



20 June 2019



Source: Refinitiv

Market data

| | |
|--------------|---------|
| EPIC/TKR | TRX |
| Price (p) | 5.0 |
| 12m High (p) | 11.9 |
| 12m Low (p) | 4.8 |
| Shares (m) | 1,172.0 |
| Mkt Cap (£m) | 58.0 |
| EV (£m) | 50.2 |
| Free Float* | 41% |
| Market | AIM |

*As defined by AIM Rule 26

Description

Tissue Regenix (TRX) is a medical device company focused on regenerative medicine. Patented decellularisation technologies remove DNA, cells and other material from animal/human tissue and bone, leaving scaffolds that can be used to repair diseased or worn-out body parts. Its products have multiple applications.

Company information

| | |
|----------|----------------------------------------------------------------|
| CEO | Steve Couldwell |
| CFO | Gareth Jones |
| Chairman | John Samuel |
| | +44 330 430 3052 |
| | www.tissuregenix.com |

Key shareholders

| | |
|--------------------|-------|
| Directors | 4.3% |
| Invesco | 28.8% |
| Woodford Inv. Mgt. | 26.2% |
| IP Group | 13.7% |
| Baillie Gifford | 6.3% |
| Jupiter AM | 6.0% |

Diary

| | |
|--------|---------------------------------------|
| 27 Jun | AGM |
| 2H'19 | Potential EU approval of OrthoPure XT |

Analysts

| | | |
|---------------|---------------|----------------------------------------------------------------|
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TISSUE REGENIX

Credit facilities expand cash runway to 2021

Tissue Regenix (TRX) has a broad portfolio of regenerative medicine products for the biosurgery, orthopaedics, dental and cardiac markets. It has two proprietary decellularisation technology platforms for repair of soft tissue (dCELL) and bone (BioRinse). Following the acquisition of CellRight in the US in 2017, TRX embarked on a revised commercialisation strategy, which is clearly gaining traction. Sales grew 47% in 2018, reflecting strong demand, particularly for DermaPure in the US. To support further business expansion, including investment in facilities and working capital, credit facilities of up to \$20m/£16m have been secured.

- **Strategy:** TRX is building an international regenerative medicine business with a product portfolio using proprietary dCELL and BioRinse technology platforms, underpinned by compelling clinical outcomes. It aims to expand its global distribution network, via strategic partnerships, to drive sales momentum.
- **Credit facilities:** TRX has entered into an agreement with MidCap Financial Trust to access credit facilities composed of a term loan of \$15.0m and a revolving credit line of up to \$5m. The loan is structured into three tranches, providing cash until 2021 on current forecasts. The first \$7.5m/£5.9m tranche has been drawn down.
- **2018 results:** Sales grew 47% to £11.6m (£7.9m 2017 *pro forma*), largely driven by the US performance of DermaPure (+79%). The EBIT loss, at -£8.32m, was 14% lower helped by an overall increase in DermaPure margins. Period-end cash of £7.8m was achieved by tight control of both operating costs and working capital.
- **Risks:** TRX is exposed to many of the risks common to medical device companies, including the regulatory hurdles based on the manufacture and distribution of human tissue products, and the commercial risks of operating in a highly competitive market. A hybrid sales strategy, however, mitigates the latter.
- **Investment summary:** TRX has three near-term value drivers: sales of BioSurgery products in the US; expansion of CellRight and TRX technologies into the orthopaedics/spine and dental markets; and preparation for the EU launch of OrthoPure XT in 2019. Management has been prudent in securing a US dollar loan that relieves some of the working capital pressure during this growth period and is non-dilutive for shareholders.

Financial summary and valuation

| Year-end Dec (£m) | *2016 | 2017 | 2018 | 2019E | 2020E | 2021E |
|--------------------|--------|--------|-------|-------|-------|--------|
| Sales | 1.44 | 5.23 | 11.62 | 16.24 | 21.43 | 27.66 |
| EBITDA | -10.55 | -8.98 | -7.15 | -6.01 | -3.53 | -0.34 |
| Underlying EBIT | -10.85 | -9.69 | -8.32 | -7.20 | -4.75 | -1.59 |
| Reported EBIT | -11.06 | -10.82 | -8.69 | -7.14 | -4.70 | -1.54 |
| Underlying PBT | -10.74 | -9.64 | -8.51 | -7.51 | -5.65 | -2.52 |
| Statutory PBT | -10.95 | -10.77 | -8.88 | -7.45 | -5.59 | -2.47 |
| Underlying EPS (p) | -1.28 | -0.90 | -0.67 | -0.61 | -0.42 | -0.14 |
| Statutory EPS (p) | -1.30 | -1.02 | -0.70 | -0.61 | -0.41 | -0.13 |
| Net (debt)/cash | 8.17 | 16.42 | 7.82 | -3.72 | -6.77 | -14.69 |
| Capital increase | 0.00 | 37.99 | 0.00 | 0.00 | 7.00 | 0.00 |
| P/E (x) | - | - | - | - | - | - |
| EV/sales (x) | - | 9.6 | 4.3 | 3.1 | 2.3 | 1.8 |

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

2018 full-year results

Financials – key features

TRX making good progress on revised growth strategy outlined in 2018

In the full-year trading update (February 2019), TRX's sales growth was just ahead of expectations, rising 47% to £11.6m (from £7.90m, 2017 *pro-forma* for acquisition of CellRight in August 2017). This was driven largely by the BioSurgery business unit, which sells DermaPure branded products through three distinctive channels: a small direct salesforce, national/regional distributors, and via an exclusive strategic partnership with Arms Medical. The company is clearly making good progress in executing against the revised growth strategy that it outlined in January 2018.

- ▶ **Sales:** Sales grew 47% on a *pro-forma* basis to £11.6m (£7.9m *pro-forma*), following the acquisition of CellRight in August 2017. There was growth across all three business units, but BioSurgery performance was particularly strong.
- ▶ **BioSurgery:** There was strong demand for DermaPure products in the US, where underlying sales rose 79% to \$4.4m/£3.4m (\$2.5m/£1.9m).
- ▶ **Gross margins:** There was a 1.1ppt increase in the gross margin for the year, from 49.8% in 2017 to 50.9% in 2018, with improved sales traction from DermaPure being offset by the increased focus on distribution partners.
- ▶ **SG&A:** Although there appeared to be a large (15.2%) increase in SG&A in 2018 to -£12.61m (-£10.94m), this was due mostly to the full-year contribution of CellRight costs, the impact of which was limited by the use of distributors.
- ▶ **EBIT:** The underlying EBIT loss was £8.3m, a 14% improvement on 2017.
- ▶ **Net cash/(debt):** Cash on the balance sheet at 31 December 2018 was £7.8m, helped, in particular, by careful management of working capital and SG&A costs.

Actual results vs. expectations

When the trading statement was announced in February 2019, the 2018 year-end cash position of £7.8m was well ahead of our forecast (£6.3m). Given that working capital was already tightly controlled, we therefore reduced our operating cost forecasts for the year. However, the release of the full set of numbers on 4 June 2019 showed that, while operating costs did indeed decline in the period and were in line with our revised forecasts, management of working capital was also greater than anticipated, with a -£0.49m change, compared with our forecast -£0.74m. This was offset by the 117% growth in COGS in 2018, which was £0.61m greater than forecast, reflecting, in part, unanticipated demand for certain lower-margin DermaPure products.

| TRX – FY'18 results – actual vs. expectations | | | | | |
|-----------------------------------------------|--------------|---------------|-------------|---------------|--------------|
| Year-end Dec (£m) | 2017 actual | 2018 actual | Growth | 2018 forecast | Delta Δ |
| Sales | *7.90 | **11.62 | 47% | 11.60 | -0.02 |
| COGS | -2.63 | -5.70 | 117% | -5.09 | +0.61 |
| SG&A | -10.94 | -12.61 | 15% | -10.25 | -0.01 |
| R&D | -2.69 | -4.00 | 49% | -4.00 | +0.00 |
| Underlying EBITDA | -8.98 | -7.15 | -20% | -6.58 | +0.57 |
| Underlying EBIT loss | -9.69 | -8.32 | -14% | -7.74 | +0.58 |
| Cash position | 16.42 | **7.82 | -52% | 7.82 | +0.00 |
| Change in working capital | -1.25 | -0.49 | -61% | -0.74 | -0.25 |
| Capital expenditure | -0.13 | -0.29 | 123% | -0.3 | -0.01 |
| Net cash/(debt) | 16.42 | **7.82 | -52% | 7.82 | +0.00 |

*Pro-forma; **Reported in trading update (February 2019)
Source: Hardman & Co Life Sciences Research

Operations – key features



Source: Tissue Regenix

Following its acquisition of CellRight in August 2017, TRX embarked on a revised commercial strategy to increase sales momentum. In 2018, top-line sales growth was successfully achieved by selling BioSurgery and Orthopaedic products both directly and via distribution partners, at the same time as successfully integrating the CellRight business and leveraging operational synergies. For example, as part of the integration process, technology transfer of DermaPure production to the San Antonio facility was achieved ahead of schedule, which, along with the CTS processing and supply relationship, positions TRX to meet growing demand. We note other highlights below, most of which are detailed in our TRX 2018 news round-up note¹ (<https://www.hardmanandco.com/research/corporate-research/2018-in-review-foundations-laid-for-osteobiologics/>).

BioSurgery

Distribution

TRX is looking at ways to maximise opportunities for the enlarged group by broadening its product offering and through geographical expansion. In February 2018, the company signed an exclusive distribution agreement with the specialist urogynaecology distributor ARMS Medical, accelerating sales of DermaPure in the US and allowing TRX to focus its direct sales on the Orthopaedic Trauma, Plastics, Reconstruction and Revision Orthopaedics, Wound Care and General Surgery markets.

GPO coverage

TRX initially focused on securing Medicare reimbursement, maintaining its 100% coverage of state reimbursement. TRX has since been building relationships with US Group Purchasing Organisations (GPOs) in order to reach in-patients, particularly important for surgical procedures. GPO agreements were strengthened with the three-year contract extension with Premier, Inc in 2018; post-period, in April 2019, TRX successfully secured approval with an undisclosed GPO for even further coverage. This significantly increased the commercial opportunity for DermaPure, now potentially available to 95% of institutions that purchase via large US GPOs.

Orthopaedic and dental

HTA licence achieved

A key goal of the CellRight integration process was to obtain a Human Tissue Authority (HTA) licence to enable importation of CellRight's products from the US into the UK (and, over time, into Europe), supporting international growth. The HTA licence was received in June 2018, allowing TRX to begin identifying global distribution partners for its BioRinse portfolio.

Distribution partnerships

TRX secured a long-term, multi-year OEM distribution agreement with the specialist orthopaedic surgical solutions distributor, Arthrex Inc. (Arthrex), for the US market in March 2018. This agreement was extended to Europe in 4Q'18 with initial training for European sales reps in 1Q'19. Having Arthrex as a strategic partner is a significant achievement for TRX, not least because it has the biggest share of the Sports Medicine market, at ca.33%, and is very well-known in the field.

These agreements supported 31% *pro forma* sales growth from TRX's orthopaedics business unit in 2018 – excellent validation of the commercialisation strategy.

¹ '2018 in review: foundations laid for osteobiologics' 17 December 2018.

Post-period financing event

Credit facilities up to \$20m

To support further business expansion, credit facilities of up to \$20m/£16m have been secured with MidCap Financial Trust...

Amid the increasing demand for DermaPure products and the expanding US business, discussed above, management has been prudent in securing credit facilities of up to \$20m with MidCap Financial Trust (MidCap). MidCap is a US-based speciality finance company that provides financing to middle-market growth companies. The facilities provide TRX with considerable flexibility in managing its working capital requirements as it expands, while being non-dilutive to existing shareholders and without the risks associated with raising new capital in currently difficult market conditions.

Overall, the agreement validates the newly enlarged company (following the acquisition of CellRight in the US in 2017) and management's expansion strategy. Sales traction and visibility of cashflows is clearly at a level that is appealing to a lender. In addition, the loan, being in US dollars, provides a natural hedge against the predominantly US-derived sales.

\$7.5m drawn down post-period

The facilities are composed of two parts that, together, provide the option to draw down up to \$20m/£15m between 4 June 2019 and April 2021: i) the 'term loan' credit facility is a \$15m/£11.5m secured loan with a five-year term; ii) the 'revolver' is a \$3m/£2.3m revolving line of credit with the option for an additional \$2m/£1.5m. The term loan is available in three tranches, subject to certain conditions, as outlined in the table below. \$7.5m/£5.9m (gross) has immediately been drawn down from the term loan, which is interest-only for the first 12 months, with a further 12 months' interest-only period available, dependent on satisfying certain conditions. The interest is 6.75%, plus one-month US\$ LIBOR on the outstanding balance, subject to a one-month US\$ LIBOR floor of 2.25%.

| Term loan | | | |
|----------------|-------------------------|----------------|---------------------------------------------------------------------------------------------------|
| Dec period-end | Available | Total | Conditions |
| Tranche one | Immediately: 4 Jun 2019 | \$7.5m | Unconditional |
| Tranche two | Feb 2020 - Apr 2020 | \$5.0m | \$5.0m (net) equity proceeds Agreed revenue targets from both dCELL and BioRinse product sales |
| Tranche three | Feb 2021 - Apr 2021 | \$2.5m | Agreed revenue targets from both dCELL and BioRinse product sales |
| Total | | \$15.0m | |

Source: Hardman & Co Life Sciences Research

...a term loan of \$15.0m and a revolving line of credit up to \$5m

The revolver will be available for 60 months (from June 2019 to May 2024), with \$3m available immediately (but not yet drawn down), subject to conditions of sufficient accounts-receivable and finished-goods inventory being available as security. An additional \$2m is uncommitted. Interest on the outstanding balance of the revolver is payable monthly in arrears at an annual one-month US\$ LIBOR plus 4.5%, subject to a US\$ LIBOR floor of 2.25%. An annual rate of 0.5% is payable on the capital amount exercised but undrawn on the revolver, payable one month in arrears.

Finally, TRX has agreed to grant MidCap a 3% warrant coverage on the term loan, representing ca.\$0.45m in total, with the first warrant instrument entered into on 3 June, with the first \$7.5m drawn. This represents ca.\$0.23m/£0.17m, or 2,967,304 shares at the current share price. The exercise price is equal to the 10-day VWAP for the 10 days ahead of execution of the instrument. Similar instrument agreements will be entered into on the drawdown of Tranches two and three.

Use of proceeds

In our last note on TRX, *Expanded GPO coverage secured*, published on 10 April 2019, we suggested that, with a 2019 cash position forecast of £3.1m, TRX was likely to take on debt to fund the increasing working capital requirements and, that if progress was particularly strong, additional capital would be needed for investment in manufacturing capacity. Both requirements, for working and investment capital, are being satisfied with the current secured credit facilities.

The increasing demand for TRX's products, particularly in the US, necessitates expansion in facilities such as cleanrooms and warehousing, in addition to increasing its working capital requirements; these are driven uniquely by the drawn-out procedures for processing human tissue and by the stringent regulatory requirements at each stage. For example, processing of a single donor dermis can take five days and must be carried out in complete isolation of other donated tissue. Moreover, investment in R&D for real world clinical and outcome studies will be necessary to remain competitive when negotiating with GPOs and other payers. We anticipate that capital expenditure and R&D spend will increase from 2020. In 2019, therefore, the \$7.5m loan drawdown is expected to initially aid the management of working capital as production of DermaPure products is increased to meet demand.

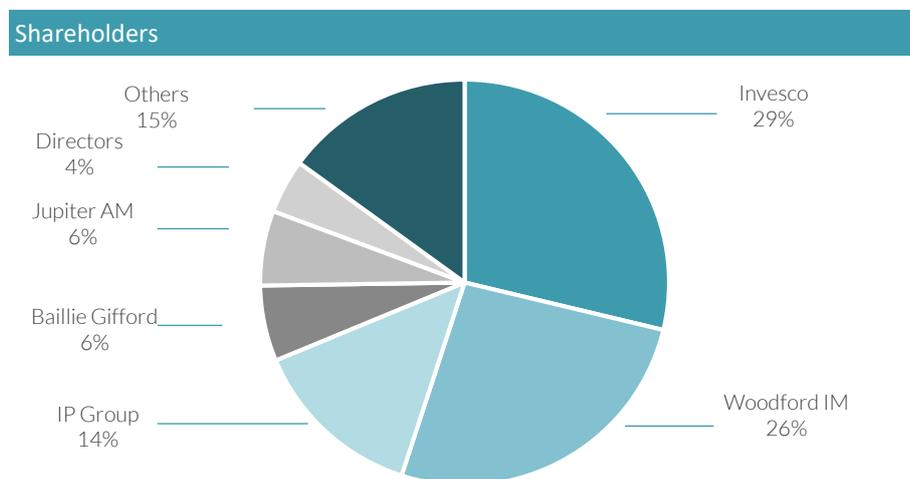
Share capital

Shareholding

TRX's share price lifted 12% on the news of the credit facility, from 5.75p to 6.5p, but it has since drifted back to 6.0p (as at Friday 14 June close), possibly as a result of media comment surrounding the suspension of the Woodford Equity Income Fund (WEIF). The Woodford Patient Capital Trust is not affected by the suspension of the WEIF. To date, there is no information to suggest that either fund has reduced its holding in TRX.

At the time of writing (14 June 2019), TRX had 1,171,971,322 shares in issue. Woodford Investment Management remains the company's second-largest shareholder (26.2% holding), with TRX comprising approximately 0.15% of the Woodford Patient Capital Trust and 0.32% of the Woodford Equity Income Fund (as of 30 April 2019).

The intrinsic value of TRX and its fundamental growth drivers remain unaffected by short-term disruption to trading of its shares. In our view, the company's ability to secure the second tranche of the loan, dependent on the agreed conditions, remains unchanged.



Source: Hardman & Co Life Sciences Research

Financials and investment case

Changes to forecasts

Forecasts updated to include all three tranches of MidCap term loan...

We last updated our TRX forecasts on 10 April 2019 in our report, 'Expanded GPO coverage secured', to reflect the 2018 sales and cash position provided in its trading statement. In this report, we have updated our sales and cash forecasts following the full release of the 2018 results and to incorporate news of the MidCap credit facility agreement that closed on 4 June 2019.

MidCap loan extends cash runway to 2021

Our forecasts assume that all three tranches of the MidCap loan are drawn down. The first \$7.5m/£5.9m tranche was drawn on 4 June 2019 to satisfy management's immediate working capital requirements and growth investment plans. However, it is insufficient to satisfy the funding requirement for forecast growth in the business over the next three years. Therefore, we also expect the second and third tranches of the loan to be drawn down at the earliest possible time, as set out in the term loan conditions. In our opinion, it is likely that TRX will both seek, and be able, to raise capital above the minimum \$5m (gross) required to meet the conditions of the second tranche drawdown in 2020. This will provide management with the maximum possible flexibility going forward, and we have included this in 2020 forecasts. Finally, we expect that TRX will refinance its debt in 2021 to allow it to cover the amortised loan payments beginning in that year.

...which provides TRX with sufficient funding into 2021

Once the pressure on working capital has moderated, the cash from the term loan is expected to be invested into the expansion of manufacturing capacity to satisfy demand, and in product differentiation via studies to generate up-to-date health economics data for both DermaPure and BioRinse products, allowing TRX to remain competitive in the US. This leaves the company with sufficient funding into 2021, at which point we anticipate that some new debt on more favourable terms will be sought.

| Net cash/(debt) | | | |
|---------------------------|--------------|--------------|---------------|
| Year-end Dec (£m) | 2019E | 2020E | 2021E |
| Change in working capital | -1.06 | -1.43 | -1.70 |
| Operating cashflow | -7.05 | -4.96 | -2.04 |
| Net interest | -0.31 | -0.90 | -3.64 |
| Capital expenditure | -2.90 | -4.06 | -2.03 |
| Capitalised R&D | -0.33 | -0.29 | -0.29 |
| Free cashflow | -9.97 | -10.05 | -7.92 |
| Cash | 2.20 | 3.09 | 1.39 |
| Net cash/(debt) | -3.72 | -6.77 | -14.69 |

Source: Hardman & Co Life Sciences Research

Challenges ahead

On the one hand, the increased demand for the mostly high margin DermaPure products is extremely positive. The increase in production has been managed within the existing facility via the introduction of a second shift operation, by transferring some clean room facilities from BioRinse to DermaPure, and by outsourcing some DermaPure supply and manufacturing to Community Tissue Services (CTS) in the US. We understand that these changes are beginning to gain traction, with increases in efficiency evident week-on-week. The resultant pressure on BioRinse does impact our 2019 sales forecasts, as detailed in the table below, although some pressure on BioRinse is expected to ease in 2H'19, resulting in back-end weighted 2019 sales. Once the planned expansion, funded by the new credit facility, is complete,

manufacturing capacity is expected to be sufficient to meet anticipated demand for both Orthopaedic and BioSurgery products.

A combination of factors, including the outsourcing of some BioSurgery manufacturing to CTS, which has some associated fixed costs, and the introduction of the second manufacturing shift, is expected to result in a reduction in gross margins in the short term. This should be partially offset by productivity and efficiency gains in 2H'19. Overall, the investment in growth will flow through to EBIT over the next three years, resulting in increased forecast losses as shown in the following table.

| Changes to forecasts | | | | | | |
|------------------------|-------------------|--------------|----------------|-------------------|--------------|----------------|
| Year-end Dec (£m) | ----- 2019E ----- | | | ----- 2020E ----- | | |
| | Old | New | Change | Old | New | Change |
| Sales | 18.67 | 16.24 | -13.0% | 25.73 | 21.43 | -16.7% |
| COGS | -7.63 | -8.75 | 14.7% | -10.37 | -10.74 | 3.6% |
| SG&A | -10.3 | -13.20 | 28.1% | -10.71 | -12.93 | 20.8% |
| Underlying EBIT | -2.76 | -7.20 | 160.8% | 1.34 | -4.75 | -454.8% |
| Reported EBIT | -3.26 | -7.14 | 119.1% | 0.84 | -4.70 | -659.3% |
| Underlying PBT | -2.75 | -7.51 | 173.0% | 1.35 | -5.65 | -518.5% |
| Underlying EPS (p) | -0.17 | -0.61 | 259.1% | 0.17 | -0.42 | -345.0% |
| Cash | 3.12 | 2.20 | -29.4% | 3.42 | 3.09 | -9.5% |
| Change in working cap. | -1.82 | -1.06 | -41.9% | -2.07 | -1.43 | -31.0% |
| Capex | -0.3 | -2.90 | 866.7% | -0.36 | -4.06 | 1027.8% |
| Free cashflow | -2.89 | -9.97 | 244.8% | 0.63 | -10.05 | -1695.5% |
| Net (debt)/cash | 3.12 | -3.72 | -219.1% | 3.42 | -6.77 | -297.9% |

Source: Hardman & Co Life Sciences Research



Source: Tissue Regenix

Conclusion and outlook

2019 is expected to be an exciting, but challenging year. The reduction in EPS from -0.17p to -0.61p for 2019E is a combination of revised sales, margin, and R&D forecasts. However, the company has recently entered a new growth phase, with its commercial strategy already validated by agreements with strategic partners such as Arthrex, and a successful FDA audit of the CellRight facilities in San Antonio in 2019. Demand for DermaPure appears to be strong, with a targeted sales philosophy delivering a strong rate of clinician adoption. In the near term, new products such as OrthoPure XT and SurgiPure XD are expected to reach the market. 2018 was a year of change, as summarised in the table below, and management's focus on signing more deals, whether strategic partnerships or out-licensing TRX's technology to maximise the opportunity while allowing a focus on existing markets, should stabilise the business into the future.

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

Source: Hardman & Co Life Sciences Research

Profit & Loss

- ▶ **Sales:** Demand for DermaPure in the US is expected to drive sales performance in fiscal 2019. Increased manufacturing capacity, efficiency and productivity looks set to deliver both BioSurgery and Orthopaedic product sales growth from early 2020. Launch of additional products is likely to boost performance in the US and the UK within the forecast period.
- ▶ **COGS:** With TRX employing a mixed sales model, in the short-term, COGS will be impacted by the signing of new distributors and tempered by the fixed salaries plus commissions associated with a smaller direct sales force.
- ▶ **Gross margin:** Volatility is expected over the forecast period. On the one hand, DermaPure gross margins are on an overall rising trend, but on the other, there are additional fixed costs associated with the outsourcing of some DermaPure manufacturing to CTS. 2019 is likely to see a rebasing of TRX's margins as the revised commercialisation strategy comes into effect, along with the absorption of the cost of the second manufacturing shift, but then trend upwards thereafter.
- ▶ **EBIT:** Control of administration costs is likely to support an improving EBIT in the forecast period. R&D investment is likely to increase from 2020, with the bottom line benefitting from an expected acceleration in sales traction.

| Profit & loss account | | | | | | |
|---------------------------------|---------------|--------------|--------------|--------------|--------------|--------------|
| Year-end Dec (£m) | *2016 | 2017 | 2018 | 2019E | 2020E | 2021E |
| GBP:USD | 1.347 | 1.289 | 1.312 | 1.312 | 1.312 | 1.312 |
| Sales | 1.44 | 5.23 | 11.62 | 16.24 | 21.43 | 27.66 |
| COGS | -0.73 | -2.63 | -5.70 | -8.75 | -10.74 | -13.07 |
| Gross profit | 0.71 | 2.61 | 5.92 | 7.49 | 10.69 | 14.59 |
| Gross margin | 49.2% | 49.8% | 50.9% | 46.1% | 49.9% | 52.8% |
| SG&A | -8.44 | -10.94 | -12.61 | -13.20 | -12.93 | -12.67 |
| R&D** | -3.13 | -1.35 | -1.64 | -1.49 | -2.51 | -3.51 |
| Underlying EBITDA | -10.55 | -8.98 | -7.15 | -6.01 | -3.53 | -0.34 |
| Depreciation | -0.30 | -0.48 | -0.60 | -0.62 | -0.65 | -0.68 |
| Amortisation | 0.00 | -0.23 | -0.58 | -0.58 | -0.58 | -0.58 |
| Other income | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Underlying EBIT | -10.85 | -9.69 | -8.32 | -7.20 | -4.75 | -1.59 |
| Share-based costs | -0.21 | -0.03 | 0.06 | 0.06 | 0.06 | 0.06 |
| Exceptional items | 0.00 | -1.10 | -0.42 | 0.00 | 0.00 | 0.00 |
| Statutory EBIT | -11.06 | -10.82 | -8.69 | -7.14 | -4.70 | -1.54 |
| Net interest | 0.11 | 0.05 | -0.19 | -0.31 | -0.90 | -0.93 |
| Underlying PBT | -10.74 | -9.64 | -8.51 | -7.51 | -5.65 | -2.52 |
| Extraordinary items | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Statutory PBT | -10.95 | -10.77 | -8.88 | -7.45 | -5.59 | -2.47 |
| Tax payable/credit | 1.03 | 1.35 | 0.62 | 0.35 | 0.58 | 0.81 |
| Underlying net income | -9.71 | -8.29 | -7.89 | -7.16 | -5.07 | -1.71 |
| Statutory net income | -9.92 | -9.42 | -8.26 | -7.10 | -5.02 | -1.66 |
| Ordinary 0.5p shares: | | | | | | |
| Period-end (m) | 760.1 | 1,171.0 | 1,171.7 | 1,172.7 | 1,263.0 | 1,264.0 |
| Weighted average (m) | 760.1 | 920.5 | 1,171.6 | 1,172.2 | 1,217.9 | 1,263.5 |
| Fully-diluted (m) | 806.6 | 960.8 | 1,224.4 | 1,225.0 | 1,270.7 | 1,316.3 |
| Underlying basic EPS (p) | -1.28 | -0.90 | -0.67 | -0.61 | -0.42 | -0.14 |
| Statutory basic EPS (p) | -1.30 | -1.02 | -0.70 | -0.61 | -0.41 | -0.13 |
| Underlying fully-dil. EPS (p) | -1.20 | -0.86 | -0.64 | -0.58 | -0.40 | -0.13 |
| Statutory fully-dil. EPS (p) | -1.23 | -0.98 | -0.67 | -0.58 | -0.39 | -0.13 |
| DPS (p) | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |

*11 months to December

**R&D restated to match the reported number, which excludes some R&D staff costs

Source: Hardman & Co Life Sciences Research

Balance sheet

- ▶ **R&D:** A modest amount of R&D investment in products that have received regulatory approval is capitalised and included in intangible assets, which will then 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.
- ▶ **Net cash/(debt):** Forecasts simply show the effect of the cashflow statement on the cash position. We have assumed that that all three tranches of the MidCap term loan are drawn down, and that with rapid progress, a capital increase above the minimum \$5m (gross) will be sought in 2020 at the time of drawing down the second tranche. In the event that there is good sales traction, TRX is likely to take on some additional, cheaper, debt to refinance the MidCap loan in 2021, allowing as much flexibility as possible going forwards.
- ▶ **Gross cash:** At the end of fiscal 2019E, we are forecasting a cash position of £2.2m, which increases to £3.1m in fiscal 2020E including drawdown of the next tranche of the loan facility.

| Balance sheet | | | | | | |
|-------------------------|--------------|--------------|--------------|--------------|--------------|---------------|
| @31 Dec (£m) | *2016 | 2017 | 2018 | 2019E | 2020E | 2021E |
| Shareholders' funds | 11.54 | 39.52 | 32.57 | 25.47 | 27.46 | 25.80 |
| Cumulated goodwill | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Total equity | 11.54 | 39.52 | 32.57 | 25.47 | 27.46 | 25.80 |
| Share capital | 3.80 | 5.86 | 5.86 | 5.86 | 6.32 | 6.32 |
| Reserves | 7.74 | 33.67 | 26.71 | 19.61 | 21.14 | 19.48 |
| Capitalised R&D | 9.24 | 10.21 | 9.28 | 8.52 | 7.56 | 7.52 |
| Long-term debt | 0.00 | 0.00 | 0.00 | 5.92 | 9.86 | 16.08 |
| Short-term loans | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| less: Cash | 8.17 | 16.42 | 7.82 | 2.20 | 3.09 | 1.39 |
| Invested capital | 12.60 | 34.76 | 34.83 | 38.49 | 42.57 | 48.79 |
| Fixed assets | 1.09 | 2.99 | 2.83 | 5.11 | 8.53 | 9.88 |
| Intangible assets | 0.55 | 19.31 | 19.94 | 21.40 | 21.40 | 21.40 |
| Capitalised R&D | 9.24 | 10.21 | 9.28 | 8.52 | 7.56 | 7.52 |
| Inventories | 0.66 | 2.87 | 2.33 | 3.26 | 4.30 | 5.55 |
| Trade debtors | 0.43 | 1.47 | 2.47 | 3.20 | 4.02 | 5.03 |
| Other debtors | 2.70 | 2.70 | 2.29 | 2.29 | 2.29 | 2.29 |
| Tax liability/credit | -0.15 | -0.82 | -0.79 | -0.65 | -0.42 | -0.19 |
| Trade creditors | -0.62 | -1.52 | -0.86 | -1.45 | -1.89 | -2.46 |
| Other creditors | -1.30 | -2.44 | -2.66 | -3.16 | -3.20 | -0.21 |
| Debtors less creditors | 1.07 | -0.61 | 0.45 | 0.21 | 0.79 | 4.46 |
| Invested capital | 12.60 | 34.76 | 34.83 | 38.49 | 42.57 | 48.79 |
| Net cash/(debt) | 8.17 | 16.42 | 7.82 | -3.72 | -6.77 | -14.69 |
| Inventory days | - | 200 | 73 | 73 | 73 | 73 |
| Debtors days | - | 102 | 77 | 72 | 68 | 66 |
| Creditor days | - | 211 | 55 | 61 | 64 | 69 |

*11 months to December

Source: Hardman & Co Life Sciences Research

Cashflow

- ▶ **Working capital:** The working capital requirement is expected to increase each year, reflecting the expansion phase of the company and an increase in production.
- ▶ **Amortisation:** The 2018 amortisation charge of £0.58m covers a full 12 months of the CellRight ownership. Amortisation costs will rise when products associated with R&D that has been capitalised R&D are launched, under IAS38.
- ▶ **Cashflow:** Operating cashflow remains negative in the forecast period, with free cashflow after investments impacted by the remainder of the acquisition costs, plus loan interest/interest, and capital payments increasing year-on-year. The increase in capex is expected to span a period of 24 to 30 months.
- ▶ **Funding:** As stated earlier, forecasts show the cash requirement over the next three years. We have included drawdown of all three tranches of the term loan in our forecasts, with the expectation that the debt will be refinanced on favourable terms in 2021.

| Cashflow | | | | | | |
|-----------------------------------|---------------|---------------|--------------|---------------|---------------|---------------|
| Year-end Dec (£m) | *2016 | 2017 | 2018 | 2019E | 2020E | 2021E |
| Underlying EBIT | -10.85 | -9.69 | -8.32 | -7.20 | -4.75 | -1.59 |
| Depreciation | 0.30 | 0.48 | 0.60 | 0.62 | 0.65 | 0.68 |
| Amortisation | 0.00 | 0.23 | 0.58 | 0.58 | 0.58 | 0.58 |
| <i>Inventories</i> | -0.60 | -0.50 | 0.54 | -0.93 | -1.04 | -1.25 |
| <i>Receivables</i> | -0.09 | -0.78 | -1.19 | -0.73 | -0.82 | -1.02 |
| <i>Payables</i> | 0.11 | 0.04 | 0.16 | 0.60 | 0.44 | 0.57 |
| Change in working capital | -0.58 | -1.25 | -0.49 | -1.06 | -1.43 | -1.70 |
| Other | 0.00 | 0.00 | 0.00 | 0.02 | 0.00 | 0.00 |
| Company op. cashflow | -11.13 | -11.33 | -8.06 | -7.05 | -4.96 | -2.04 |
| Net interest | 0.11 | 0.05 | 0.07 | -0.31 | -0.90 | -3.64 |
| Tax paid/received | 0.32 | 1.54 | 1.23 | 0.62 | 0.15 | 0.08 |
| Operational cashflow | -10.70 | -9.74 | -6.77 | -6.74 | -5.71 | -5.60 |
| Capital expenditure | -0.49 | -0.13 | -0.29 | -2.90 | -4.06 | -2.03 |
| Capitalised R&D | -0.55 | -0.09 | -0.12 | -0.33 | -0.29 | -0.29 |
| Sale of fixed assets | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Free cashflow | -11.73 | -9.96 | -7.17 | -9.97 | -10.05 | -7.92 |
| Dividends | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Acquisitions | 0.00 | -19.95 | -1.56 | -1.57 | 0.00 | 0.00 |
| Other investments | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Cashflow after investments | -11.73 | -29.91 | -8.74 | -11.53 | -10.05 | -7.92 |
| Share repurchases | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Capital increase | 0.00 | 37.99 | 0.00 | 0.00 | 7.00 | 0.00 |
| Currency effect | 0.00 | 0.17 | 0.13 | 0.00 | 0.00 | 0.00 |
| Change in net debt | -11.73 | 8.25 | -8.61 | -11.53 | -3.05 | -7.92 |
| Opening net cash/(debt) | 19.91 | 8.17 | 16.42 | 7.82 | -3.72 | -6.77 |
| Closing net cash (debt) | 8.17 | 16.42 | 7.82 | -3.72 | -6.77 | -14.69 |
| OCFPS (p) | -1.41 | -1.06 | -0.58 | -0.57 | -0.47 | -0.44 |

*11 months to December

Source: Hardman & Co Life Sciences Research

Company matters

Registration

Incorporated in the UK with company registration number 05969271

UK operations:

Unit 1&2
Astley Lane Industrial Estate
Astley Way
Swillington
Leeds
LS26 8XT

+44 330 430 3052

www.tissueregenix.com

US operations:

1808 Universal City Boulevard
Universal City
San Antonio
Texas
78148

Board of Directors

The Board consists of two executive directors and five non-executive directors. Their representation on the various committees is shown in the following table.

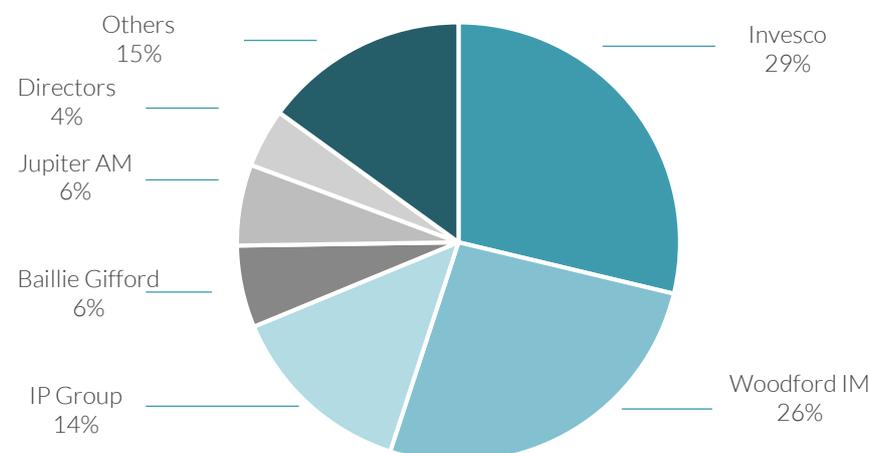
| Board of Directors | | | |
|-------------------------|-------------------------------|--------------|-------|
| Position | Name | Remuneration | Audit |
| Chairman | John Samuel | | |
| Chief Executive Officer | Steve Couldwell | | |
| Chief Financial Officer | Gareth Jones | | |
| Non-executive director | Allan Miler | M | C |
| Non-executive director | Jonathan Glenn | M | M |
| Non-executive director | Randeep Singh Grewal | C | M |
| Non-executive director | Shervanthi Homer-Vanniasinkam | | |

M = member; C = chair
Source: Company reports

Share capital

The company has 1,171,971,322 Ordinary shares of 0.5p in issue. There are also 46.8m options and ca.2.97 warrants outstanding.

Major shareholders



Source: Company reports

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