

## The LentiVector<sup>®</sup> Platform Company A leader in gene and cell therapy

# Interim results for six months ended 30 June 2017





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## **Operational highlights**

- Novartis collaboration progressing well
- MHRA licence granted for Group's lentiviral vector manufacture and supply
- £2m Innovate UK grant collaboration to enhance LentiVector<sup>®</sup> platform
- TRiP yield enhancement technology published in Nature Communications
- In-house programmes continue to be prepared for clinical studies & partnering



### Novartis partnership progress since March 2017

- Biologic Licence Application CTL019
  - March 2017 FDA accepted BLA filing for paediatric ALL
  - July 2017 FDA ODAC voted unanimously in favour
  - Potential approval anticipated by early October
- Additional indication DLBCL
  - June 2017 JULIET study data presented in DLBCL shows 45% 3 month overall response rate
  - Breakthrough therapy designation granted by FDA
  - Filing expected later in 2017
- Commercial supply agreement
  - New 3 year agreement covering commercial and clinical supply
  - Potential \$100m revenues, including \$10m upfront payment



## LentiVector® platform

- Regulatory approvals
  - FDA pre-licence inspection as part of CTL019 BLA process
  - MHRA licence to manufacture and distribute lentiviral vector material for commercial supply
- Next generation bioprocessing
  - Single-use, serum-free, 200 litre bioreactor process
  - Larger volumes, less time in clean rooms, higher yield per unit output all contributing to 10-fold reduction in cost of patient dose
- TRiP yield enhancement
  - Suppresses undesirable over-expression of therapeutic genes during production process
  - Facilitates up to tenfold improvement in yield
- Further partnerships
  - Several feasibility studies ongoing
  - Potential new deals over next 12 months



## Business development – extensive lentiviral vector clinical/pre-clinical trial activity





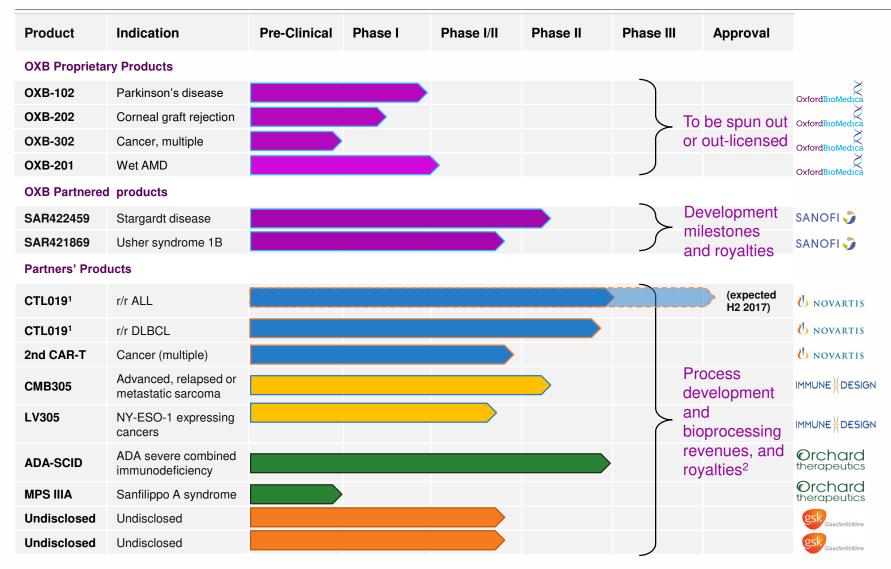
#### In-house development pipeline

- Continuing to prepare priority programmes (OXB-102, OXB-202, OXB-302) for clinical studies
- OXB-102
  - Improvements made to delivery device
  - H2 2017 regulatory dossier to be submitted to the MHRA for approval of the device and manufacture of 2<sup>nd</sup> batch of vector
  - Treatment of patients could begin in early 2018
- Financial partnership arrangements are being explored for each of the priority programmes
- Modest investment being made to maintain the momentum in priority programmes to maximise value



#### **Product pipeline**

## LentiVector Enabled





<sup>1</sup> USAN name is tisagenlecleucel

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<sup>2</sup> GSK partnership is a option fee and royalty agreement

# Financial review

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OxfordBioMedica

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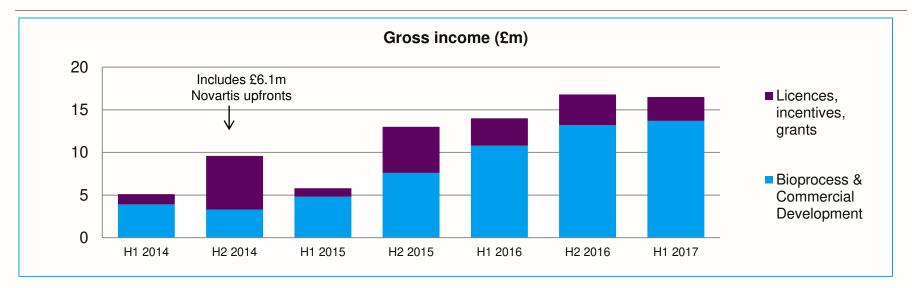
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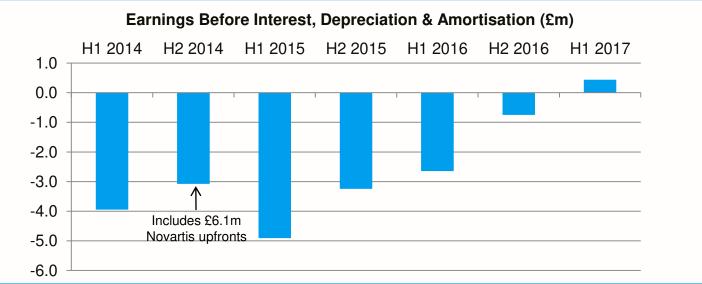
## **Financial highlights**

- Revenue increased by 26% to £15.7 million (H1 2016: £12.5 million)
- Operating loss reduced to £2.2 million (H1 2016: £6.9 million)
- Cash outflow before financing activities reduced to £2.2 million (H1 2016: £3.2 million)
- Debt refinancing complete with significantly improved terms from \$55 million
  Oaktree Capital Management facility
- Cash at 30 June 2017 £10.2 million (31 December 2016: £15.3 million)
- Cash at 31 July 2017 £22.1 million following \$10 million upfront receipt from Novartis and 2016 R&D tax credit



#### Gross income<sup>1</sup> and EBIDA<sup>2</sup>



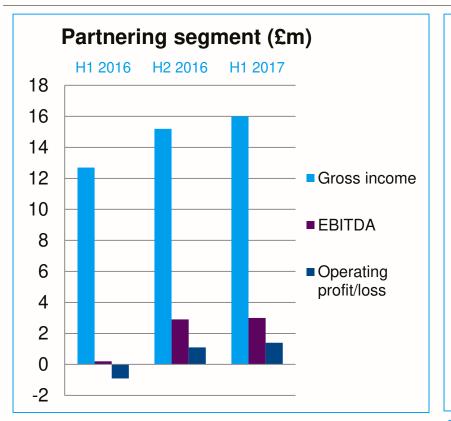


<sup>1</sup> Gross income = aggregate of revenue and other operating income <sup>2</sup> EBIDA = Earnings Before Interest, Depreciation and Amortisation

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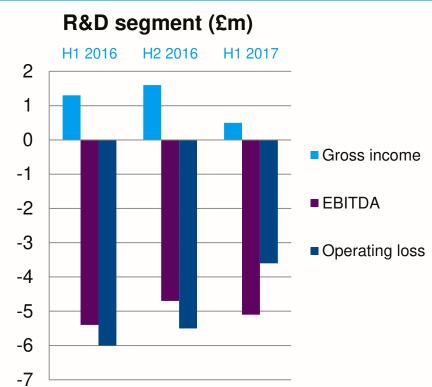


### **Segmental analysis**



#### Partnering segment

- Gross income received from partnership arrangements
- Now generating cash
- Infrastructure in place to support further growth



#### R&D segment

- Covers costs of investing in LentiVector<sup>®</sup> technology and product development (discovery, pre-clinical and preparation for clinical studies)
- Costs include employees and directly related internal costs, external project expenditure, and allocation of Group overheads



#### Potential catalysts over next 12 months

- Novartis progress
  - FDA approval of CTL019<sup>1</sup> for r/r ALL and product launch
  - Submission of DLBCL for approval
  - 2<sup>nd</sup> CAR-T programme to enter clinic
- LentiVector<sup>®</sup> delivery platform
  - Further contracts with new and existing partners giving us long-term economic interest in partners' product candidates
  - Established 200L bioreactor serum-free suspension platform to produce lentiviral vectors at significantly lower cost per dose
- In-house products
  - Spin out / out-license of in-house product candidates



### Vision of Oxford BioMedica – by end of 2018

## Core LentiVector<sup>®</sup> platform R&D

New product candidates emerging from research/discovery using the LentiVector<sup>®</sup> platform

Lead gene-modified NK cell therapeutic candidate emerging from the GCLC research collaboration

Technical developments – continuous improvement of the LentiVector<sup>®</sup> platform

Feeds further product partnership opportunities

#### **Product pipeline**

#### **OXB** priority products

- Successful spin outs and/or out-licensing
- Products progressing in Phase I/II studies

#### Novartis

- CTL019<sup>1</sup> launched
- Oxford BioMedica supplying commercial material
- Royalties from CTL019<sup>1</sup>
- Second CAR-T product into clinical development
- Further CAR-T programmes

#### Sanofi

• SAR422459 to be in a pivotal trial

#### Immune Design

LV305 progressing well in clinical development

#### **Orchard Therapeutics**

- ADA-SCID pivotal trial close to completion
- MPS IIIA in clinical development

#### Several further partnerships

 Economic interests in a range of gene and cell therapy products

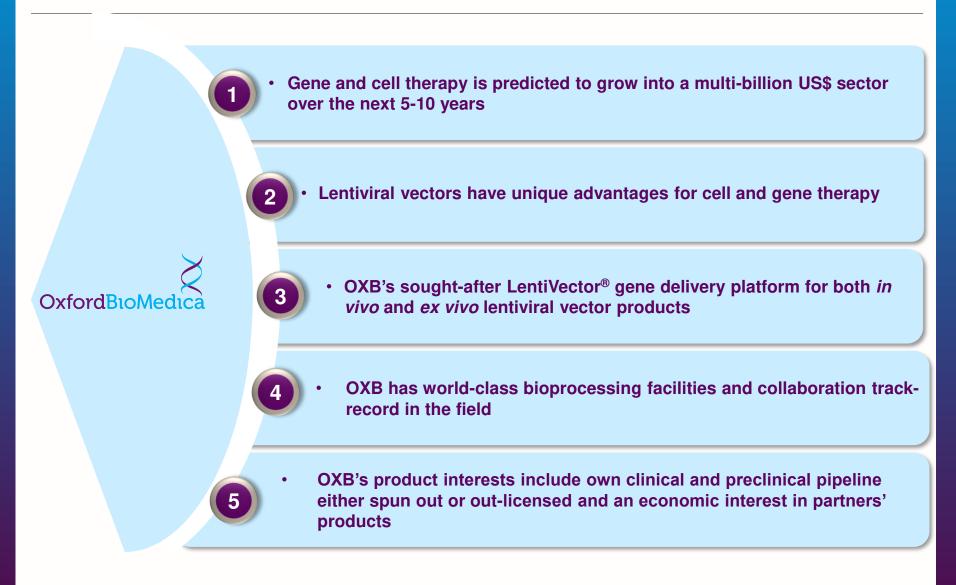
#### Bioprocessing

## Facilities operating at high capacity



<sup>1</sup> USAN name is tisagenlecleucel

### Summary: a leading gene and cell therapy company



<sup>1</sup> Clive Glover, GE Healthcare "Sales of cell and gene therapy will reach \$10 billion by 2021", October 2015.



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