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# Oxford BioMedica

## Partnering strategy delivering profitability

**OXB is a specialist advanced therapy viral-vector biopharmaceutical company. It offers vector manufacturing and development services, while retaining proprietary drug candidates. OXB will also receive royalties on commercial products developed with its LentiVector® platform. The first half of 2018 delivered significant growth in gross income, primarily through licensing income on signing new partnership deals with Axovant Sciences (AXON) and Bioverativ (BIVV). OXB out-licensed its proprietary Parkinson's gene-therapy to AXON in a $842.5m deal, and the $105m BIVV deal is for haemophilia gene-therapy development.**

- **Strategy:** OXB has four strategic objectives: delivery of process development (PD) services that embed its technology in partners' commercial products; commercial manufacture of lentiviral vector; out-licensing of proprietary candidates; and investment in R&D and the LentiVector platform.

- **Interim results:** Excellent progress in signing strong partnership deals boosted gross income (sales and other income) by 118% to £36.0m in the six months to June 2018. This was the first period that OXB received royalties (undisclosed) from Novartis, demonstrating pull-through from the partnering strategy.

- **EBITDA positive:** 1H'18 was the first period that OXB has been EBITDA positive, with earnings up 522% to £9.4m (-£2.2m). Irregular payments of licensing income will underly lumpy profitability in the next three years. Underlying EPS is expected to be in the region of 15.7p for the full year.

- **Manufacturing expansion:** In March, OXB raised £20.5m gross (ca.£19.3m net) via a Placing of 174.4m (3.49m after 1-for-50 consolidation) Ordinary shares, at a price of 11.75p (587.5p) per share. The planned use of proceeds is investment in new facilities to meet the growing demand for vector bioprocessing.

- **Investment summary:** OXB is at a very interesting juncture. Heavy investment in state-of-the-art GMP manufacturing facilities for production of gene-therapy vector has resulted in supply agreements with Novartis, Bioverativ, AXON, and in Cystic Fibrosis, on top of existing partnerships – positioning the group on the road to significant bioprocessing service income, milestones, and royalties.

**Financial summary and valuation**

| Year-end Dec (£m) | 2015 | 2016 | 2017 | 2018E | 2019E | 2020E |
|---|---|---|---|---|---|---|
| Group revenue | 15.91 | 27.78 | 31.49 | 46.21 | 60.80 | 80.30 |
| EBITDA | -11.73 | -6.78 | -2.63 | 15.45 | 15.93 | 25.78 |
| Underlying EBIT | -13.35 | -10.45 | -7.00 | 11.03 | 11.08 | 20.47 |
| Reported EBIT | -14.08 | -11.32 | -5.67 | 12.92 | 9.92 | 19.20 |
| Underlying PBT | -16.25 | -15.34 | -16.38 | 6.67 | 7.18 | 16.64 |
| Statutory PBT | -16.98 | -20.31 | -11.76 | 8.56 | 6.02 | 15.38 |
| Underlying EPS (p) | -23.91 | -21.00 | -21.99 | 15.74 | 15.82 | 31.96 |
| Statutory EPS (p) | -25.33 | -29.95 | -14.56 | 18.57 | 14.05 | 30.04 |
| Net (debt)/cash | -17.90 | -19.05 | -22.54 | -2.28 | -1.27 | 12.21 |
| Shares issued | 0.14 | 17.50 | 0.39 | 19.40 | 0.10 | 0.10 |
| P/E (x) | - | - | - | - | - | 28.1 |
| EV/sales (x) | - | - | - | - | - | 22.8 |

*Source: Hardman & Co Life Sciences Research*

**Pharmaceuticals & Biotechnology**

*Source: Eikon Thomson Reuters*

**Market data**

| | |
|---|---|
| EPIC/TKR | **OXB** |
| Price (p) | 900.0 |
| 12m High (p) | 1064.4 |
| 12m Low (p) | 415.0 |
| Shares (m) | 66.0 |
| Mkt Cap (£m) | 594.4 |
| EV (£m) | 589.2 |
| Free Float | 63% |
| Market | LSE |

**Description**

Oxford BioMedica (OXB) is a UK-based biopharmaceutical company specialising in cell and gene therapies developed using lentiviral vectors, gene-delivery vehicles based on virus particles. In addition to vector development and manufacture, OXB has a pipeline of therapeutic candidates and undertakes innovative pre-clinical R&D in gene-medicine.

**Company information**

| | |
|---|---|
| CEO | John Dawson |
| CFO | Stuart Paynter |
| Chairman | Lorenzo Tallarigo |
| | +44 1865 783 000 |
| | www.oxfordbiomedica.co.uk |

**Key shareholders**

| | |
|---|---|
| Directors | 0.3% |
| Vulpes | 17.6% |
| M&G | 17.6% |
| Canaccord Genuity | 5.0% |
| Aviva | 3.9% |
| Hargreaves Lansdown | 3.7% |
| Shah | 3.1% |

**Diary**

**Analysts**


| | |
|---|---|
| Martin Hall | 020 7194 7632 |
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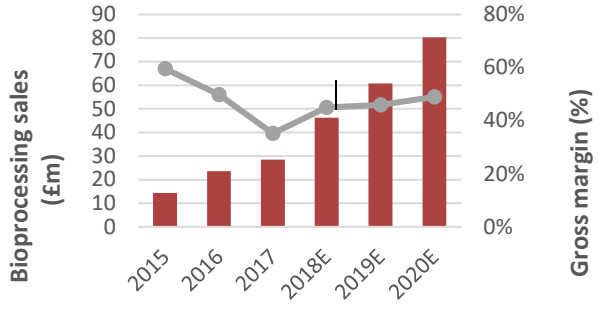
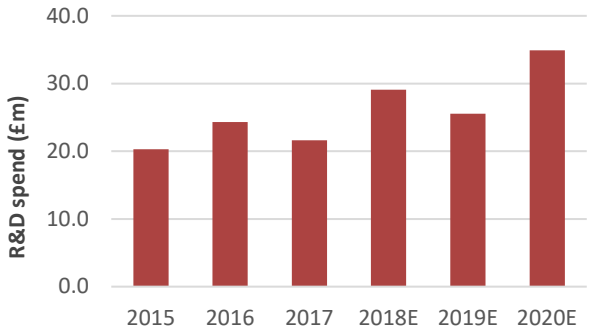
## Sales and gross margin



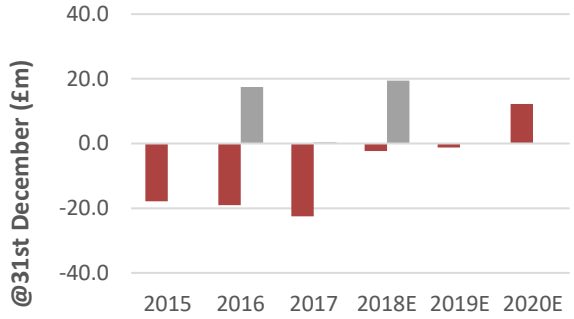

- Oxford BioMedica's current sales are from bioprocessing (and process development) fees, plus additional income such as licensing up-fronts and development milestones
- Royalties will be receivable after partners' therapies reach the market, with royalties from Novartis being received already
- The gross margin has dipped through investment in infrastructure, but is likely to trend higher towards 60-70% when operating at full capacity

## R&D investment



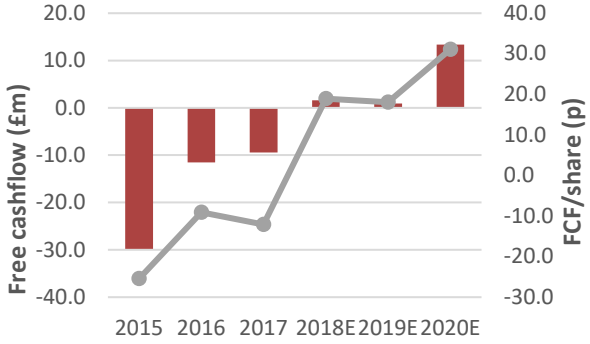

- Oxford BioMedica intends to out-license/spin-out proprietary candidates for clinical development
- Underlying R&D spend, mostly on its own discovery programmes, was -£14.9m in 1H'18
- R&D spend will increase modestly to maintain momentum of proprietary candidate development while partners are identified

## Net cash/capital increases




- During 2016, the company raised new funds of ca.£17.5m in two share issues
- On 9 March 2018, the company raised new funds of £19.3m (net) through a Placing of shares at 11.75p for investment in manufacturing capacity
- At 30 June 2018, OXB had net cash of £5.1m, compared to -£22.5m on 31 December 2017, composed of £44.0m cash and £38.8m debt

## Free cashflow




- OXB turned cash-generative from an operational standpoint in 1H'18
- Actual cash fluctuates, dependent on the timing of receipt of milestones and royalties
- Free cashflow will be affected by the investment being made to increase bioprocessing manufacturing capacity

*Source: Company data; Hardman & Co Life Sciences Research*

# Interim results – 2018

## Key highlights

### *Financial*

- **Gross income:** Excellent progress in signing strong partnership deals boosted gross income (sales and other income) by 118% to £36.0m (£16.5m) in the six months to June 2018.
- **Sales:** Bioprocessing and process development income grew 12% on 1H'17 to £15.4m (£13.7m), driven by the bioprocessing of vector batches and process development for Novartis and Orchard Therapeutics. Timing of recognition of payments from partners secured in 1H'18 meant that this core revenue was below expectations by -£10.2m, with FY'18 expected to be back-end weighted.
- **Other income:** Success in completing deals in 1H'18 increased other income (licensing-fees, royalties, grants) to £20.6m (£0.8m). This included a $5.0m/£3.6m upfront payment from Bioverativ (BIVV), £10.2m of the $25m/£18.2m upfront from Axovant Sciences (AXON), and royalty payments from Novartis's sales of Kymriah.
- **Gross margin:** Margins were down on 1H'17, to 34.4% from 49.0% – in line with the planned increases in manufacturing capacity, headcount growth pushed COGS up 26% to -£10.1m (-£8.0m).
- **Costs:** Administration costs came in at -£2.0m (£2.3m) in 1H'18, a 10% decline on the prior period – the cost increases associated with the growth of the business and investment in manufacturing capacity are allocated between COGS and R&D costs by the company. As such, R&D spend grew 34% to -£14.1m.
- **EBITDA:** This half was the first period that the company was EBITDA positive, with earnings growing 522% to £9.4m (-£2.2m). This was below our forecasts due to the lumpiness of the payments from recently signed deals.
- **Net cash/(debt):** OXB ended the period in a net cash position (£5.1m), comprised of £44.0m cash and long-term debt of £38.8m ($55m Oaktree loan facility), driven by operating cashflow of £16.8m, licensing deals, and the £19.5m net proceeds raised in the Placing in March.

**1H'18 sales summary**

| £m | 1H'17 | 1H'18 | Delta | Growth |
|---|---|---|---|---|
| Sales | 13.7 | 15.4 | +1.7 | 12% |
| Other income | 0.8 | 20.6 | +19.8 | N/M |
| **Gross income** | **16.5** | **36.0** | **+19.4** | **118%** |

*Source: Company reports; Hardman & Co Life Sciences Research*

### *Operational*

- **New partnership deals:** During 1H'18, OXB was successful in signing a new partnership deal with Bioverativ (Sanofi). The $105m deal is for a collaboration and process development partnership to develop gene-therapies for haemophilia.
- **Proprietary products:** In June, OXB signed its second deal of 2018 – the AXO-Lenti-PD programme (formerly OXB-102) was out-licensed to the US biotech company Axovant Sciences for a total $842.5m. A Phase I/II clinical trial of the gene-therapy for Parkinson's disease should begin by the end of FY'18.

- **Novartis:** The bioprocessing deal with Novartis to supply vector for manufacture of Kymriah is progressing well, with 1H'18 being the first period in which OXB has received royalty payments. Kymriah received a second marketing authorisation from the FDA in 1H'18, for treatment of adult patients with DLBCL.
- **Manufacturing capacity:** In March 2018, OXB raised £20.5m gross (ca.£19.3m net) through the issue of 174.4m new Ordinary 1p shares, at a price of 11.75p per share, with existing and new shareholders in the UK and the US. The planned use of proceeds was investment in new facilities to meet demand for vector bioprocessing. Post-period end, the company announced that it had signed a 15-year lease on a new facility in Oxford, with four new GMP clean room suites scheduled to be ready early in 2020.

# Financial update

## Actual vs. expectations

OXB's strategy to deliver near-term value and sustainability by providing bioprocessing and process-development services to partners, in order to support its proprietary research and development, is bearing fruit. The first half of fiscal 2018 was the first period in which the company delivered profitability. EBITDA was £9.4m (-£2.2m), driven primarily by licensing-income from newly signed licensing and collaboration deals. The company is investing heavily in manufacturing facilities to continue the growth of the 'core' bioprocessing/process development (PD) business, permitting additional licensing and collaboration deals going forward.

### *Gross income*

Taken together, sales and other income (gross income) accelerated 118% to £36.0m (£16.5m) in 1H'18. Readers should note that, for consistency among companies, Hardman & Co categorises income according to the following:

- **Group revenue:** True sales from delivery of products or services – batch bioprocessing and PD services in the case of OXB.
- **Other income:** Licensing fees (upfront and milestone) payments, royalties and grant income – all ca.100% margin.

Until FY'17, when OXB introduced a change to the segmental reporting of revenue and disaggregated it also into sales and licensing income for the first time, we had categorised OXB's reported gross income based on our best estimate of individual items. Within sales, we included an 'additional income' line to allow for the ca.100% margin items (e.g. process development incentive payments) that were reported as revenue, but on which we did not have sufficient visibility to reallocate as other income. Given the change in disclosure in FY'17, we have decided to remove the 'additional income' line going forward. Our gross income has always been the sum of group revenue and other income (includes reported 'other operating income'), which is the same as the gross income reported by the company.

1H'18 gross income was £16.3m below our expectations, primarily due to the timing of recognition of upfront payments for process development work and vector batches from new partnership deals.

**Actual vs. expectations**

| Period to June (£m) | 1H'17 actual | 1H'18 actual | Growth (%) | 1H'18 forecast | Delta Δ |
|---|---|---|---|---|---|
| **Gross income** | 16.5 | 36.0 | 118% | 52.3 | -16.3 |
| Bioprocessing and PD | 13.7 | 15.4 | 12% | 25.6 | -10.2 |
| Additional income | 2.0 | 0 | N/M | 0 | N/M |
| **Group revenue** | 15.7 | 15.4 | -2% | 25.6 | -10.2 |
| COGS | -8.0 | -10.1 | 26% | -11.8 | +1.7 |
| SG&A | -2.3 | -2.0 | -10% | -7.0 | +5.0 |
| R&D | -10.5 | -14.1 | 34% | -16.4 | +2.3 |
| **Other income** | 0.8 | 20.6 | 2354% | 26.7 | -6.1 |
| **Underlying EBIT** | -4.2 | 9.8 | -331% | 17.1 | -7.3 |
| Depreciation & Amort. | -2.1 | 11.9 | -676% | 19.3 | -7.4 |
| **EBITDA** | -2.2 | 9.4 | -522% | 26.0 | -16.6 |
| Underlying EPS (p) | -11.7 | 11.7 | -200% | 26.0 | -14.3 |
| **Net cash/(debt)** | -23.7 | 5.1 | -122% | 11.3 | -6.2 |

*PD: Process development.*

*Source: Hardman & Co Life Sciences Research*

## *Trading performance: bioprocessing & process development*

The company reported a strong trading performance from its LentiVector platform in 1H'18, the result of batch supply for Novartis and Orchard. This continues the positive trend that has emerged over the past three years. Growth of 12%, from £13.7m in 1H'17 to £15.4m in 1H'18, was less than in the comparable period, reflecting a deceleration following the intense activity to support Novartis's clinical trials of Kymriah in 2017, and also the timing of process development and bioprocessing activities concomitant with partners' clinical development programmes. For instance, the expected $5m/£3.6m payment for the pre-manufactured batch from Axovant has been deferred to around the end of the 2018 financial year. We had also forecast the start of process development fees from the BIIV deal, signed in February 2018, in 1H'18. Such payments are likely to come in by the end of the full year instead, and as such we have not altered full year forecasts.

Readers should note that the £15.4m group revenue includes £0.76m at 100% margin from a milestone payment from OXB's strategic partnership with Orchard Therapeutics (see page 8), and ca.£2.5m accrued capacity reservation from Novartis.

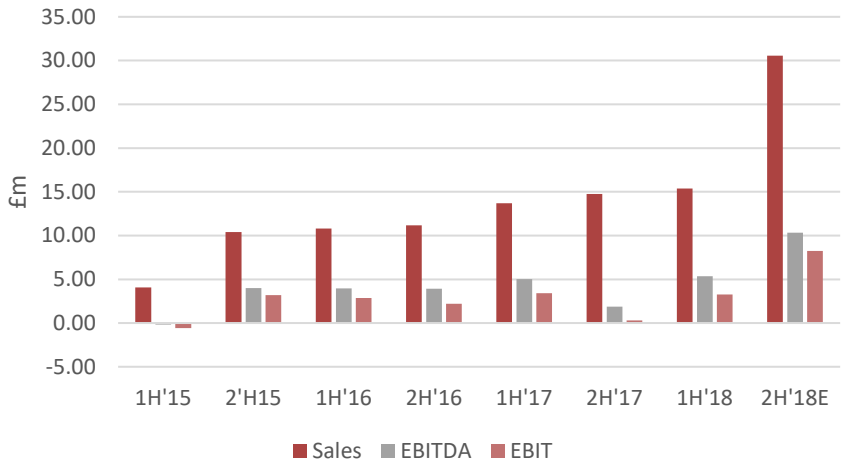
Group COGS are essentially the manufacturing and process development costs (including headcount) for the 'Platform' segment, supporting group revenue generation from partnered programmes. Although there will be some headcount and other overhead costs that are related to internal activities, an illustration of the pre-R&D trading performance still produces a positive trend.

**Analysis of Platform segment**

| | 1H'15 | 2'H15 | 1H'16 | 2H'16 | 1H'17 | 2H'17 | 1H'18 | 2H'18E |
|---|---|---|---|---|---|---|---|---|
| Group revenue | 4.05 | 10.39 | 10.81 | 11.17 | 13.69 | 14.77 | 15.36 | 30.56 |
| COGS | -2.39 | -3.45 | -4.85 | -6.98 | -8.00 | -10.45 | -10.08 | -15.18 |
| Gross profit | 1.66 | 6.94 | 5.96 | 4.19 | 5.69 | 4.32 | 5.29 | 15.38 |
| Gross margin | 41.0% | 66.8% | 55.1% | 37.5% | 41.6% | 29.3% | 34.4% | 50.3% |
| SG&A | -2.25 | -3.76 | -3.11 | -1.98 | -2.28 | -4.04 | -2.04 | -7.15 |
| EBIT | **-0.59** | **3.18** | **2.85** | **2.21** | **3.41** | **0.29** | **3.25** | **8.23** |
| EBIT margin | **-14.6%** | **30.6%** | **26.4%** | **19.8%** | **24.9%** | **1.9%** | **21.1%** | **26.9%** |
| D&A | 0.40 | 0.80 | 1.10 | 1.70 | 1.60 | 1.60 | 2.10 | 2.10 |
| EBITDA | -0.19 | 3.98 | 3.95 | 3.91 | 5.01 | 1.89 | 5.34 | 10.33 |
| EBITDA margin | -4.7% | 38.3% | 36.5% | 35.0% | 36.6% | 12.8% | 34.8% | 33.8% |

*Source: Hardman & Co Life Sciences Research*

**Platform segment – positive operational trend**




*Source: Hardman & Co Life Sciences Research*

***Positive and improving trend in operating performance of Platform segment***

### *Other income*

Receipt of the £5m/$3.6m BIIV upfront payment in the first half, along with approximately half of the $25m/£18.2m AXON upfront payment and ca.£4.5m of BIVV/AXON licensing income, resulted in transformational growth to £20.6m (£0.8m). Also contributing was £0.7m of the £3m Innovate grant (which is being accrued over a three-year period) and royalty payments from Novartis – the rate has not been disclosed; however, the payments in 1H'18 were anywhere between £0.8m and £1.6m, or 4%-8% of Novartis's Kymriah sales ($28m/£20.3m in 1H'18).

Deferral of part of the AXON upfront (ca.£8m), and reallocation of the Novartis capacity reservation to group revenue from other income, contributed to this line coming in below our expectations by ca.£6.0m.

## Stronger balance sheet

### *Cash position*

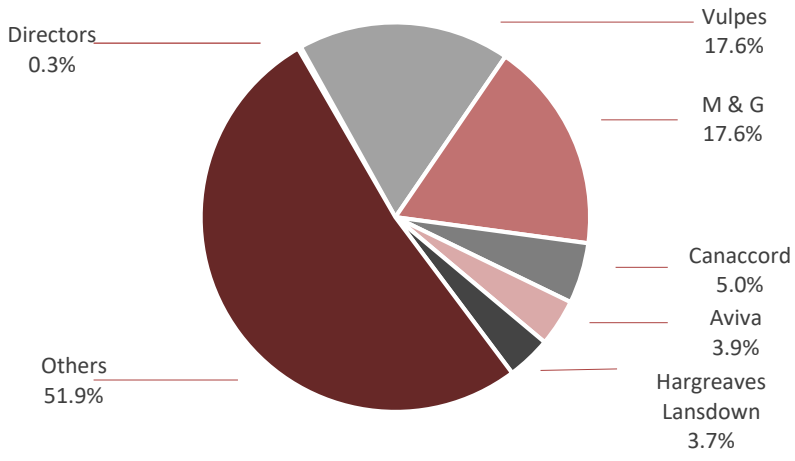
Despite an extra working capital outflow of ca.£2m in 1H'18, operational cashflow generated £16.8m, and after capital expenditure of £6m (£1m in 1H'17) to support an expansion of manufacturing capacity, free cashflow was £10.8m. Combined with the £19.3m net proceeds from the Placing, this left cash of £44.0m as at 30 June 2018.

### *Placing and share consolidation*

As part of its strategy to invest in manufacturing capacity to meet increasing demand for lentivirus vector, OXB undertook a Placing on 9 March 2018 to raise £19.3m (net) new funds specifically for investment in new bioprocessing facilities. Through an accelerated book build, it raised £20.5m gross through the issue of 174,346,817 new Ordinary 1p shares at 11.75p per share, with existing and new shareholders in both the UK and the US. This represented a discount of 5.7% to the middle market price at the time of the announcement. The new shares represented 5.3% of the enlarged share capital and were admitted to trading on the main market on 14 March 2018.

The company also undertook a 50-for-1 share consolidation on 30 May 2018. At the time of writing, there were 66,039,775 Ordinary shares outstanding. Major shareholders and their holdings are shown below.

**Major shareholders (shares in issue = 66,039,775)**




*Source: Hardman & Co Life Sciences Research*

## *Revaluation of non-core investments*

In November 2016, OXB signed a strategic alliance with Orchard Therapeutics Ltd under which OXB would initially develop and supply lentiviral vectors for two of Orchard's cell-based therapies for treating life threatening orphan diseases. As part of the deal, OXB received a 1.95% stake in Orchard which, at that point in time, equated to 735,000 Ordinary shares in the company. In its 2016 annual report, the fair value of these shares was included as an investment valued at £0.657m, or 89.4p per share. This holding was revalued in OXB's 2017 accounts to £2.954m following a capital increase by Orchard at 401.9p per share.

During 1H'18, OXB has satisfied a development milestone, which has resulted in the company receiving a further 188,462 Ordinary shares in Orchard, which was recognised as revenue within bioprocessing and process development, and included as an additional balance sheet investment in its interim report.

**OXB investment in Orchard Therapeutics**

| | | Shares in OT | Latest price | Value |
|---|---|---|---|---|
| 29 Nov 2016 | Licensing agreement | 735,000 | 89.4p | £0.657m |
| 25 May 2018 | Milestone | 188,462 | 401.9p | £0.757m |
| **Current** | **Total holding** | **923,462** | **654.9p** | **£6.05m** |

*Source: Hardman & Co Life Sciences Research*

Subsequent to the period end, Orchard has raised gross new capital of £114.1m through the issue of 17.42m shares at 654.9p per share. This is likely to result in OXB revaluing its investment in Orchard, subject to agreement from its auditors, when it reports full year numbers for 2018. This would value OXB's stake in Orchard at ca.£6.1m and result in a non-cash revaluation gain of ca.£2.2m in the 2018 accounts. To date, this has been a very successful partnership and investment.

## *Oaktree loan*

On 30 June 2017, OXB announced a $55m loan agreement with Oaktree Capital Management LLP, which was on terms (interest of 9.0% plus US$ three-month LIBOR, subject to a minimum of 1.0%) that were much more favourable than its existing facility with Oberland Capital. At the beginning of the period, $50m of the Oaktree facility had been drawn down, with the fair value of the capital less capitalised legal and other costs appearing in the balance sheet as long-term loans of £36.9m.

During 1H'18, OXB accrued interest on this loan of £3.0m, of which £2.3m was paid to Oaktree. In addition, the strength of sterling over the reporting period resulted in a forex conversion loss of £1.2m. Consequently, the sterling value of this debt in the balance sheet on 30 June 2018 had increased to £38.8m.

The Oaktree loan is due for repayment no later than 29 June 2020. Given that OXB is in a much more stable financial position today compared with just 12 months ago, the Board must decide whether to continue with this relatively expensive loan, or to repay/refinance it. This is not an easy decision. On the one hand, it is relatively expensive money for OXB for the next two years, but on the other hand, it provides management with greater flexibility in uncertain times and while it embarks on investment programmes in capacity to meet demand and in R&D to progress own development opportunities. Moreover, repayment would incur significant early redemption charges. In our opinion, at this point in time, it is better to have as much cash in the bank as possible and retain maximum flexibility for its investment programmes rather than save a modest amount on the interest charge.

# Operational update

The arrival of the gene-based medicines era (see note published September 2017[1]) is generating rapidly increasing demand for the vectors and other gene-delivery mechanisms that underpin them. OXB is ideally placed to supply commercial quantities of clinical-grade lentivirus vector to a growing market, while not being directly exposed to the risks inherent to development of gene-based medicines. Its bioprocessing/process development activities – the 'core' business – is currently spread across five partnership deals and 11 therapeutic programmes, creating:

- a buffer against clinical trial failures;
- long-term returns in the form of royalty, by implanting its IP within partners' therapies;
- near-term value that supports the business's proprietary R&D activities.

The proprietary programmes are important, since successful commercialisation of a wholly-owned gene-therapy would deliver the greatest long-term value.

## Partnerships

### New partnership with Bioverativ

In February 2018, OXB signed a collaboration and licence agreement with BIVV for the development, and potential manufacture, of vectors for haemophilia gene therapies. OXB received $5m up-front and is eligible to receive milestone payments of up to $100m, thus establishing a 'normal' deal structure. BIVV is a US-based haemophilia and rare blood disorders biopharma company that was acquired in January 2018 by Sanofi for $11.6bn. BIVV's 2017 sales were $1.1bn from its two approved drugs. See our note 'Bioverativ deal – establishes structure', published February 2018[2].

### Novartis partnership

#### *Kymriah royalties*

In May 2018, Kymriah, for which OXB is the sole commercial supplier of vector, received its second FDA approval, for the treatment of relapsed or refractory (r/r) adult DLBCL patients. It had received US approval r/r ALL in paediatric patients in 2H'17, which alone led to the $12m of sales in 1Q'18. Total sales of Kymriah grew 33% to $16m in 2Q'18 – at a conservative 4% royalty rate, this would suggest royalty payments of ca.£0.8m to OXB in 1H'18. OXB's royalty income is set to accelerate along with the Kymriah launches staged in new markets over the coming 3-5 years.

#### *Kymriah launch progress*

Kymriah also received a positive opinion from the EMA's CHMP in June for the treatment of r/r adult DLBCL patients and r/r paediatric/young adult ALL patients. Post-period end, European and Canadian approval was granted in both indications, and the industry is awaiting a decision from the Japanese regulator.

[1] http://www.hardmanandco.com/docs/default-source/company-docs/oxford-biomedica-documents/12.09.17-new-era-for-cell-and-gene-therapies.pdf
[2] http://www.hardmanandco.com/docs/default-source/company-docs/oxford-biomedica-documents/28.02.18-bioverativ-deal-establishes-structure.pdf

To be ready for rollout throughout Europe, Novartis is investing up to €78.8m in gene-based medicine manufacturing facilities in Switzerland. In addition, Novartis recently signed an agreement for manufacturing CAR-T therapies with CELLforCURE, one of the first and largest Contract Development and Manufacturing Organisations in Europe to produce cell and gene therapies.

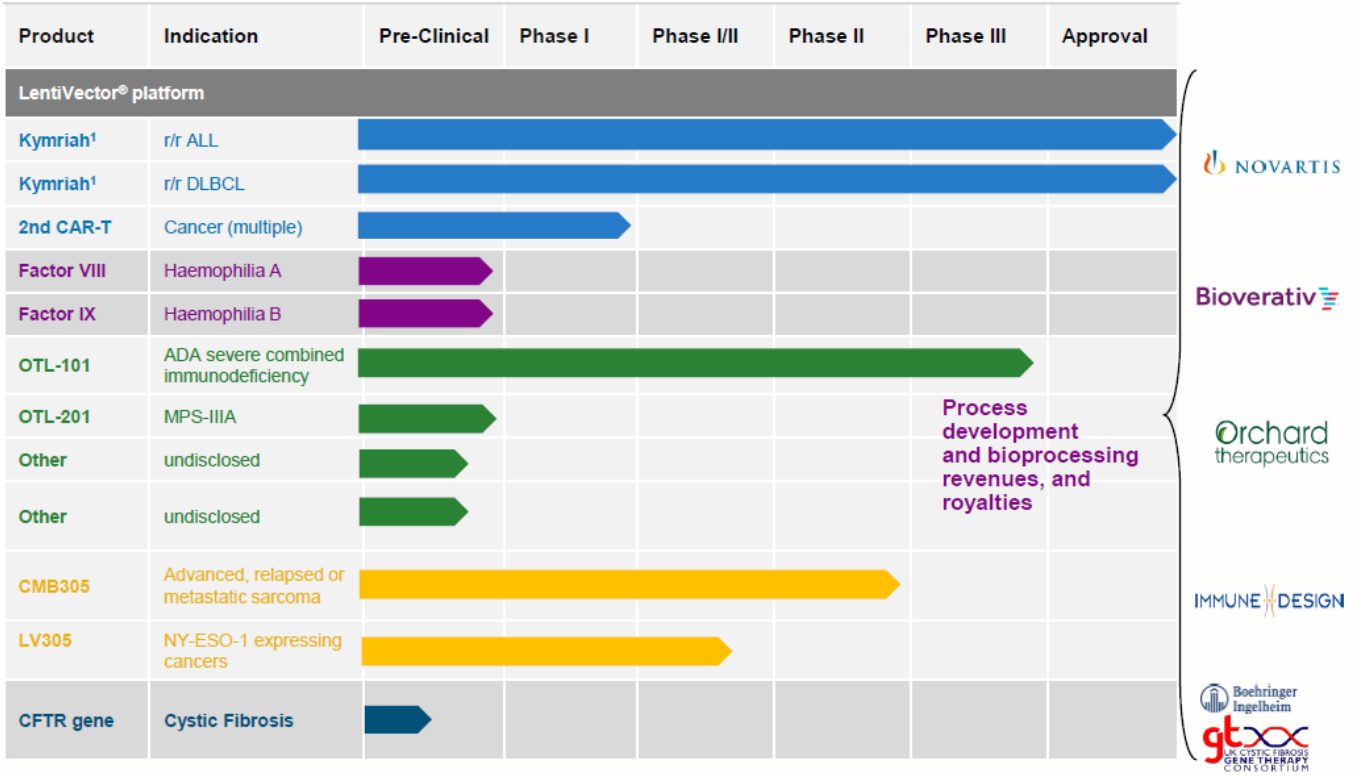
### *Reimbursement*

The reimbursement environment remains uncertain in both the US and Europe. NICE in the UK has recommended against reimbursement of both Kymriah and Yescarta (Gilead) in DLBCL. It is, however, exciting and encouraging that, on NICE's cost-effectiveness recommendation, NHS England has agreed to make Kymriah available to young patients with ALL. Forecasting the potential in the UK is difficult because the price agreed in the commercial deal with the NHS is not disclosed; the therapy's list price is £282,000 for ALL in the UK, compared with $475,000/£345,203 in the US, which is paid on achievement of certain patient outcomes (outcomes-based pricing).

## Orchard Therapeutics

In April 2018, GSK and Orchard Therapeutics signed a strategic partnership, with GSK transferring its rare diseases portfolio (which included Strimvelis, the first approved gene therapy) to Orchard in exchange for a 1.99% stake in Orchard. As such, the GSK programmes that were partnered with OXB were transferred to Orchard, adding to the existing Orchard-OXB partnered portfolio. Orchard's lead programme, OTL-101 for ADA-SCID, is in Phase II/III development, with regulatory submissions for approval by the FDA by the end of 2018.

**Summary: Bioprocessing and process development partnerships**




*Source: Oxford BioMedica*

## Post-period deal for cystic fibrosis gene-therapy

As described in our note published 14 August 2018 '*Risk-sharing in cystic fibrosis gene-therapy*'[3], post-period a collaboration was agreed with the UK cystic fibrosis (CF) Gene Therapy Consortium/Imperial Innovations to develop a CF gene-therapy. Separately, Boehringer Ingelheim has signed an option to license the therapy. As a severe genetic disorder affecting over 70,000 people and with few licensed treatments, CF represents a huge unmet need for which an effective gene-therapy would represent a paradigm shift. If successful, it has potential to be first-in-class.

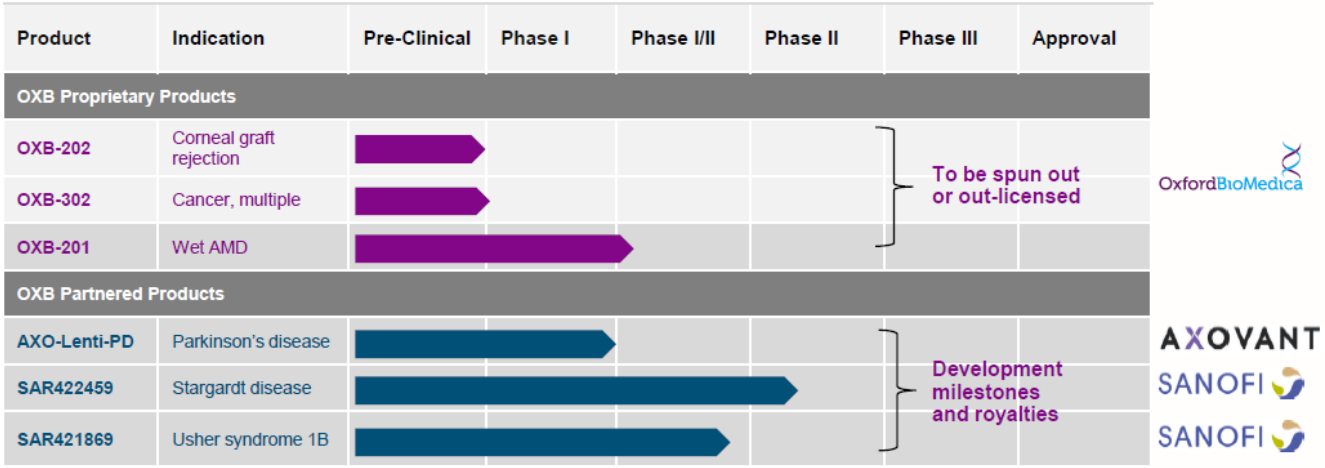
**OXB deals, 2017-18**

| Term | Novartis deal 2 extension* | Bioverativ | Axovant | UK CFGTC, Imperial Innovations /BI |
|---|---|---|---|---|
| Type | Manufacturing | Collaboration/licensing | Licensing | Collaboration/option |
| Year | 2017 | 2018 | 2018 | 2018 |
| Therapy area/type | Oncology, CAR-T cell-therapy | Haemophilia, *in vivo* gene-therapy | Parkinson's disease, *in vivo* gene-therapy | CF, *in vivo* gene-therapy |
| Duration | 3-5 years | Unknown | Unknown | N/A |
| Up-front on signing | $10m | $5m | $30m (incl. $5m designated for manufacturing) | Not disclosed |
| MS, incentives, service payments | $90m min. | $100m max (reg. & sales MS) | $812.5m max. (dev., reg. & sales MS) | Not disclosed |
| PD | Yes | Yes | **Yes – separately funded by Axovant** | Yes |
| Clinical supply | Yes | **Potential** | **Potential** | **Potential** |
| Commercial supply | Yes | No | **Potential** | **Potential** |
| Royalty | Yes | Yes | Tiered: 7%-10% | Not disclosed |

*MS: milestone payments; reg: regulatory; dev: clinical development*
**For original Novartis deal terms, refer to our note 'Gene-therapy for Parkinson's: clinical progression' published 14 June 2018*
*Source: Company announcements; Hardman & Co Life Sciences Research*

# Proprietary products

**Summary: Proprietary product pipeline**




*Source: Oxford BioMedica*

[3] http://www.hardmanandco.com/docs/default-source/company-docs/oxford-biomedica-documents/14.08.18-risk-sharing-in-cystic-fibrosis-gene-therapy.pdf

## Axovant partnership

Progress is being made in development of AXO-Lenti-PD towards the clinic, with a Phase I/II trial due to start by the end of the year. OXB out-licensed its Parkinson's *in vivo* gene-therapy candidate (formerly ProSavin, now AXO-Lenti-PD) to AXON for a potential $842.5m/£624.1m (up-front $30m/£22m) towards the end of 1H'18. See our note published June 2018 for details[4].

# LentiVector platform

### *Manufacturing demand*

OXB estimates that the lentivirus vector market will be $800m by 2026[5]. Such vectors are difficult to produce, and there are few organisations that have the expertise to make them in commercial quantities at clinical grade, increasing the demand on those that have both the expertise and the capacity. OXB is readying itself to meet ca.30%/£160m of the demand within the eight years through its bioprocessing/process development partnerships, in order to remain a leader in the market.

### *Manufacturing capacity increase*

As such, it is investing heavily in manufacturing capacity and processes. To remain competitive with leading multi-channel contract development and manufacturing organisations (CDMOs), such as Lonza (LONN), OXB needs to scale up capacity in terms of warehousing and fill-finish suites. Plans for expansion were outlined during the Placing in March, with the announcement that the new site had been secured being released along with the interim results.

As discussed earlier, the Board has taken the pro-active decision to invest in a new facility that will house additional GMP clean rooms for vector manufacturing, add a fill-and-finish capability (currently out-sourced), and provide warehousing. Furthermore, the footprint of the proposed new facility is sufficiently large to allow the addition of another three GMP vector manufacturing suites. The cost of initial planned expansion (phases one and two) is in the order of £19m, which will be spread over three years (estimated to be £8m, £8m, £3m). The first phase should be completed at the end of 2019, with 50% of the new capacity scheduled to be live in 2020. At this point in time, capacity at OXB will be broadly equivalent to one of Lonza's smaller manufacturing sites. OXB is adopting a modular design approach that will allow capacity growth as needed to meet demand. For example, another GMP vector manufacturing suite could be added relatively easily in an unutilised part of the new facility, without causing disruption, for ca.£4m.

**Planned increase in manufacturing capacity**

| Oxfordshire sites | Current | Planned by 2020 | 2020 |
|---|---|---|---|
| Footprint | 2,245m$^2$ | 4,200m$^2$ | 6,445m$^2$ +3,600m$^2$ unutilised |
| Cleanrooms | 3 | 4 | 7 |
| Fill-and-finish | Outsourced | In-house | All in-house |
| Warehousing | ✗ | ✓ | ✓ |
| Cost | £26m | £19m | - |

*Source: Hardman & Co Life Sciences Research*

[4] http://www.hardmanandco.com/docs/default-source/company-docs/oxford-biomedica-documents/14.06.18-gene-therapy-for-parkinsons-clinical-progression.pdf

[5] OXB Placing document – 9 March 2018.

**Scalability of bioreactors**

*Source: Sartoriusi*

The additional cleanrooms will initially house the 200l bioreactors that are currently in use for development-scale bioprocessing (technology partially funded by the £2m Innovate UK grant awarded in August 2017). The space available allows flexibility to buy in larger volume bioreactors (up to 2,000l), as suspension culture technology advances. Reflecting the company's progression to a competitive CMDO, alongside its proprietary offering, the addition of fill-and-finish and warehousing capabilities should improve margins by reducing sub-contracted costs, improving manufacturing timeframes, and de-risking production through an in-house end-to-end cold chain.

This will be augmented by commercial scale-up of OXB's proprietary next-generation TRiP technology, for more efficient and higher-yield vector bioprocessing. The TRiP system (Transgene Repression in vector Production) suppresses over-expression of therapeutic genes during the manufacturing process. Over-expression is a common problem that can reduce the yield of gene therapy vectors, so TRiP technology will be beneficial in a range of gene-based medicines. Data from application of the system to production of a variety of viral vector types were published in the journal Nature Communications in March 2017. TRiP is patent protected until 2034.

### *Innovate UK grant*

OXB was awarded a second grant from Innovate UK, the UK's innovation agency, in January 2018 in line with the government's strategy to develop the UK into a global hub for manufacturing of advanced therapies. The grant is for £3m, accrued over three years, which will be used to support equipment purchases for manufacturing expansion. A smaller portion will be used to transition GMP suites from adherent to suspension cultures.

This builds on the £2m award to OXB and collaborators, including the UK Cell and Gene Therapy Catapult, in August 2017, which was used for development of high-quality vector manufacturing technology for gene-based medicines. The wider aims were reducing the time-to-clinic of such therapies and of increasing patient access by reducing costs.

## Changes to forecasts

We have not made material changes to our full year forecasts. The $10m Novartis capacity reservation payments accrued 2018-2020 have been reallocated to group revenue from other income, and we have reallocated ca.£6m SG&A costs to R&D and COGS for FY'18. We expect group revenue to be back-end weighted. Reported EBIT has been increased for the FY'18 to account for revaluation of its investment in Orchard.

**Changes to forecasts**

| Year to | ---------- 2018E ---------- | | | -------- 2019E ------- | | | -------- 2020E ------- | | |
|---|---|---|---|---|---|---|---|---|---|
| Dec (£m) | old | new | change | old | new | change | old | new | change |
| Gross income | 74.8 | 74.8 | 0% | 79.1 | 79.2 | 0% | 105.8 | 106.0 | 0% |
| **Group revenue** | **43.8** | **46.2** | **6%** | **58.2** | **60.8** | **4%** | **79.3** | **80.3** | **1%** |
| COGS | -20.1 | -25.4 | 26% | -31.4 | -32.8 | 4% | -40.4 | -41.0 | 1% |
| SG&A | -15.3 | -9.2 | -40% | -10.5 | -9.7 | -7% | -9.5 | -9.6 | 1% |
| R&D | -28.0 | -29.1 | 4% | -26.2 | -25.5 | -2% | -35.7 | -34.9 | -2% |
| Other income | 31.0 | 28.6 | -8% | 20.9 | 18.4 | -12% | 26.5 | 25.7 | -3% |
| **EBITDA** | 15.7 | 15.5 | -1% | 15.8 | 15.9 | 1% | 25.5 | 25.8 | 1% |
| Operating profit | 12.0 | 12.9 | 8% | 9.8 | 9.9 | 1% | 18.9 | 19.2 | 1% |
| Underlying EPS | 15.9 | 15.7 | -1% | 15.6 | 15.8 | 1% | 31.5 | 32.0 | 1% |
| **Net cash/(debt)** | -2.3 | -2.3 | 1% | -4.4 | -1.3 | -71% | 5.8 | 12.2 | 112% |

*Source: Hardman & Co Life Sciences Research*

# Financials and investment case

## Profit and Loss

- **Gross revenue:** The sum of bioprocessing revenue, process development fees, and all licensing fees – up-fronts, milestones and royalties – and grants, to show that our numbers, although presented differently, equate to those reported.
- **Bioprocessing/PD:** This will be the main growth driver over the next three years. Other income is lumpy – forecasts do not include future new deals.
- **EBITDA:** 1H'18 was the first profitable period, bringing our expected EBITDA to £15.5m for the full year.

**Profit & Loss account**

| Year-end Dec (£m) | 2015 | 2016 | 2017 | 2018E | 2019E | 2020E |
|---|---|---|---|---|---|---|
| GBP:EUR | 1.38 | 1.18 | 1.14 | 1.14 | 1.14 | 1.14 |
| GBP:USD | 1.53 | 1.35 | 1.29 | 1.29 | 1.29 | 1.29 |
| **Gross revenues** | **18.77** | **30.78** | **39.36** | **74.80** | **79.20** | **106.00** |
| Bioprocessing + PD* | 14.44 | 23.60 | 28.46 | 46.21 | 60.79 | 80.25 |
| Additional income | 3.54 | 3.80 | 3.03 | 0.00 | 0.00 | 0.00 |
| **Group revenue** | **15.91** | **27.78** | **31.49** | **46.21** | **60.80** | **80.30** |
| COGS | -5.84 | -11.84 | -18.44 | -25.42 | -32.83 | -40.95 |
| **Gross profit** | **10.07** | **15.94** | **13.05** | **20.79** | **27.97** | **39.35** |
| Gross margin | 59.6% | 49.9% | 35.2% | 45.0% | 46.0% | 49.0% |
| SG&A | -6.01 | -5.09 | -6.31 | -9.24 | -9.73 | -9.64 |
| R&D | -20.27 | -24.30 | -21.61 | -29.11 | -25.54 | -34.93 |
| **EBITDA** | **-11.73** | **-6.78** | **-2.63** | **15.45** | **15.93** | **25.78** |
| Depreciation | -1.26 | -3.34 | -4.11 | -4.21 | -4.63 | -5.09 |
| Amortisation | -0.36 | -0.34 | -0.26 | -0.21 | -0.21 | -0.21 |
| Other income | 2.86 | 3.00 | 7.87 | 28.59 | 18.38 | 25.69 |
| **Underlying EBIT** | **-13.35** | **-10.45** | **-7.00** | **11.03** | **11.08** | **20.47** |
| EBIT margin | 83.9% | 37.6% | -22.2% | 23.9% | 18.2% | 25.5% |
| Share-based costs | -0.73 | -0.87 | -0.97 | -1.07 | -1.17 | -1.27 |
| Exceptional items | 0.00 | 0.00 | 2.30 | 2.95 | 0.00 | 0.00 |
| **Stat. operating profit** | **-14.08** | **-11.32** | **-5.67** | **12.92** | **9.92** | **19.20** |
| Net interest | -2.90 | -4.89 | -9.38 | -4.36 | -3.90 | -3.83 |
| Forex gain/loss | 0.00 | -4.11 | 3.28 | 0.00 | 0.00 | 0.00 |
| **Pre-tax profit** | **-16.25** | **-15.34** | **-16.38** | **6.67** | **7.18** | **16.64** |
| Exceptional items | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Reported pre-tax | -16.98 | -20.31 | -11.76 | 8.56 | 6.02 | 15.38 |
| Tax payable/credit | 3.96 | 3.67 | 2.74 | 3.70 | 3.26 | 4.46 |
| **Underlying net income** | **-12.29** | **-11.67** | **-13.61** | **10.39** | **10.45** | **21.11** |
| Statutory net income | -13.02 | -16.64 | -9.02 | 12.26 | 9.28 | 19.84 |
| | | | | | | |
| **Ordinary 50p shares:** | | | | | | |
| Period-end (m) | 51.49 | 61.76 | 62.15 | 66.04 | 66.04 | 66.04 |
| Weighted average (m) | 51.40 | 55.56 | 61.91 | 66.04 | 66.04 | 66.04 |
| Fully-diluted (m) | 53.51 | 58.00 | 67.03 | 71.26 | 71.36 | 71.46 |
| **Underlying basic EPS (p)** | **-23.91** | **-21.00** | **-21.99** | **15.74** | **15.82** | **31.96** |
| Statutory basic EPS (p) | -25.33 | -29.95 | -14.56 | 18.57 | 14.05 | 30.04 |
| **U/l fully-diluted EPS (p)** | **-22.96** | **-20.12** | **-20.31** | **14.58** | **14.64** | **29.54** |
| Stat. fully-diluted EPS (p) | -24.33 | -28.70 | -13.45 | 17.21 | 13.00 | 27.77 |
| **DPS (p)** | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |

**PD: Process Development. Source: Hardman & Co Life Sciences Research*

## Balance sheet

- **Novartis up-front payment:** accrued and included in the P&L under group revenue, this drops through to cashflow, benefiting the period-end cash balance.
- **Loan facilities:** There is no material change in the long-term debt, with the exception of £3.0m accrued interest on the loan of which £2.3m was paid to Oaktree. The strength of sterling over the reporting period resulted in a forex conversion loss of £1.2m.
- **Net debt:** At 30 June 2018, the net cash was £5.1m, due to £44.0m cash from positive fee cashflow and the March Placing, and the loan as above.

**Balance sheet**

| @31 December (£m) | 2015 | 2016 | 2017 | 2018E | 2019E | 2020E |
|---|---|---|---|---|---|---|
| Shareholders' funds | 10.89 | 12.62 | 6.70 | 38.36 | 47.74 | 67.68 |
| Cumulated goodwill | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Total equity | 10.89 | 12.62 | 6.70 | 38.36 | 47.74 | 67.68 |
| | | | | | | |
| Share capital | 25.74 | 30.88 | 31.08 | 33.02 | 33.02 | 33.02 |
| Reserves | -14.85 | -18.26 | -24.38 | 5.34 | 14.72 | 34.66 |
| Provisions/liabilities | 4.42 | 3.94 | 14.20 | 12.11 | 6.05 | 0.30 |
| Deferred tax | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Long-term loans | 27.26 | 34.39 | 36.86 | 36.86 | 36.86 | 36.86 |
| Short-term debt | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| *less:* Cash | 9.36 | 15.34 | 14.33 | 34.58 | 35.59 | 49.07 |
| *less:* Deposits | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| **Invested capital** | **33.21** | **34.95** | **40.48** | **47.95** | **50.26** | **50.98** |
| | | | | | | |
| Fixed assets | 24.40 | 27.51 | 25.37 | 32.03 | 38.41 | 40.48 |
| Intangible assets | 1.74 | 1.33 | 0.10 | 0.00 | 0.00 | 0.00 |
| Inventories | 2.71 | 2.20 | 3.33 | 5.41 | 7.12 | 9.40 |
| *Trade debtors* | *7.37* | *1.97* | *5.71* | *6.85* | *8.22* | *9.86* |
| *Other debtors* | *3.56* | *4.94* | *11.93* | *11.93* | *11.93* | *11.93* |
| *Tax liability/credit* | *2.72* | *3.00* | *2.78* | *2.76* | *3.72* | *3.26* |
| *Trade creditors* | *-3.59* | *-1.58* | *-3.68* | *-3.68* | *-3.68* | *-3.68* |
| *Other creditors* | *-5.70* | *-4.43* | *-5.05* | *-7.35* | *-15.45* | *-20.27* |
| Debtors less creditors | 4.37 | 3.90 | 11.68 | 10.51 | 4.73 | 1.10 |
| **Invested capital** | **33.21** | **34.95** | **40.48** | **47.95** | **50.26** | **50.98** |
| | | | | | | |
| **Net cash/(debt)** | **-17.90** | **-19.05** | **-22.54** | **-2.28** | **-1.27** | **12.21** |

*Source: Hardman & Co Life Sciences Research*

## Cashflow

- **Working capital:** Given that much of OXB's work is on a fee-for service basis, there is no major working capital requirement for the group. However, preparation for clinical trials and commercialisation of partners' products has required an increase in short-term working capital, with inventories increasing by £1.7m in 1H'18.
- **Free cashflow:** Counterbalancing the temporary increase in working capital, free cashflow increased £1.6m, delivering FCF/share of 18.9p.

**Cashflow**

| Year-end Dec (£m) | 2015 | 2016 | 2017 | 2018E | 2019E | 2020E |
|---|---|---|---|---|---|---|
| Underlying EBIT | -13.35 | -10.45 | -7.00 | 11.03 | 11.08 | 20.47 |
| Depreciation | 1.26 | 3.34 | 4.11 | 4.21 | 4.63 | 5.09 |
| Amortisation | 0.36 | 0.34 | 0.26 | 0.21 | 0.21 | 0.21 |
| *Inventories* | *-1.30* | *0.50* | *-1.13* | *-2.08* | *-1.71* | *-2.28* |
| *Receivables* | *-5.78* | *4.03* | *-10.73* | *-1.14* | *-1.37* | *-1.64* |
| *Payables* | *2.98* | *-3.28* | *2.73* | *0.00* | *0.00* | *0.00* |
| Change in working capital | -4.09 | 1.25 | -9.13 | -3.22 | -3.08 | -3.92 |
| Exceptionals/provisions | 0.95 | -0.75 | 10.27 | 1.84 | -0.75 | -0.75 |
| Disposals | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Other | 0.00 | 0.35 | 1.27 | 0.00 | 0.00 | 0.00 |
| **Company op. cashflow** | **-14.87** | **-5.93** | **-0.22** | **14.07** | **12.10** | **21.11** |
| Net interest | -1.46 | -3.21 | -10.76 | -4.36 | -3.90 | -3.83 |
| Tax paid/received | 3.24 | 4.08 | 3.51 | 2.76 | 3.72 | 3.26 |
| Operational cashflow | **-13.08** | **-5.06** | **-7.47** | **12.48** | **11.92** | **20.54** |
| Capital expenditure | -16.72 | -6.46 | -1.97 | -10.87 | -11.01 | -7.16 |
| Sale of fixed assets | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| **Free cashflow** | **-29.80** | **-11.52** | **-9.44** | **1.61** | **0.91** | **13.38** |
| Dividends | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Acquisitions | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Disposals | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Other investments | 0.00 | 0.00 | 0.00 | -0.76 | 0.00 | 0.00 |
| **Cashflow after invests.** | **-29.80** | **-11.52** | **-9.44** | **0.85** | **0.91** | **13.38** |
| Share repurchases | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Share issues | 0.14 | 17.50 | 0.39 | 19.40 | 0.10 | 0.10 |
| Currency effect | -1.44 | -7.13 | -2.79 | 0.00 | 0.00 | 0.00 |
| Loans/cash acquired | 0.00 | 0.00 | 8.36 | 0.00 | 0.00 | 0.00 |
| **Change in net debt** | **-31.10** | **-1.15** | **-3.48** | **20.25** | **1.01** | **13.48** |
| Hardman FCF/share (p) | -25.45 | -9.11 | -12.06 | 18.90 | 18.05 | 31.11 |
| | | | | | | |
| Opening net cash | 13.20 | -17.90 | -19.05 | -22.54 | -2.28 | -1.27 |
| **Closing net cash** | **-17.90** | **-19.05** | **-22.53** | **-2.28** | **-1.27** | **12.21** |

*Source: Hardman & Co Life Sciences Research*

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*(Disclaimer Version 8 – Effective from August 2018)*

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