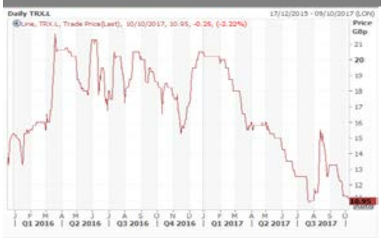
11th October 2017

hardman&co

Pharmaceuticals & Biotechnology



Source: Eikon Thomson Reuters

Market data

EPIC/TKR	TRX
Price (p)	11.0
12m High (p)	21.0
12m Low (p)	10.7
Shares (m)	1161.8
Mkt Cap (£m)	127.8
EV (£m)	104.9
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

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www.tissueregenix.com

Key shareholders

Directors	4.9%
Invesco	29.0%
Woodford Inv. Mgmt.	25.1%
IP Group	13.8%
Baillie Gifford	4.3%

Diary

10-Aug	Hardman CellRight report
1Q-18	2017 Final Results

Analysts

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Tissue Regenix

Dual revenue stream growth

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 the launch of DermaPure, focus has been on expanding in the US wound care and orthopaedic markets: in August 2017, TRX acquired CellRight Technologies, bringing in synergistic bone regeneration technology. FY'17 results will be the first to reflect the acquisition and will include 5 months of the enlarged entity. The 1H'17 results presented here are for stand-alone TRX, and show organic growth, both from the EU jv and from DermaPure, to a £1.38m total.

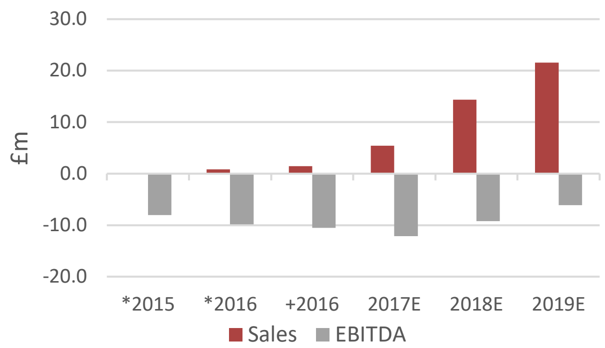
- **Strategy**: To build a regenerative medicine business with a portfolio of products using the proprietary dCELL platform; underpinned by compelling clinical and economic outcomes to drive higher adoption rates; whilst retaining the strategic and corporate flexibility that the three therapeutic corporate entities provide.
- **Interims**: TRX reported 1H'17 results to end June 2017, not affected by CellRight, with sales beating our forecast by +£0.20m to £1.38m. Net cash was better than expected at £3.61m on 30th June, subsequently strengthened by the £40m capital increase for working capital and the acquisition of CellRight.
- **Sales:** Both DermaPure (US) and GBM-V (jv in EU) sales were above expectations by around £0.1m each. Reported growth was +118% to £1.38m (£0.63m); note, there were no jv sales in 1H'16 and the accounting date changed. Transitioning to more in-patient activity saw underlying DermaPure sales grow +13% to $1.1m.
- **Acquisition:** Post-period end, TRX completed the acquisition of CellRight Technologies in San Antonio, Texas for up to $30m/£23m, immediately giving greater exposure to the US orthopaedic market. TRX paid 3.8x prospective EV/sales and 12.5x EV/EBITDA for CellRight, which has traded profitably since 2014.
- **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. CellRight will boost FY2017 and accelerate the time to reach sustainable profitability and cash generation.

Financial summary and valuation

Year end Dec (£000)	*2015	*2016	+2016	2017E	2018E	2019E
Sales	100	816	1,443	5,150	13,000	21,254
EBITDA	-8,038	-9,861	-10,549	-12,250	-9,765	-6,220
Underlying EBIT	-8,189	-10,106	-10,850	-13,164	-11,445	-7,914
Reported EBIT	-8,369	-10,242	-11,060	-15,414	-11,715	-8,204
Underlying PTP	-8,021	-9,893	-10,736	-12,976	-11,388	-7,905
Statutory PTP	-8,201	-10,029	-10,946	-15,226	-11,658	-8,195
Underlying EPS (p)	-1.2	-1.3	-1.3	-1.3	-0.9	-0.6
Statutory EPS (p)	-1.2	-1.3	-1.3	-1.6	-0.9	-0.6
Net (debt)/cash	10,257	19,907	8,173	13,938	2,275	6,391
Capital increases	5	19,019	0	38,000	0	11,400
P/E (x)	-	-	-	-	-	-
EV/sales (x)	-	-	-	20.4	8.1	4.9

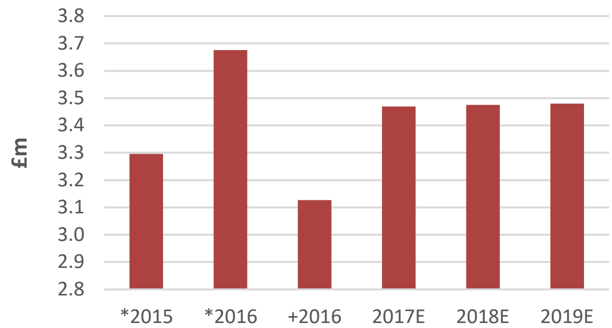
**Year to January; +11-months to December*
Source: Hardman & Co Life Sciences Research

Sales and EBITDA



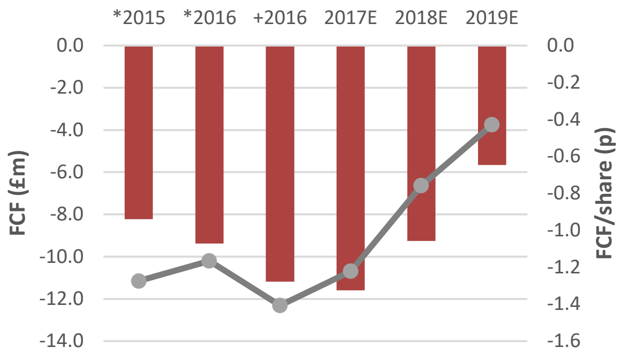
- Sales grew a reported 118% to £1.4m driven by DermaPure sales in the US and by GBM-V sales in Europe
- *Pro forma* sales growth of DermaPure in the US was estimated at +13% to $1.1m/£0.9m ($0.9m/£0.7m)
- Total sales of £5.4m are projected in 2017 due to increased US market penetration and consolidation 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



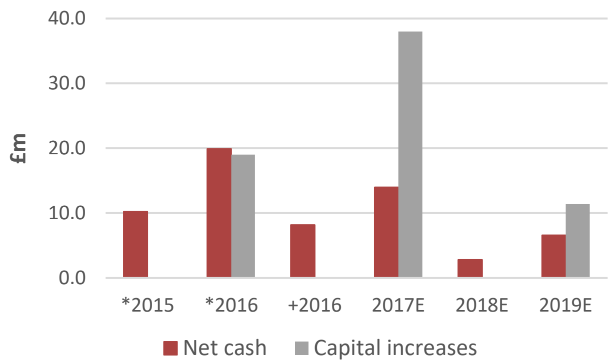
- R&D spend was -£1.8m for 1H'17, lower than anticipated due to ongoing capitalisation of R&D investment
- Capitalisation of some R&D spend on approved products is likely to continue going forward
- A total of -£12-13m R&D investment is expected over the next three years, largely on US trials of OrthoPure products

Free cashflow



- Free cashflow was -£4.6m in the interim 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 £3.6m on 30th June 2017, better than forecast by around +£2.3m
- Forecasts were adjusted for the £40m cash raise to fund the CellRight acquisition and working capital needs
- With average monthly cash burn of ca.£0.8-1.0m, forecasts are assuming a further fundraise during 1H 2019
- 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*

Key features

Operational

- **DermaPure accounts:** The focused strategy implemented in FY 2016 to target major US hospital members of TRX's agreed Group Purchasing Organisations (GPOs) is starting to impact sales. New account approvals were secured this half
- **GBM-V jv:** Good sales development through the European joint venture in Germany, which is still exclusively offering cryo-preserved human corneas. Steps have been taken to make additional cryo-preserved tissues available and to reduce supply/demand risk
- **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

Financial

- **Sales:** Six-month results to end June 2017 were not affected by CellRight; sales (DermaPure in US and GBM-V jv in EU) beat expectations by +£0.20m to £1.38m. Reported growth was +118% to £1.38m (£0.63m six-months to end July 2016)
- **DermaPure:** Underlying DermaPure sales growth was +13% to $1.07m/£0.85m (Hardman 1H'16 *pro forma* estimate: $0.94m/£0.67m). This was around £0.1m above expectations – early impact from the new, in-patient focused sales strategy
- **Joint venture:** Sales of cryo-preserved human corneas in Europe were €0.61m/£0.52m (no sales in 1H'16) from GBM-V
- **COGS:** Gross margins reduced from 81.1% in 1H'16 to 63.1% in 1H'17. This was due to the different mix of business, the inclusion of GBM-V with lower margins, and the use of sample units of DermaPure to target US accounts
- **R&D:** Investment in R&D was lower (by -£0.50m) than in the corresponding 2016 period, reaching -£1.75m for 1H'17. In part, this was due to the modest ongoing R&D investment in woundcare products being capitalised, whereas historically all R&D has been written off
- **SG&A:** Sales and marketing spend was -£4.43m (-£3.65m), in line with ongoing investment in DermaPure US commercialisation such as the focused strategy to target specific hospital members of GPO networks
- **Underlying EBIT:** Above expectations by +£1.24m to -£5.31m (-£5.39m)
- **Going concern:** Net cash at 30th June 2017 was £3.61m, better than forecast by +£2.3m due to strict control on working capital. The capital increase is forecast to extend the runway for the enlarged group through to 1H 2019

Post-period

- **Acquisition:** TRX acquired CellRight Technologies in San Antonio, Texas, for up to $30m/£23m, providing immediate greater exposure to the US market
- **Fundraise:** TRX raised £40m of gross new funds via an institutional Placing and directors' Subscription @10p per share in order to make the acquisition and provide working capital
- **Management:** New structure implemented in the US, with the founder and CEO of CellRight – Jesus Hernandez – now leading the enlarged group in the US and acting as Chief Scientific Officer for the group.

US growth

DermaPure

Source: Tissue Regenix

Role of GPOs

Source: Hardman & Co Life Sciences Research

DermaPure progress

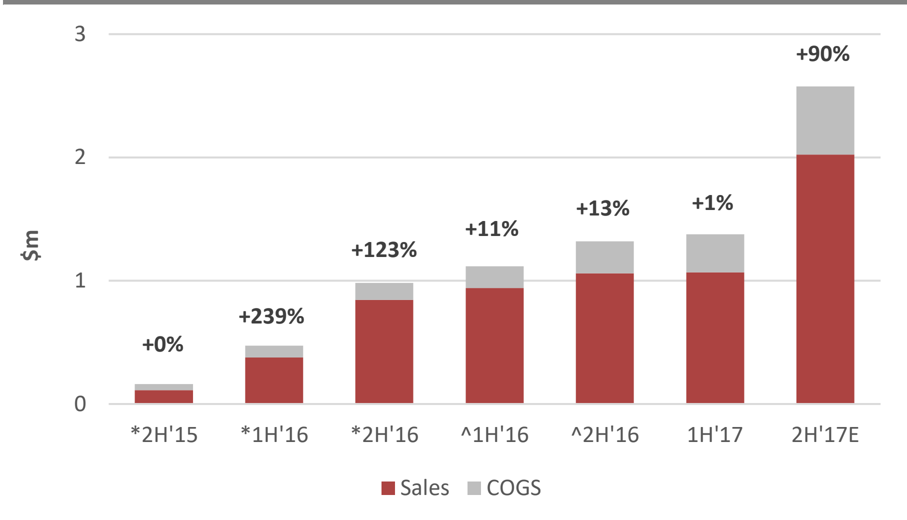
DermaPure is an allograft product made from donated human dermis using TRX's proprietary dCELL technology platform. Its target market is the advanced care of acute and chronic wounds such as severe hard-to-heal ulcers occurring in diabetic patients. The strategy to expand access across the US wound care market, first via Medicare for out-patients and then via Group Purchasing Organisations (GPOs) for the in-patient population, is starting to accelerate sales.

Latest sales figures for DermaPure during 1H'17 were £0.85m, around +£0.1m above expectations. The corresponding 2016 interim period was part of the fiscal year in which the accounting reference date changed, the result being an 11-month period from February to December being reported in FY 2016. For a reference, we estimated *pro forma* 1H'16 DermaPure sales to be $0.94/£0.67m; underlying DermaPure sales growth was therefore around +13% on 1H'16.

This uplift is likely to include the initial effects of the focused sales strategy outlined at the end of FY 2016. The sales team is currently concentrating on major hospitals across US regions that perform a high number of wound care procedures, and which are members of the GPOs with which TRX has agreements e.g. Premier Inc.

DermaPure was launched in July 2014 (2H'15) and the first GPO contract was signed in July 2016 (Magnet), covering 1% of the market. Further gains in December 2016 (Premier) and March 2017 (Vizient) have increased market coverage to 75% (2H'16, being the year of the accounting reference date change). The trend in medical devices is for increased sales volumes towards the end of the fiscal year, partly related to commissions on sales. Combined with additional accounts through GPO channels, we forecast around £2.0m in sales for the full year. This is a reduced forecast for the full year due to increased visibility on the time lag between signing new accounts and receiving first sales. Margins on DermaPure were slightly down at 71% in 1H'17 (81%) because of sample units directed to target accounts; we expect, therefore, an increase to 73% for the full year.

DermaPure sales



** Year to January. ^Year to January - Hardman estimates for pro forma year to December*
% change = revenue growth on previous half year
Source: Hardman & Co Life Sciences Research

Prospects

For DermaPure, there are likely to be additional contract approvals from individual hospitals announced within the next few reporting periods. This, combined with out-patient, Medicare-reimbursed sales will continue to drive organic growth.

With respect to orthopaedics, the CellRight acquisition will accelerate the rate of launches in this market in 2018. Commercialisation of the orthopaedics pipeline such as the OrthoPure products is not as advanced in the US as in Europe; however, technology transfer of OrthoPure HT, the human tissue version of OrthoPure XT, can now begin. The new management structure, with the founder and CEO of CellRight – Jesus Hernandez – now leading the enlarged group in the US and acting as Chief Scientific Officer for TRX, combined with the Clinical Advisory Board and President of Orthopaedics North America, puts the group in a strong position.

In terms of regulation, Tissue Regenix is in positive initial discussions with the FDA to commence a first-in-man clinical trial for OrthoPure XT in the US in 2018.

EU growth

GBM-V

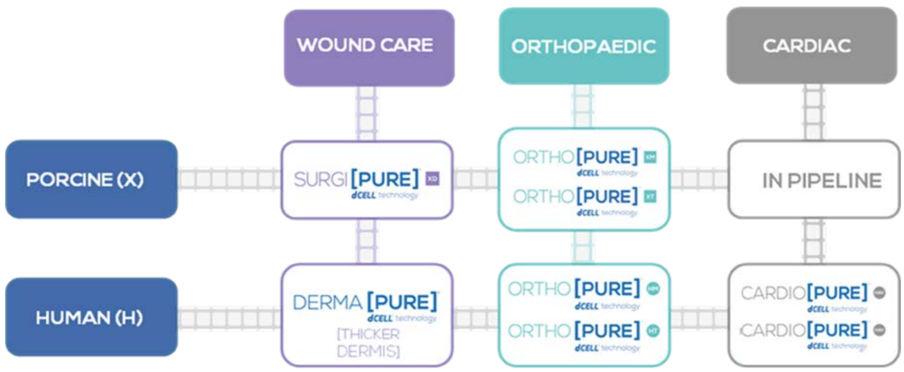
For processing of human tissue products in the EU, a joint venture multi-tissue bank, GBM-V, was successfully established in Germany in January 2016. First sales were made in the final 8 weeks of 2016 - in 1H'17, sales of human cryopreserved corneas reached £0.52m, held back slightly by the availability of donor tissue. This is being addressed; however, as a result, we have lowered forecasts to €1.0m/£0.82m sales for FY 2017.

Prospects

Between now and the end of 2018, TRX intends to launch DermaPure into the EU market. TRX is waiting on regulatory approval, which, although still expected in early 2018, is dependent on the speed of progress by the EMA. This has been affected by changes to medical device directives in the past year, one reason for the altered timeline to OrthoPure XT approval in the EU. Low initial sales are forecast in 2H'18.

The other devices in the pipeline for near term EU launch include CardioPure HAV/HPV, to be distributed via GBM-V. In addition, increased sourcing of cryopreserved tissues is underway, with additional 'non-dCELL' tissue products to be distributed going forward depending on demand.

Tissue Regenix product matrix



Source: Hardman & Co Life Sciences Research

Financial summary

Profit & Loss

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 would be about £8.45m (vs reported sales of £5.45m). Underlying *pro forma* sales growth of TRX products (ex-CellRight) and consolidation of the jv, are forecast at +90% 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**	**5,150**	**13,000**	**21,254**
COGS	-32	-154	-354	-1,822	-5,144	-7,297
Gross profit	**68**	**662**	**1,089**	**3,328**	**7,856**	**13,956**
Gross margin		81.1%	75.5%	64.6%	60.4%	65.7%
SG&A	-1,766	-7,092	-8,812	-13,022	-15,826	-18,391
R&D	-3,296	-3,676	-3,127	-3,470	-3,475	-3,480
Underlying EBITDA	**-8,038**	**-9,861**	**-10,549**	**-12,250**	**-9,765**	**-6,220**
Depreciation	-151	-245	-301	-414	-480	-494
Amortisation	0	0	0	-500	-1,200	-1,200
Other income	0	0	0	0	0	0
Underlying EBIT	**-8,189**	**-10,106**	**-10,850**	**-13,164**	**-11,445**	**-7,914**
Share based costs	-180	-136	-210	-250	-270	-290
Exceptional items	0	0	0	-2,000	0	0
Statutory operating profit	-8,369	-10,242	-11,060	-15,414	-11,715	-8,204
Net interest	168	213	114	188	57	9
Pre-tax profit	**-8,021**	**-9,893**	**-10,736**	**-12,976**	**-11,388**	**-7,905**
Exceptional items	0	0	0	0	0	0
Reported pre-tax	-8,201	-10,029	-10,946	-15,226	-11,658	-8,195
Tax payable/credit	620	527	1,034	885	886	887
Underlying net income	**-7,401**	**-9,366**	**-9,702**	**-12,091**	**-10,502**	**-7,017**
Statutory net income	-7,581	-9,502	-9,912	-14,341	-10,772	-7,307
Ordinary shares:						
Period-end (m)	654	760.1	760.1	1,161.8	1,161.8	1,221.8
Weighted average (m)	637	743.2	760.1	919.7	1,161.8	1,191.8
Fully diluted (m)	676	784.7	805.1	964.7	1,206.8	1,236.8
Underlying basic EPS (p)	**-1.16**	**-1.26**	**-1.28**	**-1.31**	**-0.90**	**-0.59**
Statutory basic EPS (p)	-1.19	-1.28	-1.30	-1.56	-0.93	-0.61
U/I Fully-diluted EPS (p)	**-1.10**	**-1.19**	**-1.21**	**-1.25**	**-0.87**	**-0.57**
Stat. Fully-diluted EPS (p)	-1.12	-1.21	-1.23	-1.49	-0.89	-0.59
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 @30th June was higher than expected at £3.6m. This has been improved by the Placing less the acquisition costs. The operational cash burn of the enlarged entity currently at about £1m per month, which suggests that TRX will have net cash of approaching £14.0m @31st December 2017 – sufficient working capital throughout 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 further working capital early in 2019; this is estimated at £12m (gross), and will give management time to assess how to fund the operations 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	37,195	26,423	30,515
Cumulated goodwill	0	0	0	0	0	0
Total equity	11,578	21,239	11,536	37,195	26,423	30,515
Share capital	3,271	3,801	3,801	5,809	5,809	6,109
Reserves	8,307	17,438	7,735	31,386	20,614	24,406
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	13,938	2,275	6,391
Invested capital	**8,771**	**10,571**	**13,569**	**32,377**	**35,197**	**35,521**
Fixed assets	435	901	1,087	3,247	3,207	3,262
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	1,697	2,715	2,487
Trade debtors	*40*	*398*	*427*	*76*	*192*	*314*
Other debtors	*1,907*	*1,927*	*2,703*	*2,203*	*1,703*	*1,203*
Tax liability/credit	*-73*	*-72*	*-147*	*885*	*886*	*887*
Trade creditors	*-312*	*-501*	*-618*	*-1,020*	*-1,683*	*-2,019*
Other creditors	*-710*	*-1,385*	*-1,300*	*-1,346*	*-1,957*	*-1,083*
Debtors less creditors	852	367	1,065	798	723	-698
Invested capital	**8,771**	**10,571**	**13,569**	**32,377**	**35,197**	**35,521**
Net cash/(debt)	**10,257**	**19,907**	**8,173**	**13,938**	**2,275**	**6,391**

**@31st January*
Source: Hardman & Co Life Sciences Research

Cashflow

TRX's cashburn is in the region of £1m per month in 2017, falling to £0.8m per month in 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, dropping to ca.£0.8m in fiscal 2018
- **Working capital:** Following the acquisition of CellRight there is likely to be a short-term increase in working capital requirement due to 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 ca.£3.5m per annum. The next key trials will be for OrthoPure XT in the US, expected to commence late 2018
- **Amortisation:** Forecasts include the amortisation of goodwill related to the CellRight acquisition being amortised over 10 years, which equates to an estimated £1.2m per annum

...suggesting that a further fundraise (ca.£12m) is needed early in 2019

- **Capital increase:** As stated earlier, our forecasts assume that TRX will raise more working capital in 2019. This needs to be in the order of £12m gross (equivalent to around net £11.4m)

Cashflow

Year end Dec (£000)	*2015	*2016	+2016	2017E	2018E	2019E
Underlying EBIT	-8,189	-10,106	-10,850	-13,164	-11,445	-7,914
Depreciation	151	245	301	414	480	494
Amortisation	0	0	0	500	1,200	1,200
Inventories	*-34*	*-30*	*-597*	*-1,036*	*-1,018*	*228*
Receivables	*0*	*-596*	*-90*	*351*	*-116*	*-122*
Payables	*0*	*862*	*106*	*402*	*663*	*413*
Change in working cap.	-213	236	-581	-283	-471	520
Other	0	0	0	0	0	0
Company op cashflow	**-8,285**	**-9,625**	**-11,130**	**-12,533**	**-10,236**	**-5,700**
Net interest	168	213	114	188	57	9
Tax paid/received	0	745	319	1,034	885	886
Operational cashflow	**-8,117**	**-8,667**	**-10,697**	**-11,311**	**-9,295**	**-4,805**
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**	**-11,663**	**-9,734**	**-5,354**
Dividends	0	0	0	0	0	0
Acquisitions	0	0	0	-20,078	-1,581	-1,581
Other investments	0	0	-550	-495	-347	-348
Cashflow after invests.	**-8,231**	**-9,378**	**-11,734**	**-32,235**	**-11,663**	**-7,284**
Share repurchases	0	0	0	0	0	0
Share issues	5	19,019	0	38,000	0	11,400
Change in net debt	**-8,226**	**9,650**	**-11,734**	**5,765**	**-11,663**	**4,116**
Opening net cash	18,483	10,257	19,907	8,173	13,938	2,275
Closing net cash	**10,257**	**19,907**	**8,173**	**13,938**	**2,275**	**6,391**
Hardman FCF/share (p)	-1.3	-1.2	-1.4	-1.2	-0.8	-0.4

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

Changes to forecasts

- **Sales:** Reduced by 19% for reasons explained earlier: time to convert new GPO accounts for DermaPure; raw material supply constraints at GBM-V; EU regulatory delays for orthopaedic approvals
- **COGS:** No changes to our product gross margin expectations, the reduction simply reflects the lower sales level and different mix
- **SG&A:** Much of the marketing costs have a direct relationship to the sales commissions; continued investment in marketing had been expected
- **EBITDA:** Losses have increased because of the leverage effect of the lower sales forecasts. In our opinion, there is scope for management to eliminate some excess cost when it has a better feel for the enlarged entity following integration of CellRight, timing of regulatory approvals, and increased activity at GBM-V
- **Net cash:** These events all flow through to the analysis of cashflow. Based on a cash burn of approximately £1m per month, the company has sufficient cash through to early 2019, by which time a better understanding of the operational requirements of the enlarged entity will be become clearer

Summary of changes to forecasts

Year end Dec (£m)		2016 PF	2017E	2018E	2019E
Sales	Old		6.71	16.59	25.27
	New	5.59	5.15	13.00	21.25
	Change		-23%	-22%	-16%
COGS	Old		-2.51	-5.87	-8.44
	New	-1.90	-1.82	-5.14	-7.30
	Change		-27%	-13%	-14%
SG&A	Old		-13.68	-16.73	-18.81
(ex-R&D; SBP)	New	-9.62	-13.02	-15.83	-18.39
	Change		-5%	-5%	-2%
R&D	Old		-3.47	-3.48	-3.48
	New	-3.45	-3.47	-3.48	-3.48
	Change		n/c	n/c	n/c
EBITDA	Old		-12.55	-9.00	-4.96
	New	-10.37	-12.25	-9.76	-6.22
	Change		+2%	-8%	-25%
EBIT	Old		-12.95	-9.48	-5.46
(underlying)	New	-10.70	-13.16	-11.45	-7.91
	Change		-2%	-20%	-45%
EPS (p)	Old		-1.30	-0.72	-0.36
(underlying basic)	New	-1.40	-1.31	-0.90	-0.59
	Change		-1%	-25%	-62%
Net cash	Old		8.59	7.75	0.60
	New	8.17	13.95	2.28	6.40
	Change		+60%	-70%*	nm

**Due to movement of anticipated capital increase from 2H 2018 into 1H 2019*
Numbers may not add up exactly due to rounding
Source: Hardman & Co Life Sciences Research

Notes

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