,717**	**-2,170**
Net interest	440	274	168	213	159	61	113	26
Tax	239	474	0	620	527	735	1,200	1,600
Operational cashflow	-3,663	-5,373	-8,117	-8,792	-11,345	-12,498	-9,404	-544
Capital expenditure	-155	-358	-114	-711	-889	-1,111	-1,389	-1,736
Sale of fixed assets	0	0	0	0	0	0	0	0
Free cashflow	**-3,818**	**-5,731**	**-8,231**	**-9,503**	**-12,234**	**-13,609**	**-10,793**	**-2,280**
Dividends	0	0	0	0	0	0	0	0
Other investments	0	0	0	0	0	0	0	0
Cashflow after investments	**-3,818**	**-5,731**	**-8,231**	**-9,503**	**-12,234**	**-13,609**	**-10,793**	**-2,280**
Share repurchases	0	0	0	0	0	0	0	0
Share issues	3	8	5	19,019	0	20,000	0	0
Change in net debt	**-3,815**	**-5,723**	**-8,226**	**9,525**	**-12,234**	**6,391**	**-10,793**	**-2,280**
Opening net cash	28,021	24,206	18,483	10,257	19,907	7,673	14,064	3,271
Closing net cash	**24,206**	**18,483**	**10,257**	**19,782**	**7,673**	**14,064**	**3,271**	**991**
Hardman cashflow/share (p)	-0.6	-0.8	-1.3	-1.2	-1.5	-1.6	-1.2	-0.1

Source: Hardman & Co Life Sciences Research

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Hardman & Co Research Limited (trading as Hardman & Co)
11/12 Tokenhouse Yard
London
EC2R 7AS
T +44 (0) 207 929 3399

Follow us on Twitter @HardmanandCo

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Hardman Team

Management Team

+44 (0)20 7929 3399

John Holmes	jh@hardmanandco.com	+44 (0)207 148 0543	Chairman
Keith Hiscock	kh@hardmanandco.com	+44 (0)207 148 0544	CEO

Marketing / Investor Engagement

+44 (0)20 7929 3399

Richard Angus	ra@hardmanandco.com	+44 (0)207 148 0548
Max Davey	md@hardmanandco.com	+44 (0)207 148 0540
Antony Gifford	ag@hardmanandco.com	+44 (0)7539 947 917
Vilma Pabilionyte	vp@hardmanandco.com	+44 (0)207 148 0546

Analysts

+44 (0)20 7929 3399

Agriculture		**Bonds**	
Doug Hawkins	dh@hardmanandco.com	Brian Moretta	bm@hardmanandco.com
Yingheng Chen	yc@hardmanandco.com		
Meghan Sapp	ms@hardmanandco.com		
Building & Construction		**Consumer & Leisure**	
Tony Williams	tw@hardmanandco.com	Mike Foster	mf@hardmanandco.com
Mike Foster	mf@hardmanandco.com	Steve Clapham	sc@hardmanandco.com
Financials		**Life Sciences**	
Brian Moretta	bm@hardmanandco.com	Martin Hall	mh@hardmanandco.com
Mark Thomas	mt@hardmanandco.com	Dorothea Hill	dmh@hardmanandco.com
		Gregoire Pave	gp@hardmanandco.com
Media		**Mining**	
Derek Terrington	dt@hardmanandco.com	Ian Falconer	if@hardmanandco.com
Oil & Gas		**Property**	
Stephen Thomas	st@hardmanandco.com	Mike Foster	mf@hardmanandco.com
Mark Parfitt	mp@hardmanandco.com		
Services		**Special Situations**	
Mike Foster	mf@hardmanandco.com	Steve Clapham	sc@hardmanandco.com
		Paul Singer	ps@hardmanandco.com
Technology		**Utilities**	
Mike Foster	mf@hardmanandco.com	Nigel Hawkins	nh@hardmanandco.com

Hardman & Co

11/12 Tokenhouse Yard
London
EC2R 7AS
United Kingdom

Tel: +44(0)20 7929 3399
Fax: +44(0)20 7929 3377

www.hardmanandco.com