



# Building the future

Annual report and accounts 2018



Oxford Biomedica in brief

Oxford Biomedica is a pioneer of gene and cell therapy with a leading position in lentiviral vector research, development and bioprocessing. Gene and cell therapy is the treatment of disease by the delivery of therapeutic DNA into a patient’s cells. This can be achieved either *in vivo* (referred to as gene therapy) or *ex vivo* (referred to as cell therapy), the latter being where the patient’s cells are genetically modified outside the body before being re-infused.

Oxford Biomedica is focused on developing life changing treatments for serious diseases. Oxford Biomedica and its subsidiaries (the “Group”) have built a sector leading lentiviral vector delivery platform, LentiVector, which the Group leverages to develop *in vivo* and *ex vivo* products both in-house and with partners. The Group has created a valuable proprietary portfolio of gene and cell therapy product candidates in the areas of oncology, ophthalmology and CNS disorders.

The Group has also entered into a number of partnerships, including with Novartis, Sanofi, Axovant Gene Therapies, Orchard Therapeutics, Boehringer Ingelheim, the UK Cystic Fibrosis Gene Therapy Consortium and Imperial Innovations, through which it has long-term economic interests in other potential gene and cell therapy products. Oxford Biomedica is based across several locations in Oxfordshire, UK and employs more than 430 people.



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The arrival of gene and cell therapy is clear. Landmark regulatory approvals of these life-changing treatments are now happening, and include the very first commercial use of Oxford Biomedica’s LentiVector® technology.

Our science is now a therapeutic reality for patients suffering from some of the most serious diseases. What we are witnessing is just the beginning...







# Innovating

**Personalised gene-based medicine is entering the mainstream. It is an area of healthcare bursting with new ideas around many unmet needs.**

**We have always seen its potential and are playing a crucial role in making new curative treatments.**

Oxford Biomedica is one of the original pioneers of gene and cell therapy.

We continue to lead the way, setting new standards and benchmarks for everyone's benefit.



## Our LentiVector technology is becoming increasingly attractive

The most commonly used vectors for gene and cell therapy are based on lentiviruses and adeno-associated viruses (AAV). Lentiviral vectors offer clear advantages over AAV such as better payload capacity and permanent modification of dividing cells such as T cells and stem cells, and there is no pre-existing immunity unlike with AAV.

With several several years of clinical data now available, our LentiVector platform has more compelling results than any other.

Read more about our LentiVector platform on page 13.



## We are the only people in the world who can do this right now

The delivery of gene and cell therapies into patients is a complex and highly specialised process, and one that has taken us many years to perfect.

Oxford Biomedica is the only group in the world with a GMP-approved facility for commercial scale lentiviral vector manufacturing. When we say we have know-how and experience we really mean it.

Read more about the opportunities within the sector on page 12.



	Lentiviral Vectors	AAV Vectors
Efficient <i>in vivo</i> gene delivery	• • •	• • •
Safe and well tolerated	• • •	• • •
Large therapeutic payload	• • •	
No pre-existing immunity	• • •	
Permanent modification of dividing cells	• • •	
IP protection	• •	•
Ease of manufacture	• •	• •

### Lentiviral Vectors vs AAV Vector

## \$8bn

### Haemophilia A and B market

Projected to increase to \$8 billion by 2026. Sanofi, with whom we have two partnered pipeline products, is expected to become the second biggest player with global sales of \$1.4 billion by 2025<sup>1</sup>.

1. Source: GlobalData, July 2017

## 63%

### Global CAR-T cell therapy market

Forecast to grow at a CAGR of over 63% from 2018 to 2022<sup>2</sup>. The majority of therapies in the global CAR-T cell therapy market are still in the early stages of clinical trials, many of which could potentially use our LentiVector technology.

2. Source: Technavio, October 2018

## Introducing the next gene and cell therapy industry standards

As we continue to trail blaze this burgeoning sector, we are constantly innovating and finding ways to make gene and cell therapy work better, be safer and more cost effective.

We have developed the TRiP System™ to maximise vector yields and particle purity and standardise downstream processes.

This new development substantially limits potential detrimental effects on vector function and purification. It can be used to benefit all delivery systems including AAV.

Read more about the TRiP System and other LentiVector platform developments on page 33.



## Developing our own new products in key areas of unmet need

We have already experienced success with our partners' products, but we also have our own products under development. As we uncover greater potential from our LentiVector platform we are pushing forward with our efforts to discover new treatments for diseases with serious unmet need, such as rare retinal and motor neurone diseases, to add to our development pipeline.

See our product development pipeline on page 16.



**Hospitals are offering CAR-T therapy Kymriah**  
The NHS agreed a commercial deal with Novartis to offer ground-breaking CAR-T therapy Kymriah, which uses our LentiVector technology, to children with advanced leukaemia. It took the NHS less than 10 days after Kymriah won marketing authorisation, making it one of the fastest funding approvals in its 70-year history.





**Expanding**

**The gene and cell therapy industry is growing rapidly and we are expanding to meet the demand.**

**To exploit our leading position we are investing in our future so that we continue to be a partner of choice for lentiviral vector manufacture.**

We have seen rapidly growing revenues from process development, bioprocessing and royalty generating partnerships over the past few years.

Our economic interest in a diverse range of products is also growing and we continue to invest in technology and proprietary gene and cell therapy concepts.



## Expanding

Gene and cell therapy is growing fast

### A highly valuable market

The gene and cell therapy sector is developing into a multi-billion \$ market. We estimate that the lentiviral vector manufacturing market alone will grow to be worth \$800 million by 2026.<sup>1</sup>

### Upsurge in gene and cell therapies

The potential gene and cell therapy holds for curative treatments for a broad range of diseases with inadequate options makes it an incredibly exciting, and urgent area of healthcare.

The US Food and Drug Administration (FDA) currently has around 800 active gene and cell therapy-based investigational new drugs on file and has forecast another 200 applications each year from 2020. It is a booming sector bursting with potential.

<sup>1</sup> Company estimates

Read more in the sector and technology overview on page 12.



## 40%

#### Increase in workforce

We are planning to create over 160 new highly skilled positions at our facilities in Oxford in 2019 to meet the expected growth in demand for gene and cell therapies.

## £20m

#### Investment in new facility

Our new full-service site was funded through our successful Placing in March 2018. This investment will allow us to exploit the immediate market opportunity and meet expected long-term demand.



#### Manufacturing facility

Our new manufacturing facility is approximately 84,000 sqft (7,800 sqm). The Phase 1 and Phase 2 expansion will fit out around 45,000 sqft (4,200 sqm) for four GMP clean room suites and two fill and finish suites as well as offices, warehousing and QC laboratories, with space available for future expansion.

### Doubling our capacity

Oxford Biomedica is already working with some of the biggest names in pharma, helping them to progress and deliver gene and cell therapies. We are experiencing huge demand for our LentiVector technology, process development and manufacturing services. This important revenue stream is running at full, or close to full capacity.

We already have two independent GMP approved manufacturing facilities, together with state-of-the-art laboratories with process development and analytical capabilities. Our new manufacturing facility, due to begin operations in 2020, will more than double our capacity enabling us to meet existing contracts and take on new ones. In addition, we have taken a lease on another building which will become our discovery and innovation facility.

Read more in the Chief Executive Officer's review on page 29.

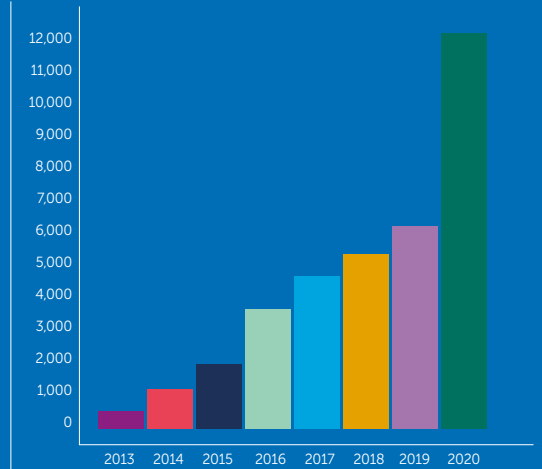


### A unique position

Oxford Biomedica has a wealth of in-house expertise and know-how and is in a unique position to provide partners with a truly one-stop-shop-solution.

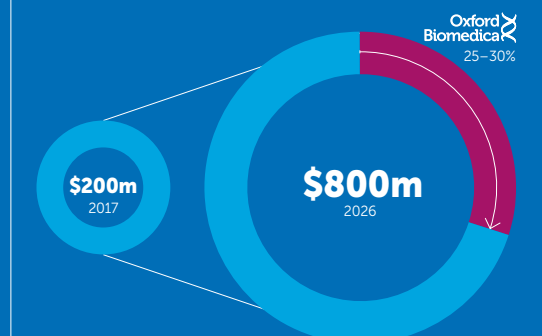
During 2019 we intend to increase our workforce considerably with the creation of another 160 highly skilled positions.

Read more in the Chief Executive Officer's review on page 29.



#### Bioprocessing capacity through to 2020

We are planning to more than double our current capacity for bioprocessing and GMP manufacturing over the next 18 months.



#### Lentiviral vector bioprocessing market expected to grow to \$800 million by 2026<sup>1</sup>

The global lentiviral vector bioprocessing market is expected to grow rapidly over the next few years. We are targeting 25% to 30% of this market (excluding milestones and royalties).

<sup>1</sup> Company estimates



**Gene and cell therapy is very much here and now and we're right at the heart of this healthcare revolution, working on our own life-changing products and those of our partners.**

**We're ready to deliver the next wave of new weapons for patients to fight back.**

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A global opportunity

The market for advanced therapy medicinal products (ATMPs), and gene and cell therapies in particular, is experiencing unprecedented growth.

Participation in merger and acquisitions (M&A) by the large pharmaceutical companies, global partnerships and product approvals have all propelled regenerative medicines into public discourse. But it was 2018 that delivered the true potential of this burgeoning sector into the mainstream. This followed the approval of three innovative gene and cell therapies in 2017. From our partner, Novartis, Kymriah received initial approval for acute lymphocytic leukaemia. It was the first and only CAR-T cell therapy to be approved for two different indications. Gilead followed suit after its acquisition of Kite Pharma as Yescarta, indicated for Non-Hodgkin’s lymphoma, became the second CAR-T cell therapy to be approved. Spark Therapeutics’ gene therapy Luxturna was approved in late 2017 for vision loss.

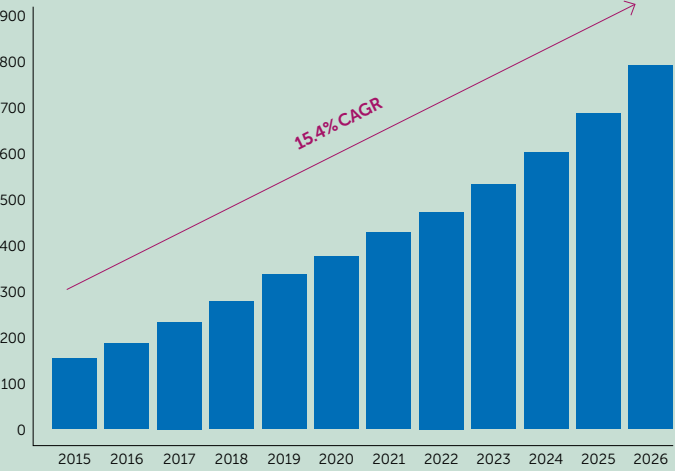
These landmark approvals marked a transition for the field from experimental to commercial and they pave the way for more advanced therapy approvals in the years to come. The US Food and Drug Administration (FDA) is preparing for the coming wave and expects that, by 2020, it will see more than 200 applications a year requesting permission to begin gene and cell therapy trials. It already has more than 800 such applications in process and has stated its intention to hire 50 clinical reviewers to handle the upsurge. By 2025, the FDA predicts it may approve 10–20 new gene and cell therapy products a year.

Gene and cell therapies use viral vectors to deliver genetic material into patients’ cells. The two most common viral vectors used for this purpose are lentiviral vectors such as our LentiVector platform, and adeno-associated viral vectors, or AAV. Each has its own applications however lentiviral vectors have become increasingly attractive for clinical applications due to their ability to efficiently and effectively introduce genetic material into non-proliferating cells, and to carry larger payloads so they can treat a wider range of diseases and genetic disorders.

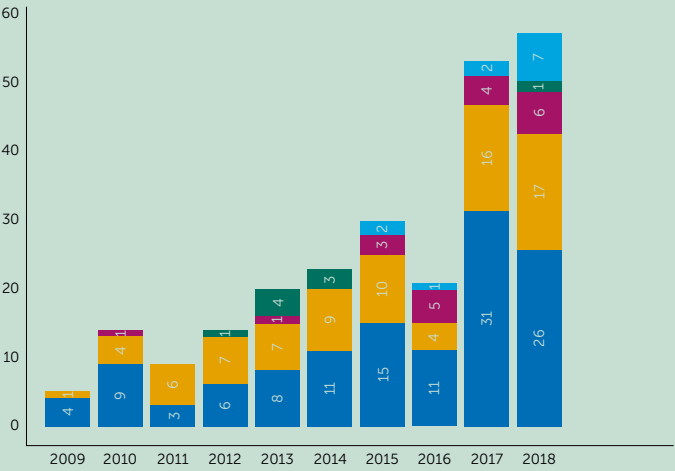
We estimate that the market for lentiviral vector manufacturing was worth approximately \$200 million in 2017 and that it will grow at a 15.4 per cent. compound annual growth rate from \$158 million in 2015 to \$800 million by 2026.\* As the only Group in the world with a GMP-approved facility for commercial-scale lentiviral vector manufacturing, Oxford Biomedica is ideally positioned to take advantage of the expected increase in demand.

\*Source: Company estimates

Further information on the sector can be found on the Group’s website at [www.oxb.com](http://www.oxb.com).



Lentiviral vector bioprocessing market (\$m)  
Source: Company estimates



Number of lentiviral vector clinical trials initiated by year and phase

Phase  
■ Phase I  
■ Phase II  
■ Phase III  
■ Phase I/II  
■ Phase II/III

Source: Journal of Gene Medicine, December 2018

World-leading LentiVector gene delivery platform

Our LentiVector platform provides stable gene delivery with very high efficiency. It achieves permanent therapeutic benefit through gene integration and long-term expression.

The LentiVector platform has particular advantages in localised delivery to non-dividing cells, such as neurons in the brain and retinal cells in the eye, as well as in dividing cells where permanent modification is required.

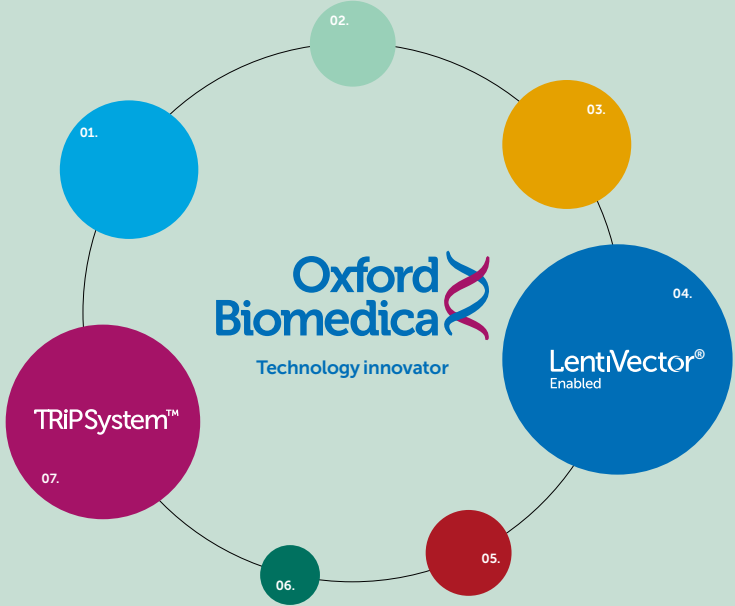
We have data demonstrating more than seven years of stable, dose-dependent gene expression in patients after direct *in vivo* administration.

Several factors affect the choice of gene delivery system, including target cell type, duration of gene expression and payload capacity. Lentiviral vectors provide several key features that make them well suited to a range of gene and cell therapy applications:

- Significant payload capacity.
- Target specific cell types by pseudotyping of envelope.
- Permanent modification of dividing cells, such as T-cells or stem cells.
- No pre-existing immunity.
- Long-term gene expression.

Continuous innovation

- 01. Analytics  
Our analytics capabilities have been developed to support production and supply processes which are essential for satisfying international regulatory expectations.
- 02. Data analytics and artificial intelligence  
We have collected unique data from our extensive process development experience that enables us to use machine learning to optimise our manufacturing process, further increasing the performance of our platform.
- 03. Automation and robotics  
Our significant investment in automation and robotics has increased productivity while reducing development timings and process risk.
- 04. Vector engineering  
Our engineering principles ensure cost-effective and timely delivery of pipeline products.
- 05. Packaging and producer cell lines  
Our packaging and production cell lines enable a simplified and scalable manufacturing process while reducing costs.
- 06. 200L serum-free suspension culture  
Our suspension process improves production yield and efficiency while reducing cross-contamination risks with less manual handling and single use systems. Our serum-free medium is also a significant safety advantage.
- 07. TRiP System  
The TRiP System offers a new standard in lentiviral vector manufacturing and can be used in other viral vector systems.

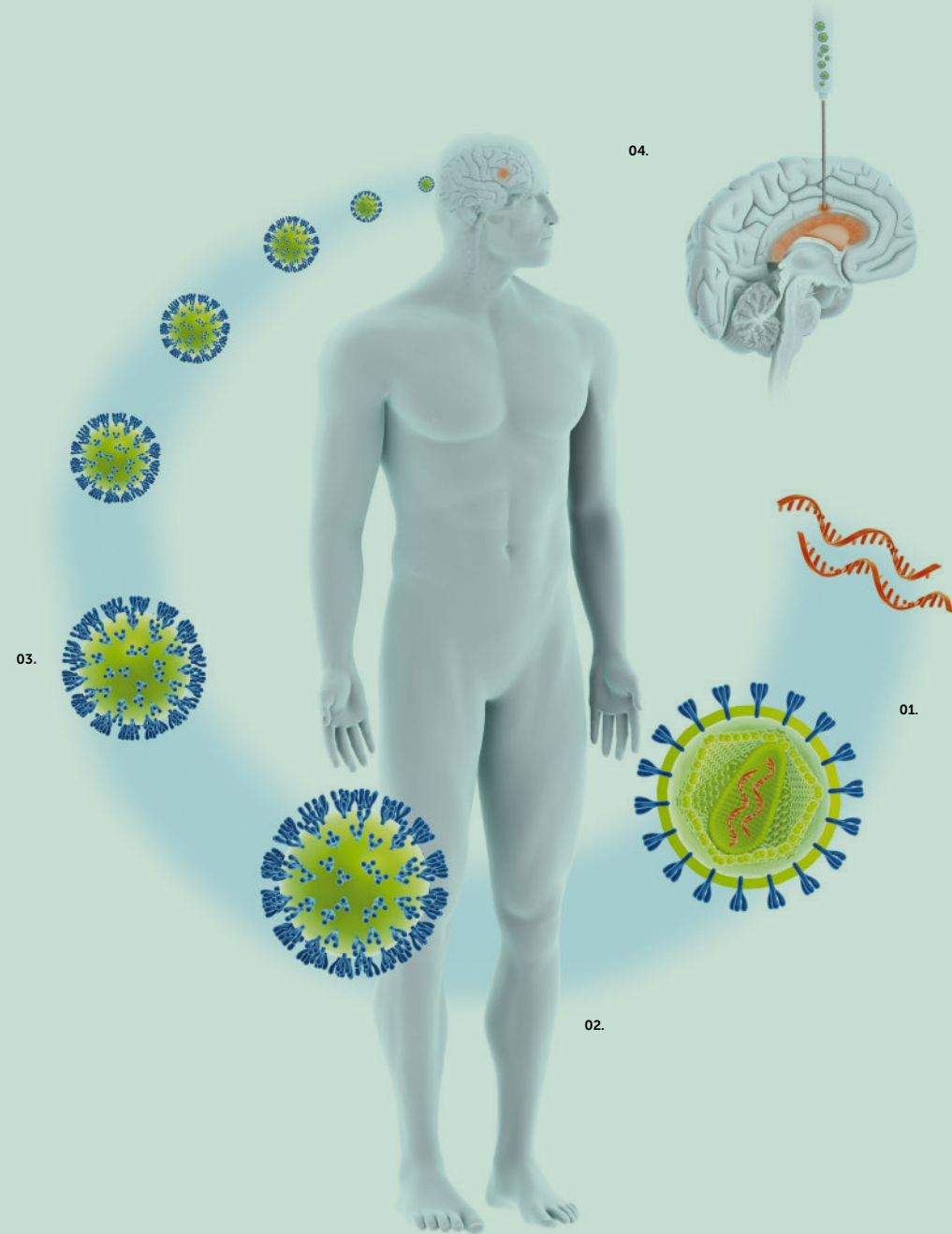




How our technology works for Parkinson’s disease  
**AXO-Lenti-PD gene therapy treatment for Parkinson’s disease (an Axovant product)**

- 01. Therapeutic gene expression cassette**  
The therapeutic genes that need to be delivered to the target cell to treat the disease are engineered into the vector genome. In the case of AXO-Lenti-PD three genes need to be delivered to the cells in the brain region that is low in dopamine.
- 02. Making a safe vector from a virus**  
To make a safe vector system the viral genes are removed; this also creates space for the therapeutic vector payload.

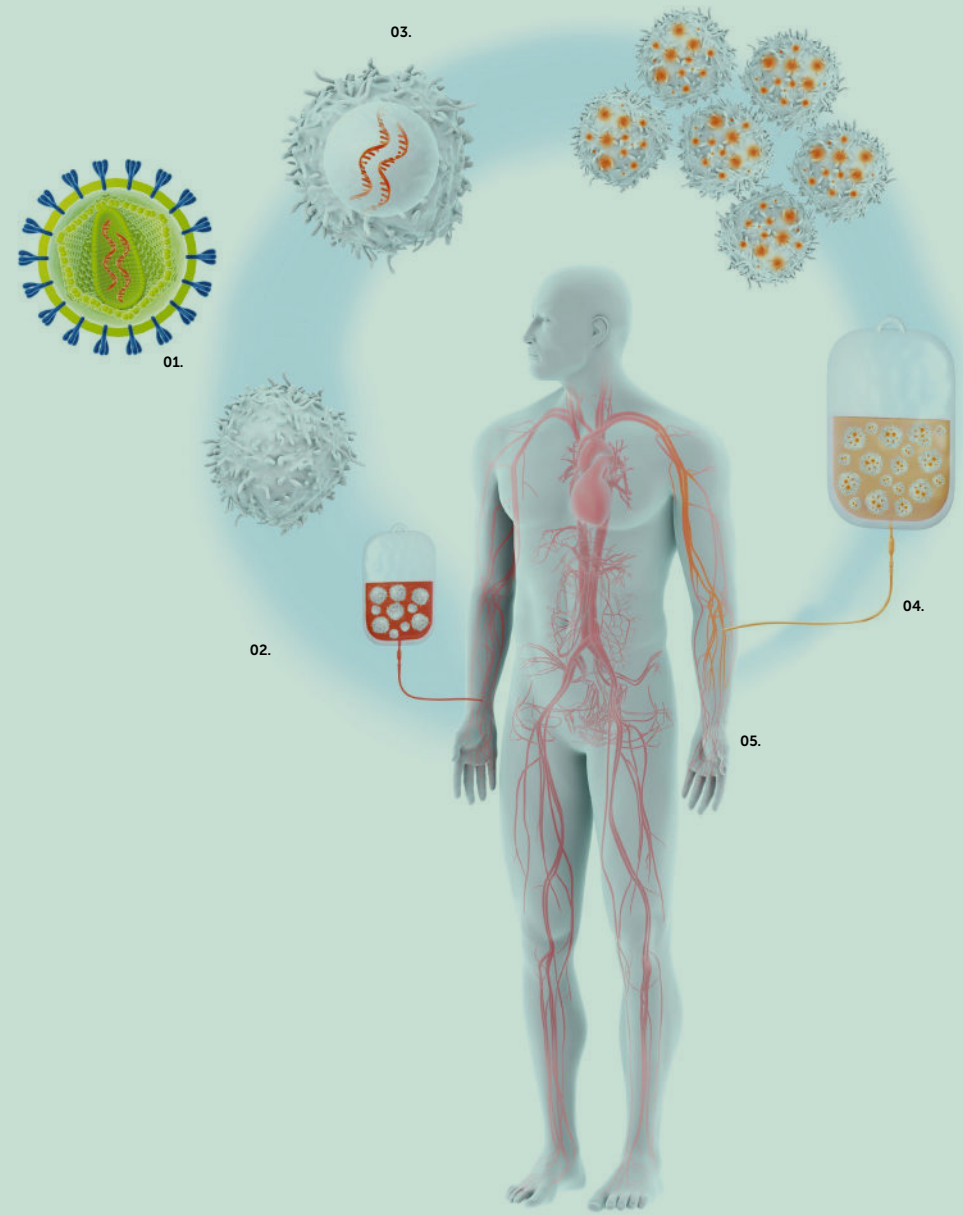
- 03. Lentiviral vector generation**  
High quality lentiviral vector product is produced under GMP conditions at large scale suitable for use in the clinic.
- 04. AXO-Lenti-PD vector is administered to the target tissue**  
Stereotactic surgery is used to deliver the vector product to the target tissue. The vector enters the neuronal cells and modifies them to create endogenous factories making dopamine, the neurotransmitter lacking in Parkinson’s disease.



How our technology works for cancer  
**Kymriah (CTL019) – a CAR T-cell therapy for cancer (a Novartis product)**

- 01. OXB produces GMP lentiviral vector encoding CAR targeting CD19 which is expressed on B-cell cancers**
- 02. T-cells isolated from patients**
- 03. Lentiviral vector encoding CAR targeting CD19 used to transduce expanded T-cells**  
T-cells harvested from a patient are transduced with the lentiviral vector encoding the anti-CD19 chimeric antigen receptor. The resulting CTL019 modified T-cells are expanded ex vivo prior to infusion into the patient.

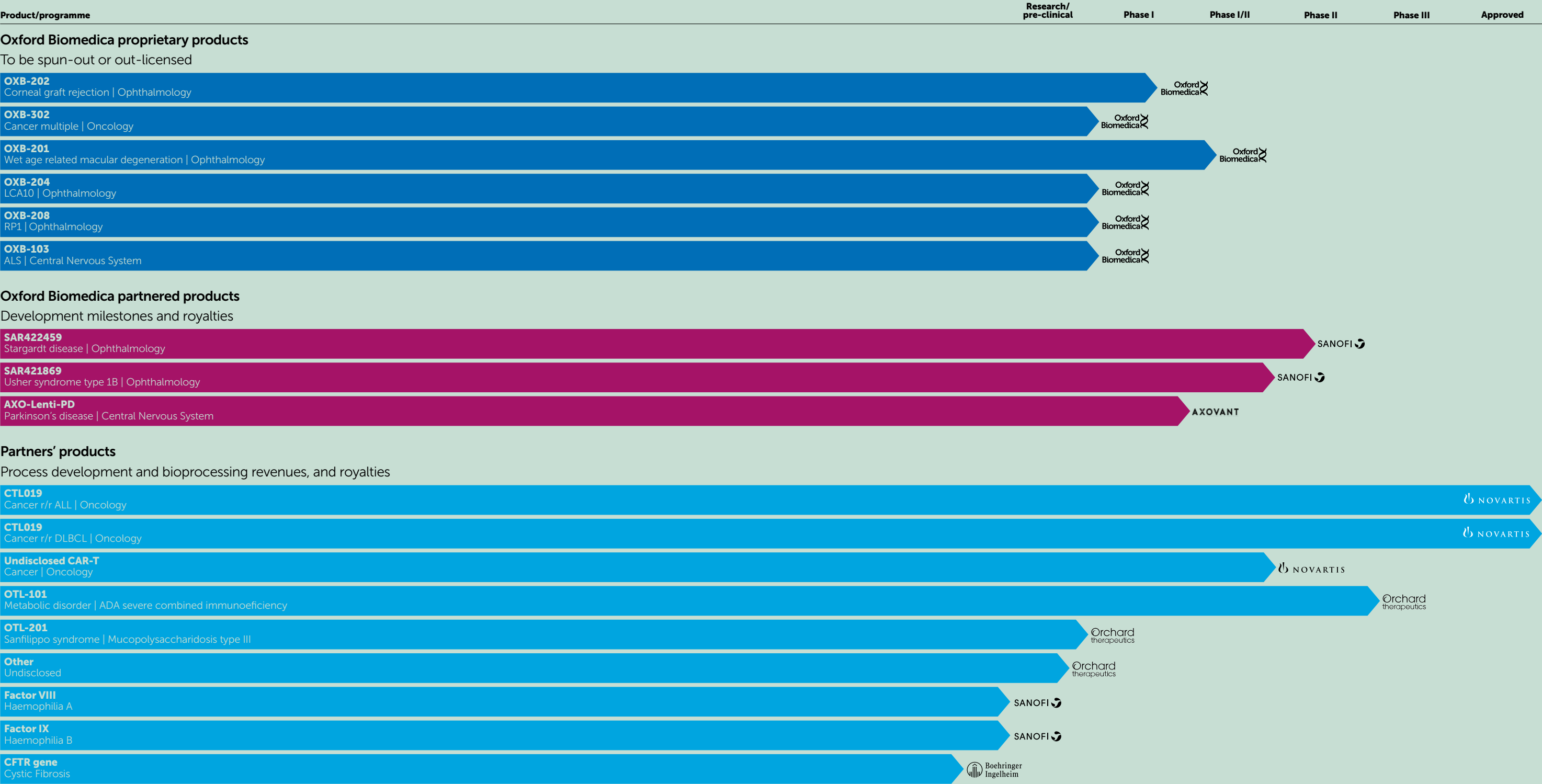
- 04. The modified T-cells are infused back into the patient**
- 05. Once inside the patient, the CTL019 cells multiply and target, 'hunt' cancer cells and destroy them**  
The CTL019 cells destroy tumour cells expressing CD19 and persist in the body to guard against residual or recurring disease.





Product pipeline

We are working on several internal product candidates and have interests in an expanding range of partner programmes.







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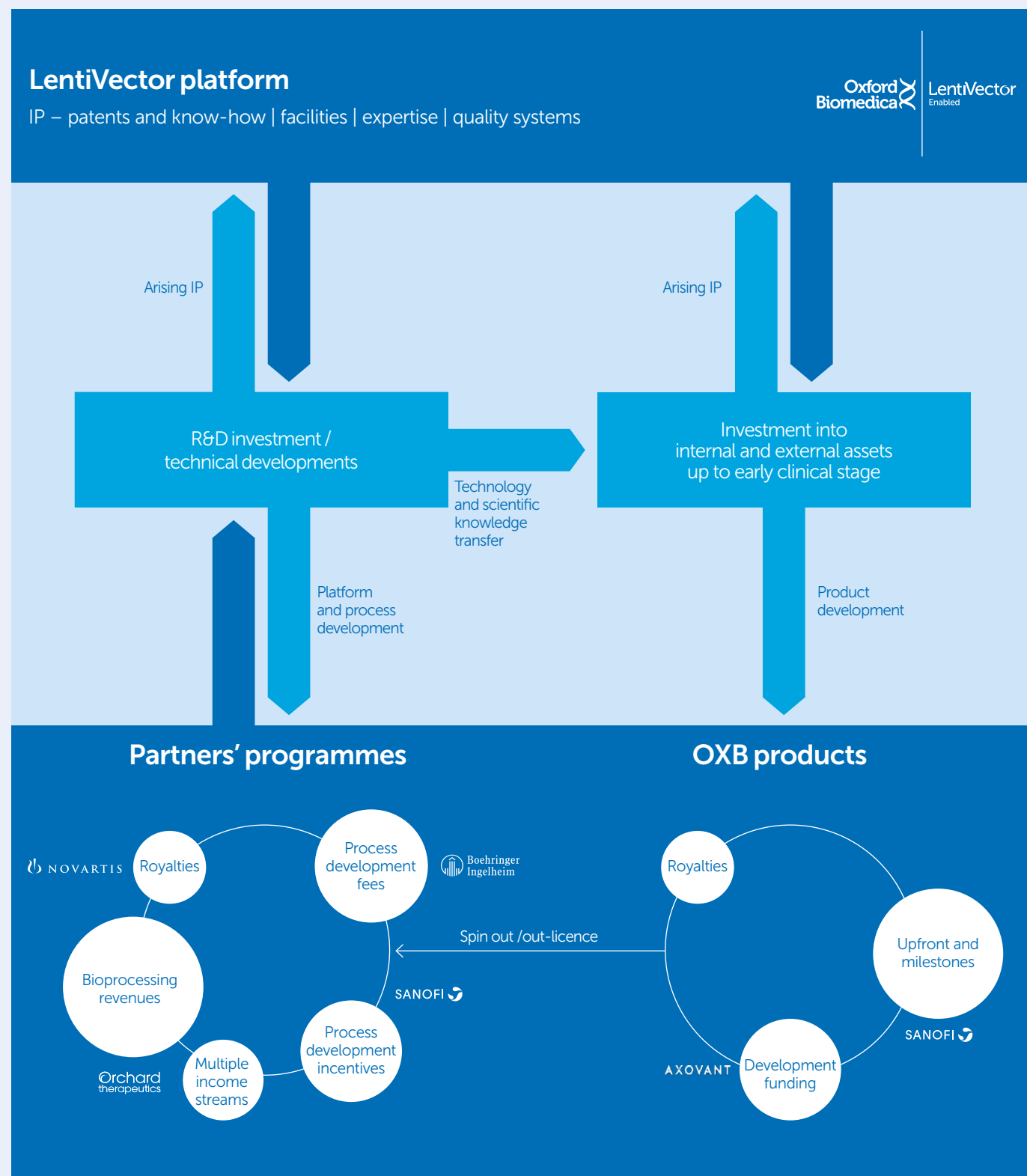
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**Our business model and strategy**

During 2018 the Board reviewed the Group's current business model and strategy. It was decided that the business model and strategy was still very relevant but required minor modifications. The Group is now willing to make modest investment into internal and external assets up to early clinical stage before looking to spin out or out-licence to a partner. This strategy has been validated through the Axovant deal for OXB-102 (now AXO-Lenti-PD) for Parkinson's disease entered into in June 2018.

Our business model, built on our world-leading LentiVector gene delivery platform is the result of over 20 years of pioneering science and process development using lentiviral vectors, initially for *in vivo* therapies. Oxford Biomedica was the first organisation globally to use lentiviral vectors in an *in vivo* setting and therefore we had to design and develop vectors and manufacturing processes which would be both safe and effective. This work was the foundation of our unique combination of skills, patents and know-how which, together with our GMP clean room and laboratory facilities, combine to form our LentiVector gene delivery platform.

Lentiviral vectors are key components of many promising new gene and cell therapies, and so our LentiVector-Enabled platform provides us with opportunities to generate short- and longer-term value through:

**In-house development**

We have our own portfolio of LentiVector-Enabled platform gene and cell therapy product candidates. We decided that later stage clinical studies of these candidates will be developed with third party finance, using either out-licensing or by spinning out the programmes into one or more special purpose vehicles (SPVs). This will significantly reduce the cost and risk associated with clinical development, while providing us with potential equity stakes in the SPVs, and/or potential upfront, milestone and royalty payments, as well as bioprocessing and process development revenues. We will modestly invest in internal and external assets up to early stage clinical development, with a view to building a pipeline of candidates ready for clinical studies.

**Partnering**

We can provide our bioprocessing and process development expertise and facilities to third parties who want to accelerate the development of their own lentiviral vector programmes. In return for which, we receive short and medium term revenues, and longer term royalties based on licences to our extensive know-how and patents.

**Freedom-to-operate licensing**

We can provide other organisations with licences to use our important patents relating to lentiviral vector safety features and manufacturing efficiencies.

The graphic opposite illustrates our business model. The foundation is our world-leading LentiVector platform, and our goal is to exploit this by gaining interests in a diverse range of gene and cell therapy products which can be both internally generated and as a result of our relationship with partners and collaborators.

The platform technology is still some way from being fully mature so we are continuing to invest R&D funds in improving the technology to retain our leading position, as this is what attracts other companies to work with us.

**Principal risks facing the business**

The principal risks facing the business, including how they are managed and mitigated, are set out in detail on pages 52 to 58. The main risks are:

- Risks associated with pharmaceutical product development including product safety issues, lack of efficacy, and failure to obtain regulatory approval.
- Risks to our bioprocessing revenue from failure to manufacture lentiviral vector to the required standard.
- Exposure to one or more of our partners ceasing to develop their products and thereby no longer requiring our services.
- Failure to comply with the terms of the Oaktree loan facility.
- Failure to out-licence or spin-out the Group's priority product development candidates so that development stops.
- Inability to attract and/or retain highly skilled employees.



Delivered in 2018  
Operational highlights

Novartis’ commercialised product Kymriah

- Kymriah approved by the US Food and Drug Administration for the treatment of relapsed and refractory B-cell diffuse large B-cell lymphoma (r/r DLBCL), the second indication in the US.
- The European Commission, Health Canada and the Therapeutic Goods Administration of Australia also approved Kymriah for the treatment of children and young adults with r/r B-cell acute lymphoblastic leukaemia (r/r ALL) and adult patients with r/r/ DLBCL.
- NHS England announced that Kymriah will be made available to children and young adults in England and the first patients have now been treated.

LentiVector delivery platform for gene and cell therapy partnerships

- \$105 million collaboration and licence agreement signed with Bioverativ (now part of Sanofi) to access Oxford Biomedica’s LentiVector platform and manufacturing technologies in the field of haemophilia.
- Partnership formed with the UK Cystic Fibrosis Gene Therapy Consortium, Boehringer Ingelheim and Imperial Innovations to develop a novel inhaled gene therapy for cystic fibrosis.

Proprietary product development

- \$842.5 million exclusive worldwide agreement signed with Axovant Sciences (now Axovant Gene Therapies) for OXB-102 (now known as AXO-Lenti-PD) for the treatment of Parkinson’s disease.
- Phase 1/2 clinical study for AXO-Lenti-PD began and patients from the first dose cohort have been treated. Based on initial feedback from members of the DMC, received in March 2019, Axovant plans to proceed to the second dose cohort.
- Three proprietary OXB assets selected to advance from research through pre-clinical development: OXB-204 and OXB-208 target inherited retinal diseases, while OXB-201 is in development for the treatment of amyotrophic lateral sclerosis (ALS).

Capacity building

- Signed a fifteen year lease on a new 84,000 sqft (7,800 sqm) manufacturing facility in Oxford, close to Oxford Biomedica’s Windrush Court headquarters. Offices and warehousing are now in operation, with the additional GMP suites expected to be operational in 2020.
- Signed a further lease on an additional 32,000 sqft (2,975 sqm) discovery and innovation facility next to Windrush Court. The facility will bring together a multidisciplinary team of researchers, automation, bioprocessing and process development experts to drive innovations that will lead to new scientific and technical advances to support our pipeline and our platform.
- Formed a £4 million digital framework initiative, supported by a £2 million grant from Innovate UK, the UK’s innovation agency, to build digital and robotics capabilities designed to drive improvements in analytical methodology, supply times and cost of goods. Announced and R&D collaboration with Microsoft in March 2019 to support the initiative.

Delivered in 2018  
Financial highlights

+72%

Gross income<sup>1</sup>  
Gross income increased by 72% to £67.9 million (2017: £39.4 million).

+78%

Revenue  
Revenue increased by 78% from £37.6 million to £66.8 million.

£10.8m

Capital expenditure  
Capital expenditure £10.8 million (2017: £2.0 million).

+38%

Adjusted operating expenses<sup>2</sup>  
Adjusted operating expenses increased by 38% to £31.7 million (2017: £22.9 million).

+28%

Operating expenses  
Operating expenses increased by 28% from £28.9 million to £37.1 million.

£18.3m

License income  
£18.3 million worth of income received from the Axovant and Bioverativ deals.

£13.4m

Operating EBITDA<sup>3</sup> profit  
Operating EBITDA loss converted into a profit of £13.4 million (2017: £1.9 million loss).

£32.2m

Cash  
Cash of £32.2 million (31 December 2017: £14.3 million).

£13.9m

Operating profit  
Operating loss converted into a profit of £13.9 million (2017: £5.7 million loss).

£2.8m

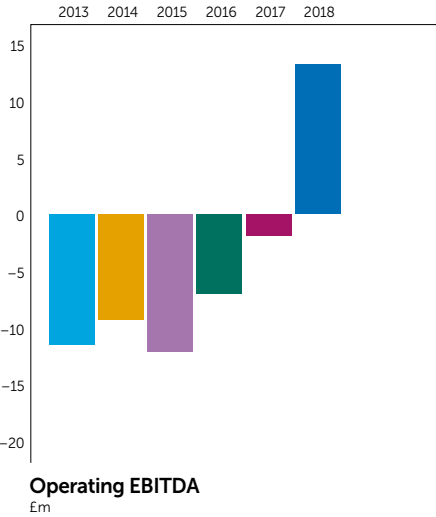
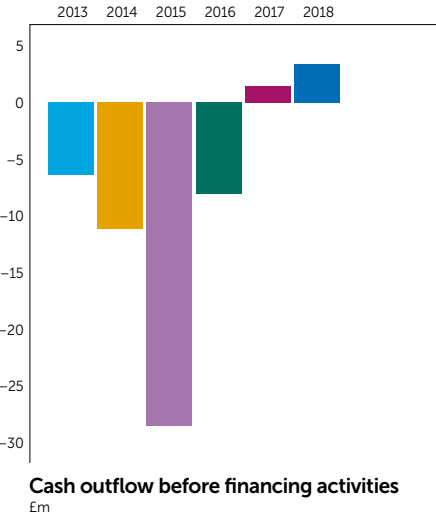
Cash inflow  
Cash inflow before financing activities increased by £1.8 million to £2.8 million (2017: £1.0 million).

£20.5m

Equity placing in March 2018  
Successful £20.5 million equity placing to fund further expansion of bioprocessing capacity.

£6.0m

Revaluation  
£6.0 million (2017: £2.3 million) gain recognised on revaluation of our investment in Orchard Therapeutics.



Key financial indicator definitions (non-GAAP Alternative Performance Measures)  
1. Gross Income is the aggregate of revenue (£66.8 million) and other operating income (£1.1 million) (2017: £37.6 million and £1.8 million respectively). A reconciliation to GAAP measures is provided on page 40.  
2. Adjusted operating expenses is Research, Development and Bioprocessing costs plus Administrative costs less Depreciation, Amortisation and share based payments. A reconciliation to GAAP measures is provided on page 40.  
3. Operating EBITDA is Earnings Before Interest, is Tax, Depreciation, Amortisation, revaluation of investments and share based payment. A reconciliation to GAAP measures is provided on page 40.





"The gene and cell therapy market is rapidly transforming into a multi-billion dollar opportunity and the Group's strategy is delivering significant shareholder value – we expect this to continue."

Dr. Lorenzo Tallarigo  
Chairman

**It has been a year of transformation for Oxford Biomedica, not only with significant revenue growth and cash flow generation but also in reaching profitability. These great strides made in 2018 are testament to Oxford Biomedica's leading position in the innovation, development and manufacturing of lentiviral vectors, and the expertise of its people.**

#### Strategic opportunities

Our mission is to deliver life-changing gene and cell therapies to patients. It encompasses our strategy to support our partners in the development and commercialisation of their own gene and cell therapy programmes with our world-leading manufacturing capabilities while in addition pursuing a selective gene and cell therapy portfolio internally through early clinical development.

Our recent successes demonstrate that we have a strategy and business model that works. As is the nature of gene therapy development, reproducibility of results in late-stage trials is high and therefore much value can be created in early clinical studies. It is for this reason that we continue to explore the potential of our product pipeline in a focused and disciplined way.

Moving forward into 2019 and beyond, we see further significant opportunities both to advance the development of our in-house programmes, where we have particular expertise, and to create future out-licensing opportunities similar to our recent landmark deal with Axovant. In addition, our strategy to seek to retain manufacturing rights for our out-licensed programmes provides potential, additional long-term economic interest through their development and commercialisation.

#### Driving innovation

We've spent the past 20 years honing our manufacturing expertise and capabilities. To date, Oxford Biomedica is the only FDA-approved commercial supplier of lentiviral vectors. While we're immensely proud of this accreditation, we are not resting on our laurels. We strive to achieve continuous improvement in our manufacturing processes, a core group objective that aligns with one of our three values to 'deliver innovation'.

To meet the expected long-term demand and futureproof Oxford Biomedica's market leading position, we are more than doubling our manufacturing capacity with the development of new state-of-the-art clean rooms and fill/finish suites on a new site close to our headquarters in Oxford. Construction of the new facilities is progressing to plan and we expect to be operational from the second quarter of 2020.

By applying our expertise and continuing to innovate in lentiviral vector production, we believe we are well placed to take advantage of the expected growth in demand.

#### Board

We have continued to benefit from a changing Board profile, with the appointment of Heather Preston as a Non-Executive Director in March 2018. Peter Nolan has formally retired from his role as Chief Business Officer, having made a significant contribution to the business since its inception in 1996. With these developments, the Board is now composed of five Non-Executive and two Executive Directors.

#### Organisation and culture

On behalf of the Board I would like to take this opportunity to recognise all of our fantastic employees at Oxford Biomedica who have helped to get the Group to where it is today. Within the business we have a highly engaged workforce with a diverse range of capabilities, knowledge and experience. We are very grateful to our people for their continued commitment and excellent contributions during the past year. Our culture and values will continue to drive performance and help attract and retain the best talent, and we are committed to their development to ensure we have the necessary skills that we need to succeed on our growth journey.

#### The global environment

We find combined economic and political challenges around the world, including questions about international trade and future partnerships between countries. Oxford Biomedica is experienced at adapting to change, now a constant in the environment in which we are living. We continue to prepare for all scenarios around the UK's exit from the European Union this year and are well prepared for all expected eventualities. We look forward to an agreement on the final exit terms that will provide stability for our workforce and our business operations.

Despite this uncertainty, it is nevertheless an exciting time to be at the forefront of gene and cell therapy. After three decades of hope tempered by setbacks, it is now a therapeutic reality. In the past 18 months, three gene therapy products – including Novartis' Kymriah for which Oxford Biomedica is the sole lentiviral vector manufacturer – have been made available to patients and along with them we've seen a raft of new investment and clinical development activity in the sector. Oxford Biomedica has been a beneficiary of this investment activity; we are grateful for the support of our shareholders as well as that of the UK Government through its Life Sciences sector deal, to ensure pioneering new treatments and medical technologies are produced in the UK.

#### The future

The excitement and momentum in the cell and gene therapy space continues to build.

Oxford Biomedica is fortunate with its scientific excellence and world-leading position to be ideally placed to take advantage of this burgeoning industry. I look forward to the future with much confidence and optimism.

#### **Dr. Lorenzo Tallarigo**

Chairman





"The Group has played a crucial role in enabling revolutionary gene and cell therapies to become a reality. As a world leader in this space, Oxford Biomedica is now in a strong position to deliver value to both patients and shareholders."

John Dawson  
Chief Executive Officer

It is with great pleasure that I am introducing Oxford Biomedica's 2018 Annual report. In the past year we have witnessed a transformation of the gene and cell therapy industry in which life-changing, curative treatment has become a therapeutic reality for many patients – and where Oxford Biomedica has played a central role.

Against this backdrop, I am delighted to report on the successful delivery of our partnering and in-house development strategy, leveraging our lentiviral vector platform. With Oxford Biomedica's strengthened financial position, I am now able to plan for the future with confidence to maximise the opportunity we see ahead.

As we stand today, the opportunities to create value from our business model are many, however, I am cognisant that our greatest challenge is to ensure that we maintain our leading position and respond effectively to sector developments while keeping a clear focus on our strategic imperatives. That is why, for 2019, I have set out six company objectives to help drive performance. These objectives are focused on financial performance, manufacturing and the platform, technology innovation, the therapeutic pipeline, operational delivery and workforce development. They will ensure that our people remain focused on our strategy and will help us to manage our growth in a sustainable way to deliver long-term benefits for our shareholders.

2018 Performance

I am pleased to report a strong financial performance and positive cash generation in 2018 following significant commercial and operational achievements. Gross income<sup>1</sup> of £67.9 million increased by 72 percent in the year driven by £18.3 million in licence income, largely from the Axovant (now Axovant Gene Therapies) and Bioverativ (now Sanofi) deals, and by increased development services provided to our customers. Positive cash flow before financing was £2.8 million, an improvement of £1.8 million on the previous year, reflecting the significantly improved trading performance. We ended the year with cash of £32.2 million reflecting our stronger financial position and a placing which raised £20.5 million (gross) in March 2018.

1. Reconciliation to GAAP measure provided on page 40.



**Oxford Biomedica playing a central role**  
In the past year we have witnessed a transformation of the gene and cell therapy industry in which life-changing, curative treatment has become a therapeutic reality for many patients – and where Oxford Biomedica has played a central role.

\$842.5m

**OXB-102 for Parkinson's disease**  
Our landmark agreement with Axovant, worth up to \$842.5 million for OXB-102, our internally developed gene therapy for Parkinson's disease.

\$105m

**Bioverativ (Sanofi) collaboration and licence agreement**  
Our \$105 million collaboration and licence agreement with Bioverativ (Sanofi) for the development and manufacturing of lentiviral vectors to treat haemophilia continues to advance under its new ownership as part of the Sanofi team.

Delivering the strategy

Partnering

We continue to support Novartis through its submissions, launches and commercialisation of Kymriah (tisagenlecleucel) in the US, EU, Canada, Australia and other territories, which are ongoing. Kymriah is a ground-breaking one-time chimeric antigen receptor T cell (CAR-T) therapy that uses a patient's own T cells to fight cancer. It represents the first ever approval of a commercial product incorporating Oxford Biomedica's LentiVector platform.

Our landmark agreement with Axovant, worth up to \$842.5 million for OXB-102, our internally developed gene therapy for Parkinson's disease, is evidence of our strategy in action. If successful, it has the potential to generate significant revenues, both now and longer term, not only due to development, regulatory and sales milestones but also from tiered royalties on net sales of 7-10 per cent.

OXB-102, renamed AXO-Lenti-PD, is an investigational gene therapy that enables the expression of a set of three critical enzymes required for end-to-end dopamine synthesis in the brain. It is expected to provide patient benefit for many years following a single administration, should it be successful. Axovant commenced a Phase 1/2 clinical study in October 2018, with the first patients having now been dosed and initial data expected in 2019.

Our \$105 million collaboration and licence agreement with Bioverativ (Sanofi) for the development and manufacturing of lentiviral vectors to treat haemophilia continues to advance under its new ownership as part of the Sanofi team. We were encouraged by recent comments from Sanofi that gene therapies with the potential to cure life-threatening conditions are a key area and one in which the company is seeking to expand. We are ready to support the new partner for our previously-licensed ophthalmology programmes, SAR422459 for Stargardt disease and SAR421869 for Usher's Syndrome type 1b, following Sanofi's recent portfolio review.

In our third partnership agreement of the year, we established a collaboration with the UK Cystic Fibrosis Gene Therapy Consortium, Boehringer Ingelheim and Imperial Innovations to develop a novel inhaled gene therapy for cystic fibrosis. The agreement demonstrates the versatility of our LentiVector platform and represents a new therapeutic area for Oxford Biomedica.



In-house development

We continue to invest in the development of a proprietary pipeline of innovative gene therapies to treat diseases with unmet medical needs, for future out-licensing or spin-out. Following a modest investment in the early development of OXB-102 for Parkinson’s disease and its subsequent out-licensing to Axovant, we have selected three additional proprietary assets to advance from research through pre-clinical development.

OXB-204 and OXB-208 target inherited retinal diseases, where we have extensive experience from our early focus on ophthalmology indications. OXB-103 is in development for the treatment of amyotrophic lateral sclerosis (ALS), a group of rare, progressive neurological diseases. Our priority in 2019 is to secure preclinical proof of concept for two programmes from our proprietary portfolio.

Technology licensing

Our business is underpinned by our world-leading lentiviral vector technology and technology licensing is core to our business model. While our priority is to incorporate technology licences into our broader partnering agreements, we continue to seek additional opportunities to generate licensing income and royalties on future products sales by providing access to our proprietary lentiviral vector technologies, as our platform develops.

To this end, we continue to innovate, refine and enhance our technology as part of our continuous improvement programme. Our new manufacturing technology, known as Transgene Repression in vector Production or TRiP, is designed to increase viral vector yields by several multiples. Universally applicable to any viral vector or vaccine platform – it can be used with lentiviral, adenoviral and adeno-associated virus-based gene therapy – TRiP is an example of how we are innovating to stay ahead of the market and satisfy the demand for efficient, cost-effective gene delivery with viral vectors. Methods for the new system were published in Cell & Gene Therapy Insights in January 2019 and discussions with potential licensees are ongoing.

Our focus for 2019 is to drive the discovery of two new innovative technologies that either open up new product opportunities or support the development of our lentiviral vector platform.



**1. Innovators**  
We continue to innovate, refine and enhance our technology as part of our continuous improvement programme. Our new manufacturing technology, known as Transgene Repression in vector Production or TRiP, is designed to increase viral vector yields by several multiples.

**2. A global centre of excellence**  
From our roots in Oxford University, Oxford Biomedica now occupies five facilities around Oxford covering around 226,000 sqft, securing the city as a global centre for lentiviral vector development and commercialisation.

Building capacity

To meet the expected growth in demand for lentiviral vectors, we are investing £20 million in the development of a new 84,000 sqft (7,800 sqm) manufacturing facility. The planned Phase 1 and 2 expansions will fit out around 45,000 sqft (4,200 sqm) for four GMP clean room suites and two fill/finish suites as well as offices, warehousing and QC laboratories, with space available for future expansion. The new facility will create up to 100 new, highly skilled positions the company over the next two years and is on track for operation in 2020.

Aligned to our values and to further accommodate our growth, we have taken a lease on a fifth facility in Oxford and formed a new discovery and innovation facility. The centre will bring together a multidisciplinary team of research, automation, bioprocessing and process development specialists around a shared purpose: to drive innovations that will lead to new scientific and technical advances to support our pipeline and our platform. The building is located next to our headquarters and is split roughly equally between laboratories and offices. Development of the space is ongoing and it is expected to be ready for occupation in the first half of 2019.

From our roots in Oxford University, Oxford Biomedica now occupies five facilities around Oxford covering around 226,000 sqft, securing the city as a global centre for lentiviral vector development and commercialisation.

Creating a winning culture

Our success as a company is made possible by our talented employees working together for our shared mission: to deliver life-changing gene and cell therapies to patients. That is why being a great place to work is so important to us.

During the year, we experienced growth of 35 per cent in our workforce from 321 to 432 employees, and expect that number to increase to 600 by the end of 2019 To support their development and a foster a positive culture, we introduced three company values: to Have Integrity, Be Inspiring and Deliver Innovation. Together with our mission, these values define our purpose and shape the way our people work together. We have already seen some excellent examples of employees demonstrating these values and during 2019 we will seek to further embed them as they are integrated into our new performance management process.

Looking to the future

It is a privilege to lead this fantastic company through a new era for personalised, gene-based medicine. Given the momentum we are seeing, both within Oxford Biomedica and in the gene and cell industry as a whole, I am confident in our ability to deliver increased revenue growth through our partnering endeavours, and to create value from our therapeutic pipeline to deliver meaningful returns to shareholders.

I would like to say thank you to each and every one of our employees for their contributions to our performance in 2018, and for helping Oxford Biomedica to become the company it is today. I look forward to their continued contributions in 2019 and beyond to achieve our objectives and deliver our strategy.

**John Dawson**  
Chief Executive Officer



1. John Dawson

Chief Executive Officer

John Dawson joined Oxford Biomedica’s Board as Non-Executive Director in August 2008 and he was appointed Chief Executive Officer in October 2008. Previously, he held senior management positions in the European operations of Cephalon Inc., including Chief Financial Officer and Head of Business Development Europe. While at Cephalon he led many deals building the European business to over 1,000 people, and to a turnover of several hundred million US dollars and in 2005 led the US\$360 million acquisition of Zeneus by Cephalon. Prior to this time at Cephalon he was Director of Finance and Administration of Serono Laboratories (UK) Limited. He is currently a Non-Executive Director of Paion AG.

5. James Miskin

Chief Technical Officer

Dr Miskin joined Oxford Biomedica in 2000. He has more than 18 years’ experience in gene and cell therapy, 14 of which have been in the GxP (good practice) environment. In his current role, he has overall responsibility for Oxford Biomedica’s Quality systems, analytical testing and lentiviral based bioprocessing development, as well as client programmes and alliance management. He is also a named inventor on several patents in the field. He holds a Bachelor of Science degree and a PhD in Molecular Biology from the University of Leeds and subsequently conducted post-doctoral research at The Pirbright Institute for a number of years. He is a member of the UK BioIndustry Association Manufacturing Advisory Committee and the Advanced Therapies section of The Medicines Manufacturing Industry Partnership (MMIP).

2. Stuart Paynter

Chief Financial Officer

Stuart Paynter joined Oxford Biomedica and the Board in August 2017. He has 16 years’ experience in the pharmaceutical and healthcare sectors. He qualified as a chartered accountant with Haines Watts before moving to EDS. He subsequently joined Steris, and worked in a variety of roles within the healthcare and life sciences divisions prior to becoming the European Finance Director. He then moved to Shire Pharmaceuticals where he became the Senior Director of finance business partnering for all business outside of the US. He then moved to a corporate finance role before becoming the global head of internal audit. Prior to joining Oxford Biomedica he was head of finance business partnering at De La Rue plc. He is a member of the Institute of Chartered Accountants in England and Wales.

6. Kyriacos Mitrophanous

Chief Scientific Officer

Dr Mitrophanous joined Oxford Biomedica in 1997. He has over 20 years of lentiviral vector experience covering a range of technical disciplines, including the development of gene and cell therapies, delivery platform technologies, bioprocessing and analytics. He is a recognised world-class expert in the field, a named inventor on numerous lentiviral vector patents and an author of a number of key papers. In his current role, he is responsible for the development of Oxford Biomedica’s new product candidates and LentiVector platform. He holds a PhD in Molecular Biology from University College London and has conducted post-doctoral research at the University of Oxford. He is a Corporate Member of the UK BioIndustry Association Board.

3. Jason Slingsby

Chief Business Officer

Jason joined Oxford Biomedica in 2015 as Head of Business Development and was promoted to Chief Business Officer in May 2018. He has 20 years’ experience in the biotechnology industry in biologics, vaccines and gene therapy. He has worked in international business development roles at Sosei Co., Ltd. and Intercell AG and was co-founder and CEO of ProtAffin AG, a venture capital backed company in Austria and UK. Jason started his career as a post-doctoral scientist at Oxford Biomedica and first worked at the company 1997-2000. He was awarded a 1st class BA (Hons) in Biochemistry from Magdalen College, Oxford University and also completed a PhD in complex disease genetics from Imperial College London. Jason was also awarded an MBA with distinction from London Business School in 2002.

7. Nick Page

Chief Operations Officer

Nick joined Oxford Biomedica in April 2018. Prior to joining he has held a number of senior operational leadership positions in the pharmaceutical industry, most recently as Platform Head of Anti-infectives within Novartis. His 40+ years of industry experience include API, Solid oral dose, Sterile, and Radiopharmaceutical manufacturing in various organisations encompassing innovative, generic and contract manufacturing. During his career he has spent several years working in China and India as well as in Global roles. He originally qualified as a Chartered Chemist and also has an MBA from The Open University.

4. Lisa Giles

Chief Projects and Performance Officer

Lisa joined Oxford Biomedica in March 2018. She has over 25 years’ experience in the pharmaceutical industry. She joined Shire Pharmaceuticals initially in product strategy and lifecycle management expanding this over 10 years to setting up the Alliance Management and Corporate Project Management functions, moving to Business Partner to Head of International Commercial before returning to head up the Product Strategy and Lifecycle Function. She brings with her a deep knowledge of product development from discovery at the lab bench to development, commercial and manufacturing supporting lifesaving treatments to the patient. She holds a BSc (Hons) degree in Microbiology and Virology from University of Warwick.

8. Helen Stephenson-Ellis

Chief People Officer

Helen joined Oxford Biomedica in April 2018. She brings 25 years’ experience in senior Human Resources roles within the Biopharmaceutical sector, including a number of years in various HR Business Partnering roles in GSK, Merck and Astra Zeneca. Following AstraZeneca’s acquisition of MedImmune, she moved to Cambridge UK to head up HR for MedImmune’s site there, followed by a period as Global HR Director within AstraZeneca. Prior to joining Oxford Biomedica, she was Group Human Resources Director for Vernalis plc, leading HR across Vernalis’ UK and US sites. She holds a BA (Hons) degree from Northumbria University in the UK and is a member of the Chartered Institute of Personnel and Development.



Full biographies for the Board of Directors can be found on pages 60 to 61.





Novartis collaboration progress

Oxford Biomedica’s collaboration with Novartis has progressed well following the US approval and launch in 2017 of the chimeric antigen receptor T cell therapy Kymriah (tisagenlecleucel) for the treatment of children and young adults with r/r ALL.

The supplemental BLA to treat adult patients with r/r DLBCL was approved by the US FDA in May 2018. The target patient population for this second indication is considerably larger than the initial ALL indication.

Additional regulatory approvals for both indications were received from the European Commission, Health Canada and the Therapeutic Goods Administration of Australia. In September 2018, NHS England announced that children and young adults in England would be able to receive Kymriah for r/r ALL, and the first patients have now been treated. Regulatory review is underway in Japan and the outcome is awaited.

Partnering progress

The Group is making good progress with its strategic partnerships, with Orchard Therapeutics adopting the stable producer cell lines in one of their programmes. The Group continued its activities to further grow its portfolio of strategic collaborations with the addition of Bioverativ (now part of Sanofi) and the UK Cystic Fibrosis Gene Therapy Consortium, Boehringer Ingelheim and Imperial Innovations partnership.

Product development

The LentiVector gene delivery platform underpins the Group’s partnering business and is the starting point for its proprietary products.

During the period, the Group continued to prepare the priority programmes for clinical studies and to pursue potential new partnership arrangements. In June 2018, the Group entered into an exclusive worldwide licensing agreement with Axovant Sciences (now Axovant Gene Therapies) to develop and commercialise OXB-102 (now renamed as AXO-Lenti-PD) for Parkinson’s disease, worth up to \$842.5 million. This agreement with Axovant successfully executes on Oxford Biomedica’s pre-stated strategy to externalise product development beyond the end of the pre-clinical phase.



- 1. **Novartis collaboration**  
The US FDA approval to use the Novartis Kymriah treatment in adults followed the earlier approval for children and young adults in 2017 as expected. The target patient population for this second indication is considerably larger than the initial ALL indication.
- 2. **New strategic collaborations**  
During the year we added strategic collaborations with the addition of Bioverativ (now part of Sanofi) and the UK Cystic Fibrosis Gene Therapy Consortium, Boehringer Ingelheim and Imperial Innovations partnership.

During the second half of 2018 the Group completed the regulatory filings for the planned Phase 1/2 study, the manufacture of a second batch of the vector to ensure sufficient supplies for the study and to prepare the clinical study centres in Cambridge and London, UK for initiation of the study. The Phase 1/2 study for AXO-Lenti-PD, sponsored by Axovant, is now underway and the first patients have been treated.

Following the out-licensing of the Parkinson’s disease programme, three additional proprietary assets have been selected to advance from research through pre-clinical development. OXB-204 and OXB-208 target inherited retinal diseases, where Oxford Biomedica has extensive experience from its early focus on ophthalmology indications. OXB-103 is in development for the treatment of amyotrophic lateral sclerosis (ALS), a group of rare, progressive neurological diseases.

LentiVector platform development

Over a number of years we’ve developed and licensed technologies and processes to significantly improve the production of gene therapy products into scalable, serum-free suspension processes. These technical developments enhance potency, purity, yield and efficiency. We have invested significantly in automation and robotics to increase productivity and reduce development timelines.

We have developed the TRiP System to maximise vector yields and particle purity, and standardise downstream process. The TRiP System substantially limits expression of the transgene in the vector production cell that otherwise may have detrimental effects on vector biogenesis, function or purification. Methods for the new system were published in Cell & Gene Therapy Insights in January 2019 and discussions with potential licensees are ongoing.

We have generated packaging and producer cell lines enabling a simplified and scalable manufacturing process while reducing cost. These advances enhance product quality and reduce the cost of goods for our partners and in-house development programmes.

These developments continue to enhance our partner offering and provide additional revenue-generating opportunities.



- 1. **Automation and robotics**  
We have invested significantly in automation and robotics to increase productivity and reduce development timelines.
- 2. **TRiP System**  
We have developed the TRiP System to maximise vector yields and particle purity, and standardise downstream process.

TRiPSystem™



Building capacity

Oxford Biomedica is a pioneer and world leader in the field of gene and cell therapy, underpinned by its lentiviral vector delivery system, the LentiVector platform. The technology is established at commercial scale with three state-of-the-art, custom-built GMP clean rooms and laboratory facilities offering current and next generation LentiVector platform bioprocessing capabilities, with capacity for in-house platform development work and current partners’ requirements. To support the expected growth in demand for lentiviral vectors, the Group is expanding its manufacturing capacity.

In September 2018, a lease was signed on a new, 84,000 sqft (7,800 sqm) facility near to Oxford Biomedica’s headquarters in Oxford, UK. The planned Phase 1 and Phase 2 expansion will fit out around 45,000 sqft (4,200 sqm) for four GMP clean room suites and two fill/finish suites as well as offices, warehousing and QC laboratories, with space available for future expansion.

The capacity expansion secures Oxford as a bioprocessing centre for Oxford Biomedica and will create up to 100 new, highly skilled jobs over the next two years. Funded through the successful Placing in March 2018, it will allow Oxford Biomedica to exploit the immediate market opportunity, meet the expected long-term demand and futureproof the Group’s market leading position.

Aligned to the Group’s values, which include delivering innovation, and to further accommodate growth, a lease was signed on a fifth facility in Oxford. The facility will bring together a multidisciplinary team of research, automation, bioprocessing and process development specialists around a shared purpose: to drive innovations that will lead to new scientific and technical advances to support our pipeline and our platform. The building is located next to Oxford Biomedica’s headquarters and is split roughly equally between laboratories and offices. Development of the space is ongoing and expected to be ready for occupation in the first half of 2019.

Oxford Biomedica now occupies five facilities around Oxford covering around 226,000 sqft, securing the city as a global centre for lentiviral vector development and commercialisation.



**An established technology platform**  
Our LentiVector technology is established at commercial scale with three state-of-the-art, custom-built GMP clean rooms and laboratory facilities offering current and next generation LentiVector platform bioprocessing capabilities, with capacity for in-house platform development work and current partners’ requirements.

84,000 ft<sup>2</sup>

**New facility**  
In September 2018, a lease was signed on a new, 84,000 sqft (7,800 sqm) facility near to Oxford Biomedica’s headquarters in Oxford, UK.

Corporate and organisational development

During the first half of 2018, Oxford Biomedica successfully completed a £20.5 million equity fundraising for capacity expansion and fit out. In addition, the Group successfully completed a share capital consolidation in May 2018 to make the shares more attractive to a broader range of institutional investors and other members of the investing public both overseas and in the UK.

To support the increased activities of the Group, the Senior Management Team was augmented during the first half of 2018, with the appointment of a Chief Operations Officer, a Chief People Officer and a Chief Project & Performance Officer.

Peter Nolan retired from his role as Chief Business Officer and stepped down from the Board on 2 July 2018.

During the year, Oxford Biomedica benefitted from the award of two grants by the UK Government’s innovation agency, Innovate UK. To support the Group’s investment in lentiviral vector development, £3 million was awarded for manufacturing, storage and analytical equipment, as well as other items that are essential for the operation of vector GMP facilities. A further £2 million was awarded as part of a total investment of £4 million by Oxford Biomedica to support the formation of a digital framework initiative to streamline the production of next-generation medicines. The aims of both projects are aligned with the UK Government’s Life Sciences Sector Deal to help ensure that the next wave of breakthrough treatments, innovative medical research and technologies, and high skilled jobs are created in Britain.

Outlook

Oxford Biomedica has made considerable progress in 2018. With the ongoing success of its Novartis collaboration validating its LentiVector platform and partnering credentials, the Group expects its technology leadership to boost its business development activities. The Group intends to expand its portfolio of collaborations, and to attract third-party investment to accelerate the clinical development of its wholly-owned proprietary products.

Oxford Biomedica’s progress during 2018 demonstrates its leading industry position. With the Group’s collaborations supporting its continued growth, Oxford Biomedica is ideally positioned to deliver value to shareholders as a world-leading gene and cell therapy business.



Innovate UK

- 1. Next generation bioprocessing**  
We successfully completed a share capital consolidation in May 2018 to make the shares more attractive to a broader range of institutional investors and other members of the investing public both overseas and in the UK.
- 2. Business development**  
With the ongoing success of its Novartis collaboration validating our LentiVector platform and partnering credentials, we expect our technology leadership to boost our business development activities.
- 3. UK Government awards us two grants**  
In 2018 we benefitted from the award of two grants by the UK Government’s innovation agency, Innovate UK, totalling £5 million.



Strategic report  
Delivery of our 2018 objectives

2018 objectives	Performance against priorities
<b>Objective 1</b> <b>Support partner portfolio advancement</b> Targets for 2018 included supporting our partners in order to gain approval and launch key products in both the US and EU, support the progress of programmes into the clinic and also deliver on our commitments to partners.	These targets were successfully met. We supported Novartis in the EU/US approvals and launch of Kymriah for paediatric ALL and DLBCL. We also supported the progression of an undisclosed product into the clinic. Batches of material were also delivered to Novartis as scheduled/requested. We were also successful in producing documents in order to support the suspension process approval. In terms of our collaboration with Orchard Therapeutics, we were also key in supporting the production of documents required for the BLA submission and the advancement one of their products according to the schedule.
<b>Objective 2</b> <b>Progress action on implementing strategy for products</b> Our goals for 2018 included achieving the successful progression of key programmes against plan, to deliver new pre-clinical products to the Group, and also, as previously announced, to reduce the financial risk of clinical stage product development (while retaining significant financial interest) by partnering or spin-out of OXB-102 and the ocular programmes.	These goals were partially met. We successfully managed to out-licence OXB-102 (now AXO-Lenti-PD) for Parkinson’s disease to Axovant for more than \$840 million. However, our plan to spin-out/out-licence of the ocular assets was under review.
<b>Objective 3</b> <b>Business development</b> In 2018 we intended to secure further revenue and royalty generating partnership relationships, and to build further on those we already had.	These goals were fully met as we signed an agreement with Bioverativ, (now part of Sanofi), for haemophilia products in February 2018 and with Boehringer Ingelheim, the UK Cystic Fibrosis Gene Therapy Consortium and Imperial Innovations for development of a gene therapy product to treat cystic fibrosis in August 2018.
<b>Objective 4</b> <b>Corporate and organisational</b> The Board set management certain confidential targets relating to the Group’s financial performance, as well as further organisational improvement objectives.	The goal to achieve an Operating EBITDA target of around £2.6 million was met along with net cash inflow from operating activities of £6.6 million. The re-finance of the Oaktree debt was not pursued. In terms of transforming the management structure (brought in three new Senior Executive Team (SET) members in 2018) and introduced key individual training for senior managers to ensure all skill sets are required for future growth are covered.

Strategic report  
Objectives for 2019

Objectives set for 2019	
<b>Objective 1</b> <b>Partners/Capacity/Technology advancement</b> The key objective for 2019 is to service our customers as agreed with them and reach key milestones for Novartis, Orchard Therapeutics and Bioverativ (now Sanofi).	<b>Objective 4</b> <b>Business development</b> A critical success factor for 2019 is new deals. The plan is to out-licence one product, agree three platform technology deals and start two feasibility studies.
<b>Objective 2</b> <b>Patent/product advancement and innovation</b> Advance two new platform products into our portfolio, alongside technical (two new patentable inventions) and data driven innovations in our platform that are essential to keep us ahead of the competition. Valuable pipeline products such as AXO-Lenti-PD, that we have seen bring great value to the Oxford Biomedica, move forward in clinical development.	<b>Objective 5</b> <b>Organisational development</b> With the rapid pace of growth for the Group, together with competition for key staff in our field it is essential that we build a culture, competitive rewards/benefits and staff support systems to ensure a balanced productive work force for the future. Plan to enhance our organisation effectiveness programmes. It is fundamental to our future success that we innovate with the creation of our new facility and complete our new manufacturing facility on time and within budget.
<b>Objective 3</b> <b>Financial</b> The financial objectives set out for 2019 are to achieve revenue and EBITDA targets which are driven by the budget. Set in a regime of aggressively growing sales with strict control of costs, these are going to be a significant challenge. Assumptions in the budget include new manufacturing deals and a product out licensing deal, along with extinguishing refinancing the loan on more favourable terms.	





“The Group is targeting improved financial performance in 2019.”

**Stuart Paynter**  
Chief Financial Officer

### Financial transformation

2018 has continued the financial transformation of the Group with significant commercial achievements, and the signing of the Bioverativ (now Sanofi), Axovant and UK Gene Therapy Cystic Fibrosis Consortium agreements announced in February, June and August 2018. This has culminated in the Group achieving its first Operating EBITDA profit and also a profit after taxation of £7.5 million.

Selected highlights are as follows:

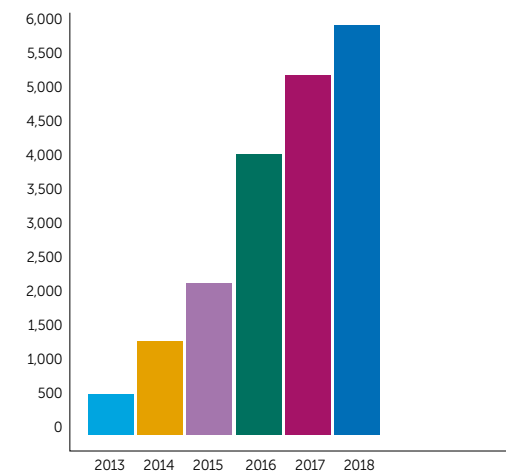
- Gross income increased by 72% over 2017, and has now increased by 1,135% since 2013 when the Platform division was created.
- Revenue increased by 78% over 2017, and has now increased by 1,137% since 2013.
- Improved operational results have resulted in Operating EBITDA, Operating EBIDA and Operating profit being converted into profits of £13.4 million, £15.8 million and £13.9 million respectively as opposed to largely losses in 2017.
- Cash generated from operations of £9.2 million in 2018 far exceeded the £1.5 million deployed in 2017 as a result of the Bioverativ (Sanofi) and Axovant licence income received.
- The Platform segment made an Operating EBITDA profit of £9.8 million<sup>1</sup> and an operating profit of £11.4 million.

The growth in gross income was largely driven by £18.3 million worth of license income received as a result of the Axovant and Bioverativ (Sanofi) deals, as well as revenues generated from increased commercial development services provided to Orchard Therapeutics, Novartis, Bioverativ (Sanofi) and Axovant. Bioprocessing results in 2018 increased from the prior year with all three bioprocessing facilities running continuously during the year and volumes 15% up in 2018. The chart opposite shows the growth in output since 2013.

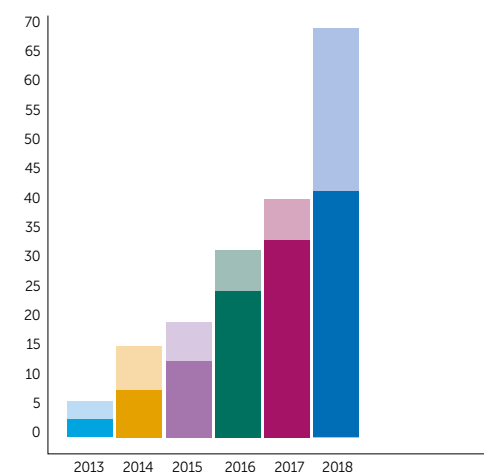
Operating costs, including Cost of Sales, grew by 28%, and by 38% when depreciation, amortisation and share option payments are excluded. Manpower, materials and subcontracted costs have increased to meet increasing customer demand, both for bioprocessing and commercial development services, but also includes an expectation of future growth in activities in 2019 and beyond. Headcount rose from 321 at December 2017 to 432 at the end of 2018.

The Group has also recognised a revaluation gain of £6 million on our equity investment in Orchard Therapeutics after its IPO at the end of 2018. Our partnership with Orchard Therapeutics has proven to be very successful and has exceeded the expectations set when originally established.

1. A reconciliation to GAAP measures is provided on page 122 (note 4, Segmental analysis).



Bioprocessing volumes



Gross income<sup>1</sup>

£m

■ Licence, milestones and grants (light tints)  
■ Bioprocessing and process development (dark tints)

With the signing of three new commercial contracts in 2018 we have strengthened our commercial pipeline and diversified our customer base. We will ensure that we continue to foster our current strong customer relationships, whilst continuing the Group's stated aim of targeting new strategic commercial partnerships to build on the platform of established growth.

We will continue our proven strategy of developing our proprietary products by seeking partnerships for later stage clinical studies. We will continue to assess the financial risk/reward profile of these projects and will seek to provide maximal returns to shareholders accordingly.

### Key Financial Performance Indicators

£m	2018	2017	2016	2015
Gross income <sup>1</sup>				
Bioprocessing/commercial development	40.6	32.6	24.0	12.4
Licences, milestones, grants	27.3	6.8	6.8	6.4
	67.9	39.4	30.8	18.8
Revenue	66.8	37.6	27.8	15.9
Operations				
Operating EBITDA <sup>2</sup>	13.4	(1.9)	(7.1)	(12.1)
Operating EBIDA <sup>3</sup>	15.8	0.8	(3.4)	(8.1)
Operating profit/(loss)	13.9	(5.7)	(11.3)	(14.1)
Cash flow				
Cash generated from/(used in) operations	9.2	(1.5)	(5.9)	(14.9)
Capex	10.1	2.0	6.4	16.6
Cash burn <sup>4</sup>	1.9	9.8	11.5	29.8
Normalised cash burn <sup>5</sup>	1.9	3.0	11.5	29.8
Financing				
Cash	32.2	14.3	15.3	9.4
Loan	41.2	36.9	34.4	27.3
Headcount				
Year-end	432	321	256	231
Average	377	295	247	196

1. Gross income is the aggregate of revenue and other operating income. A reconciliation to GAAP measures is provided on page 40.  
2. Operating EBITDA (Earnings Before Interest, Tax, Depreciation, Amortisation, revaluation of investments and Share Based Payments) is a non-GAAP measure often used as a surrogate for operational cash flow as it excludes from operating profit or loss all non-cash items, including the charge for share options. A reconciliation to GAAP measures is provided on page 40.  
3. Operating EBIDA is an internal measure used by the Group, defined as Operating EBITDA with the R&D tax credit included. The Board refers to EBIDA periodically as the R&D tax credit is, in essence, a subsidy or grant which offsets the Group's R&D expenditure. A reconciliation to GAAP measures is provided on page 40.  
4. Cash burn is net cash generated from operations plus net interest paid plus capital expenditure. A reconciliation to GAAP measures is provided on page 42.  
5. Cash burn after excluding accrued interest and early repayment charges paid due to extinguishment of the Oberland facility.

The Group evaluates its performance by making use of a number of alternative performance measures as part of its Key Financial Performance Indicators (refer table above). The Group believes that these Non-GAAP measures, together with relevant GAAP measures, provide an accurate reflection of the Group's performance over time.



The Board has taken the decision to move away from using Gross Income and Operating EBIDA as Key Financial Performance Indicators and will instead make use of Revenue, Operating EBITDA and Operating Profit in future.

Gross income/Revenue

Gross income increased to £67.9 million providing 72% growth as compared to 2017 (£39.4 million).

Revenue increased by 78% from £37.6 million in 2017 to £66.8 million in 2018.

Income generated from bioprocessing/commercial development increased by 25% to £40.6 million (from £32.6 million in 2017), and is up 464% since 2014. The main contributor to growth has been the revenues generated from increased commercial development services provided to Orchard Therapeutics, Novartis, Bioerativ (Sanofi) and Axovant.

The chart on page 39 shows the evolution of Gross Income over the past six years.

The largest portion of our gross income continues to be derived from our relationship with Novartis, but income generated from partnerships with our other customers continues to grow and now makes up a significant proportion of our gross income, thereby achieving our stated goal of diversifying our customer base.

£m	2018	2017	2016	2015
Revenue	66.8	37.6	27.8	15.9
Other operating income	1.1	1.8	3.0	2.9
Gross income	67.9	39.4	30.8	18.8

Operating EBITDA/ Operating EBIDA

£m	2018	2017	2016	2015
Gross income	67.9	39.4	30.8	18.8
Total expenses <sup>1</sup>	(54.5)	(41.3)	(37.9)	(30.9)
Operating EBITDA <sup>2</sup>	13.4	(1.9)	(7.1)	(12.1)
Depreciation, amortisation, share option charge	(5.4)	(6.1)	(4.2)	(2.0)
Revaluation of investments	6.0	2.3	–	–
Operating profit/(loss)	13.9	(5.7)	(11.3)	(14.1)

1. Cost of goods plus research, development, bioprocessing and administrative expenses excluding depreciation, amortisation and the share option charge.  
2. Operating EBITDA (Earnings Before Interest, Tax, Depreciation, Amortisation, revaluation of investments and Share Based Payments) is a non-GAAP measure often used as a surrogate for operational cash flow as it excludes from operating profit or loss all non-cash items, including the charge for share options.  
3. Operating EBIDA is an internal measure used by the Group, defined as Operating EBITDA with the R&D tax credit included. The Board refers to Operating EBIDA periodically as the R&D tax credit is, in essence, a subsidy or grant which offsets the Group's R&D expenditure.

Gross Income increased by 72% in 2018 partly offset by a 32% growth in our cost base from £41.3 million in 2017 to £54.5 million in 2018. The Operating EBITDA profit of £13.4 million is £15.3 million better than the £1.9 million loss incurred in 2017, a great achievement for the Group, and builds on the significant Operating EBITDA improvements seen across the last four years.

£m	2018	2017	2016	2015
Operating EBITDA <sup>2</sup>	13.4	(1.9)	(7.1)	(12.1)
R&D tax credit	2.5	2.7	3.7	4.0
Operating EBIDA <sup>3</sup>	15.8	0.8	(3.4)	(8.1)

Due to the conversion of Operating EBITDA losses into a large Operating EBITDA profit, Operating EBIDA has improved from a profit of £0.8 million in 2017 to a profit of £15.8 million in 2018. The R&D tax credit has only decreased slightly from the prior year as the Group continues to make a loss for tax purposes.

Total Expenses

£m	2018	2017	2016	2015
Research, Development & Bioprocessing costs	29.7	21.6	24.3	20.3
Administrative expenses	7.4	7.3	6.0	6.7
Operating expenses	37.1	28.9	30.3	27.0
Depreciation	(4.3)	(4.1)	(3.3)	(1.3)
Amortisation	–	(1.2)	(0.3)	(0.4)
Share option charge	(1.1)	(0.7)	(0.6)	(0.2)
Adjusted operating expenses	31.7	22.9	26.1	25.1
Cost of sales	22.8	18.4	11.8	5.8
Total Expenses <sup>1</sup>	54.5	41.3	37.9	30.9

£m	2018	2017	2016	2015
Raw materials, consumables and other external bioprocessing costs	18.3	13.2	9.3	6.1
Manpower-related	26.7	19.3	17.4	13.6
External R&D expenditure	1.9	1.7	2.8	3.0
Other costs	7.6	7.1	8.4	8.2
Total expenses	54.5	41.3	37.9	30.9

- Raw materials, consumables and other external bioprocessing costs have increased as a result of the increase in commercial development activities and bioprocessing volumes.
- The increase in manpower-related costs is due to the increase in the average headcount from 295 in 2017 to 377 in 2018. This is as a result of increasing our commercial development and bioprocessing capacity in line with our increased revenues.
- External R&D expenditure was higher due to increased commercial customer and technical project related spend.
- Other costs have increased due to increases in facility costs, and legal and professional fees as the group expanded, and royalties payable on income from the new license agreements. These increases were offset by a forex gain of £1.3 million as sterling weakened against the dollar.

Operating and Net profit/(loss)

£m	2018	2017	2016	2015
Operating EBITDA	13.4	(1.9)	(7.1)	(12.1)
Depreciation, amortisation and share option charge	(5.4)	(6.1)	(4.2)	(2.0)
Revaluation of investments	6.0	2.3	–	–
Operating profit/(loss)	13.9	(5.7)	(11.3)	(14.1)
Interest	(6.2)	(9.3)	(4.9)	(1.9)
R&D tax credit	2.5	2.7	3.7	4.0
Foreign exchange revaluation (non-cash)	(2.7)	3.3	(4.1)	(1.0)
Net profit/(loss)	7.5	(9.0)	(16.6)	(13.0)

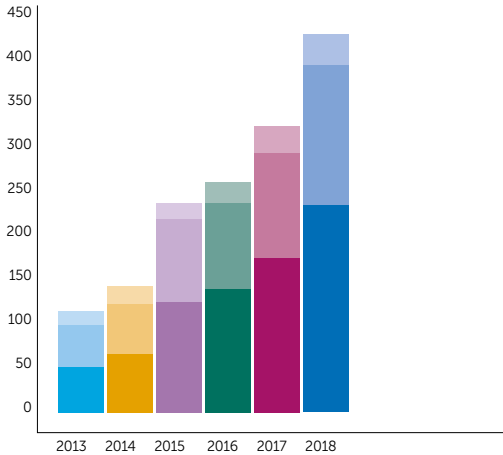
The significant achievements of 2018, culminating in an Operating EBITDA profit for the year, is further improved by a £6 million gain on revaluation of the Orchard Therapeutics investment after the company listed on Nasdaq in November 2018.

The depreciation, amortisation and share option charge was lower than 2017 due to a non-recurring £1.0 million impairment charge in 2017 to account for the write down of the Prime Boost technology and poxvirus patent intangible asset after Bavarian Nordic's Prosvac product failed its Phase 3 study.

The interest charge on our dollar denominated loan facility was significantly lower at £6.2 million in 2018 compared with £9.3 million in 2017 due to the non-recurring cost of termination of the Oberland facility in 2017.

The R&D tax credit in 2018 has only dropped down slightly from the prior year as the Group continues to make a loss for tax purposes.

The net profit in 2018 was negatively impacted by the devaluation of sterling against the dollar which has lead to a foreign exchange loss of £2.7 million being recognised upon revaluation of the dollar denominated Oaktree loan. The situation was reversed in 2017 as sterling improved against the dollar and a foreign exchange gain of £3.3 million was recognised. We have seen large fluctuations in foreign exchange rates versus sterling across the last three years as a result of uncertainties around the Brexit outcome. To some extent the Group expects to have a currency hedge against this liability as a significant portion of its anticipated future revenues are likely to be dollar denominated, such as the royalty stream arising from Novartis' sales to Kymriah patients.



Year-end headcount

■ Admin and corporate (light tint)  
■ Development (mid tint)  
■ Production related (dark tint)

Segmental analysis

Reflecting the way the business is being managed by the Senior Executive Team, the Group reports its results within two segments, namely the ‘Platform’ segment which includes the revenue generating bioprocessing and process development activities for third parties, and internal technology projects to develop new potentially saleable technology, improve our current processes and bring development and manufacturing costs down. The other segment, “Product”, includes the costs of researching and developing new product candidates.

	Platform £m	Product £m	Total £m
2018			
Gross income	55.7	12.2	67.9
Operating EBITDA	9.8	3.6	13.4
Operating profit/(loss)	11.4	2.5	13.9
2017			
Gross income	38.6	0.8	39.4
Operating EBITDA	2.9	(4.8)	(1.9)
Operating profit/(loss)	0.2	(5.9)	(5.7)

A reconciliation to GAAP measures is provided on page 122.

The Platform segment in 2018 saw an increase in gross income of 44% from £38.6 million to £55.7 million due to license income received as a result of the Axovant and Bioverativ (Sanofi) deals, as well as increased commercial development services provided. The additional revenues have resulted in the Platform segment increasing its Operating EBITDA profit from £2.9 million in 2017 to £9.8 million in 2018, an improvement of £6.9 million. The segment also generated an operating profit of £11.4 million in 2018 (2017: £0.2 million). The Group continues to target increased profitability from this segment through higher bioprocessing volumes, increased royalty payments from partners and additional commercial development services to customers.

The Product segment has generated revenues of £12.2 million and an Operating EBITDA profit of £3.6 million largely as a result of the license income recognised as part of the Axovant OXB-102 agreement. The segment also generated an operating profit of £2.5 million.

Cash flow

The Group held £32.2 million cash at 31 December 2018, having begun the year with £14.3 million. Significant movements across the year are explained below.

- The operating profit improved by £19.6 million principally as a result of revenue generated by Axovant and Bioverativ (Sanofi) deals, as well as increased revenues from commercial development services provided.

- This improvement flowed through to Operating EBITDA which improved by £15.3 million to a profit of £13.4 million (2017: £1.9 million loss).
- Cash generated from operations was £9.2 million which resulted in a £10.7 million improvement over 2017.
- Net cash generated from operations during 2018 at £12.9 million was helped by a £3.7 million R&D tax receipt, down £0.8 million from the prior year. This was due to the tax credit being capped as a result of the improved results in 2017 as compared to 2016.
- Interest paid during the year was £4.7 million, down from £10.8 million in the prior year. 2018 interest paid was only made up of Oaktree interest payments whilst 2017 interest paid included the redemption fee on the Oberland loan facility as well as the accrued interest covering the period since initial drawdown of the loan.
- Purchases of property, plant and equipment increased from £2.0 million to £10.1 million, mainly consisting of purchases of equipment and leasehold improvements for the new OxBox manufacturing facility.
- Cash burn, the aggregate of these items, was therefore reduced from £9.8 million in 2017 to £1.9 million in 2018, mainly as a result of the improvement in the cash generated from our operations.
- The net proceeds from financing during 2018 were £19.8 million, consisting almost entirely of the equity raise in February 2018 which generated £19.1 million net of fees.
- The result of the above movements is a net increase in cash of £17.9 million from £14.3 million to £32.2 million.

Cash flow movements	2018	2017	2016	2015
Operating profit/(loss)	13.9	(5.7)	(11.3)	(14.1)
Non-cash items included in operating profit/(loss)	(0.5)	3.8	4.2	2.0
Operating EBITDA profit/(loss)	13.4	(1.9)	(7.1)	(12.1)
Working capital movement	(4.2)	0.4	1.2	(2.8)
Cash generated from/(used in) operations	9.2	(1.5)	(5.9)	(14.9)
R&D tax credit received	3.7	4.5	4.1	3.2
Net cash generated from/(used in) operations	12.9	3.0	(1.8)	(11.7)
Interest paid, less received	(4.7)	(10.8)	(3.3)	(1.5)
Capex	(10.1)	(2.0)	(6.4)	(16.6)
Cash burn	(1.9)	(9.8)	(11.5)	(29.8)
Net proceeds from financing <sup>1</sup>	19.8	8.8	17.5	25.0
Movement in year	17.9	(1.0)	6.0	

1. Excludes interest paid which is shown separately above.

Balance sheet review

The most notable items on the balance sheet, including changes from 31 December 2017, are as follows:

- Investments increased by £8.0 million to £11.0 million as a result of the achievement of three equity milestones worth £2.0 million, and the remainder as a result of the revaluation of our Orchard investment based on the quoted Orchard share price at year end.
- Property, plant and equipment has increased by £6.4 million to £31.8 million as depreciation of £4.3 million only partially offset additions of £10.8 million, mainly purchases of equipment and leasehold improvements for the new OxBox manufacturing facility.
- Inventories have increased from £3.3 million to £4.3 million due to work in progress balances increasing as a result of ongoing bioprocessing commitments across 2018 and into 2019, as well as planned increases in stock levels as a result of Brexit planning.
- Trade and other receivables increased from £17.1 million to £30.6 million, due predominantly to the timing of process development milestones achieved and manufacturing orders placed at year-end, as well as £4.0 million of deposits held in escrow as part of the OxBox and new discovery and innovation facility leases.
- Trade and other payables increased from £8.7 million to £11.4 million, due to purchases of equipment and leasehold improvements for the new OxBox manufacturing facility.
- Contract liabilities and deferred Income increased from £13.1 million at the end of 2017 to £23.5 million (of which £6.4 million is non-current) at the end of 2018 due to income received in advance in relation to process development work, grant funding, manufacturing orders placed, and manufacturing slots reserved.
- The loan balance has increased from £36.9 million to £41.2 million due to a £2.7 million foreign exchange loss on revaluation of the loan, as well as accrued interest of £1.6 million.

Financial outlook

The Group is targeting improved financial performance in 2019. We have signed new commercial contracts with Axovant, Bioverativ (Sanofi) and the UK Cystic Fibrosis Gene Therapy Consortium which will bolster our commercial development and bioprocessing pipelines, and we continue to maintain an excellent relationship with Novartis, building additional bioprocessing capacity to support the continued launch of Kymriah across the globe. Orchard Therapeutics IPO’d at the end of the year in anticipation of the commercial launch of its strategic product portfolio which we continue to support in a bioprocessing and commercial development capacity.

Our customer base continues to diversify, strengthening our revenue expectations. We will continue to target new strategic commercial relationships in 2019, building on the platform of growth we established and extending our customer base.

We will continue to execute our stated strategy, of continuing the development of our proprietary products and pre-clinical pipeline whilst seeking to spin-out or out-license those candidates at an appropriate time prior to large clinical expenditures. We will seek to make strategic investments in our products, as well as acquiring enabling technologies where the opportunity exists to increase shareholder value and improve patient outcomes. We will continue to invest in early stage concepts and pre-clinical studies, and also in our key LentiVector technology platform. We will continue to manage our cost base carefully and adjust spend to meet our financial targets.

Going concern

The Group held £32.2 million of cash at the end of 2018. During 2018 the Group generated positive operational cash flows, and although the Group is making a further strategic investment in extending our bioprocessing capacity, the Group expects to generate sufficient operational cash flow to continue its growth strategy. Taking this into account, in conjunction with currently known and probable cash flows, the Directors consider that the Group has sufficient cash resources and cash inflows to continue its activities for at least twelve months from the date of these financial statements and have therefore prepared the financial statements on a going concern basis.

Although the UK’s decision to leave the European Union may significantly affect the fiscal, monetary and regulatory landscape in the UK, the Group has assessed the future impact of Brexit on its operations to be minor. Further details of our contingency planning is provided on page 58.

Stuart Paynter

Chief Financial Officer



Oxford Biomedica is committed to its role as a responsible business and we have a range of evolving policies in place to ensure we meet this objective. We focus our corporate responsibility efforts on a number of main areas:

People

We are resolutely focused on the health, safety and the welfare of our employees, their engagement and job satisfaction, and ensuring equality of opportunity and respect for diversity. We are equally focused on the safety of patients in our clinical studies, and of our neighbours in the wider community.

It is group policy to give full and fair consideration to job applications from disabled people, to provide opportunities for their training, career development and promotion, and to continue wherever possible to employ staff who become disabled.

Community

We focus on the wellbeing of the community around our facilities, conducting our business in a responsible manner. We comply with local laws and regulations and control our emissions and waste.

Environment

We monitor and responsibly manage our facilities’ carbon emissions, use of water, electricity and gas as well as waste production and disposal.

Integrity and Ethics

The Group is committed to the highest standards of ethical conduct and integrity in its business activities in the UK and overseas.

Values

Our commitment to corporate responsibility is governed by our Group values which are “Have Integrity”, “Be Inspiring” and “Deliver Innovation”. In practice, this means doing the right thing for our employees, patients and partners and delivering on our commitments. We aim to create an environment which positively challenges, engages and excites us, and we deliver ground-breaking scientific excellence by nurturing our talented people.

People

Safety

The health, safety and welfare of our employees, visitors and contractors is our first priority. The safety of all employees is important, and those working in our bioprocessing, engineering and laboratory facilities face additional risks which we endeavour to manage through maintaining our facilities and equipment to the highest standards and through specific and detailed training. Our Health and Safety Management System covers all work activities, such as working with biological and chemical materials and the operation of laboratory equipment. The Health and Safety Management System is reviewed and updated to ensure continuous improvement, and to adapt to variations in scientific work and reflect changes in legislation. Oxford Biomedica continues to have a first-class safety record. Health and Safety issues are a standing item on the Board’s agenda and the Group is committed to meet both the letter and spirit of all health and safety regulation and best practice.

Diversity

The Board and senior management are fully committed to providing equal opportunities to all employees, irrespective of race, gender, religion, national origin, disability or any other personal characteristics, and we embrace diversity in all forms.

The table below shows the gender split across our organisation as at 31 December 2018:

	Male	Female	Total	% Male	% Female
Board including Non-Executive Directors	6	1	7	86%	14%
Senior managers	20	11	31	65%	35%
All other employees	178	216	394	45%	55%
Total	204	228	432	47%	53%

The Gender Pay Gap Report for 2018 has been prepared and the Group is pleased to report an increase in representation of female employees at the more senior levels of the organisation over the past 12 months. This has had a positive impact on the Company’s gender pay gap ratio. For full details of the report please visit our website at [www.oxb.com](http://www.oxb.com).

Remuneration

With the continued growth in employee numbers to 432 at year-end, we continue to invest in strong internal procedures to ensure that we are well placed to attract and retain high quality employees. This includes the development of an independently validated and market aligned remuneration structure, which is being implemented during early 2019. We continue to review the appropriate levels of financial and non-financial remuneration for each level within our structure. In addition to cash-based reward programmes, we have modern share option plans to allow employees to participate in the success of the organisation. We provide medical insurance for all staff, along with a pension facility to enable employees to take a more flexible and personalised approach to saving for their future.

Training

Training is essential for the safety and wellbeing of our employees and others we interact with, as discussed above. In addition, our bioprocessing, laboratory and clinical processes are complex and highly regulated and our training helps us to achieve the outcomes, compliance and productivity we need to succeed as a business.

We provide training to our line managers to ensure that they are well prepared to manage, develop, support and motivate their teams.

Communication

We acknowledge the importance of communication and consultation across our business. Group-wide briefings, R&D seminars and informal all-staff meetings are held to keep employees informed of general business issues and other matters of interest, and to ensure the views of employees can be taken into account in making decisions that are likely to affect their interests. The circulation of press announcements, internal newsletters and access to work-related social media keep employees informed of business and employee activities, and enhance understanding of the financial and economic factors affecting the Group’s performance.



**Safety**  
The safety of all employees is important, and those working in our bioprocessing, engineering and laboratory facilities face additional risks which we endeavour to manage through maintaining our facilities and equipment to the highest standards and through specific and detailed training.

Community

We recognise the value of being a good local citizen in the Oxford community. We endeavour to achieve this by delivering positive benefits for the community, such as creating new high quality jobs, establishing an apprenticeship scheme and by building links with schools and other local educational establishments. We seek to behave as a responsible neighbour, complying with national and local laws and regulations, particularly with regard to emissions and waste, property planning and the traffic impact caused by our employees. We have a well-established Cycle-To-Work scheme and interest-free season ticket loans to help minimise our traffic impact on the local area.

Apprenticeship Scheme

As part of our focus of delivering local benefits and providing high skilled jobs to local community we launched an apprenticeship scheme in collaboration with Advanced Therapies Apprenticeship Community and the University of Kent. Currently three school leavers from the local community are enrolled on a training scheme in the highly skilled areas of Manufacturing and Analytical testing. We are committed to supporting the apprentices through mentoring and training and expanding the scheme in the future.

Charitable Giving

In further support of the community we worked with employees to support locally focused charities this year. This included an employee driven gift giving for the Children’s Hospital, John Radcliffe and also financial donations to two local charities. The charities selected were Sobell House (charity registration 1118646) which provides palliative and end of life care in Oxfordshire and SeeSaw (charity registration 1076321) is a local based charity providing grief support for bereaved children.

Charity	Donation
Sobell House	£1,500
SeeSaw	£1,500
Total	£3,000



- 1. Responsibility to protect the environment**  
No laboratory waste goes to landfill sites. We make every effort to keep our neighbours in the local community safe from any potential harm caused by our activities by closely managing our emissions and waste.
- 2. Donations**  
We made financial donations to two local charities in 2018, Sobell House and SeeSaw.

Environment

Environmental policies & initiatives

We fully recognise our responsibility to protect the environment and we have a strong environmental policy, objectives and guidelines in place which we review and update regularly. The Group complies with all regulations covering the processing and disposal of laboratory waste, and uses qualified licensed contractors for the collection and disposal of chemical waste and decontaminated biological materials. No laboratory waste goes to landfill sites. We make every effort to keep our neighbours in the local community safe from any potential harm caused by our activities by closely managing our emissions and waste.

Energy Savings Opportunity Scheme (ESOS)

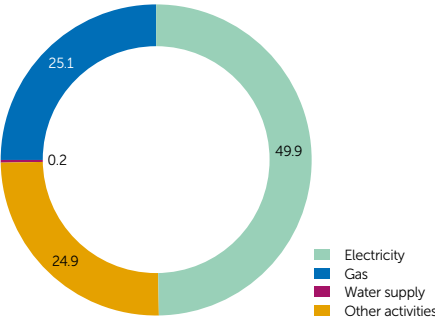
As we are now an organisation of over 250 employees we have engaged with ESOS, in compliance with EU Energy Efficiency Directive (2012/27EU). This has involved an ESOS Phase 2 energy assessment based on 2018 data covering all aspects of our energy usage. The recommendations from the audit will be incorporated into the Environmental section of our responsible Business policy.

Greenhouse gas emissions report

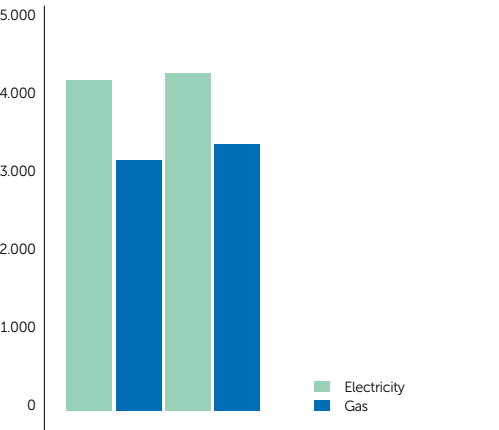
The tables below show our usage in 2018 and 2017 of energy and water at our sites in Oxford, UK. We have also estimated our total CO<sub>2</sub> emissions and have indicated our “environmental intensity” on a per employee basis, an important indicator of our activity.

2018	Unit	Usage	Usage per employee	CO <sub>2</sub> emission (tonnes)
Electricity	MW hours	4,169	11.4	1,180
Gas	MW hours	3,225	8.8	593
Water supply	Cubic metres	6,330	17.3	2
Other activities (estimated) including waste disposal and travel				590
Total				2,365

2017	Unit	Usage	Usage per employee	CO <sub>2</sub> emission (tonnes)
Electricity	MW hours	4,124	14.7	1,450
Gas	MW hours	3,108	11.1	573
Water supply	Cubic metres	4,947	17.6	2
Other activities (estimated) including waste disposal and travel				447
Total				2,472



**CO<sub>2</sub> emissions 2018 %**  
Our total CO<sub>2</sub> emissions have reduced slightly from the previous year at 2,365 tonnes in 2018 (2017: 2,472).



**Electricity and gas use (MWh)**



Energy efficiency

We are committed to energy efficiency and have a number of policies to decrease energy usage where possible. For instance, when existing lighting needs replacing we switch to LED lights which are significantly more energy efficient than traditional lighting systems.

In our Windrush laboratories we have passive infrared light sensors in all areas that have been refurbished to ensure lighting is extinguished in areas that are not currently in use.

Waste management

We continue to review our waste management systems to manage waste more effectively. This includes:

- recycling all paper and cardboard waste, aluminum cans, glass, plastics and printer toner/cartridges.
- use of different waste streams to increase processing efficiency.

Integrity and Ethics

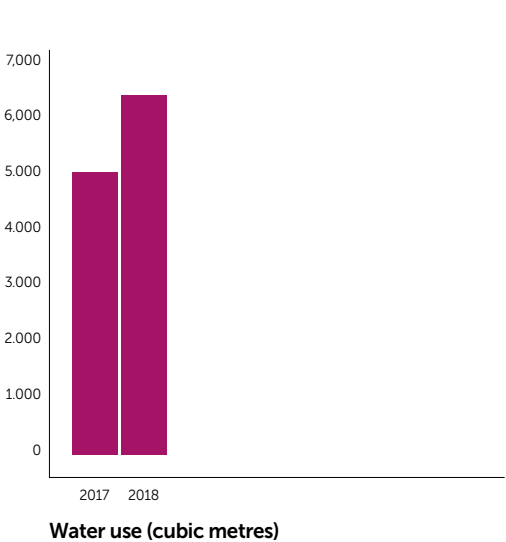
The Group is committed to the highest standards of ethical conduct and integrity in its business activities in the UK and overseas.

Anti-bribery

Oxford Biomedica’s policy on preventing and prohibiting bribery is in full accordance with the UK Bribery Act 2010 as well as other relevant overseas legislation and all employees receive training in this matter. The Group does not tolerate any form of bribery by, or of, its employees, agents or consultants or any person or body acting on its behalf. Senior management is committed to implementing effective measures to prevent, monitor and eliminate bribery.

Whistleblowing

Oxford Biomedica’s compliance activities include the prevention and detection of misconduct through policy implementation, training and monitoring. As part of this effort, the Group’s employees are encouraged to report suspected cases of misconduct in confidence and without fear of retaliation. Concerns and allegations are thoroughly investigated with disciplinary action taken where necessary, up to and including dismissal and reporting to relevant authorities.



Clinical trials

We instill transparency, safety and ethics in all aspects of our business, including the design and conduct of our clinical trials. Our clinical studies are designed with patient safety as a paramount concern and the protocols are agreed with the relevant national regulatory authorities, as well as local ethics committees and institutional review boards at clinical trial sites, before any patients are treated. We also have standard operating procedures in place under a controlled Quality Management System to ensure compliance with appropriate guidelines and legislation.

We are also committed to transparency, and our website ([www.oxb.com](http://www.oxb.com)) provides information on ongoing clinical trials. Relevant trials in the EU and EEA are automatically posted on the EU Clinical Trials Register ([www.clinicaltrialsregister.eu](http://www.clinicaltrialsregister.eu)) and we also disclose our trials on a US government-sponsored website ([www.clinicaltrials.gov](http://www.clinicaltrials.gov)).

Human rights and anti-slavery

The Group fully respects human rights and we conduct our business in accordance with the letter and spirit of UK Human Rights legislation and the UK Modern Slavery Act 2015. Oxford Biomedica’s Board of Directors has approved a Modern Slavery Transparency Statement in compliance with section 54 of the Act which can be found on our website [www.oxb.com](http://www.oxb.com). Our facilities are all located in the UK, where our policies accord with human rights regulations and our supply chain operates in territories with strong commitments to human rights safeguarding.

Animal testing

It is a regulatory requirement that all new therapeutic products must be appropriately tested for safety before they are administered to patients, and there is currently no alternative to using animal models as part of this process. We are committed to following the principles of the three “Rs” in safety testing: replacement, refinement and reduction of animal testing. These principles ensure that animal testing is only employed when necessary and where there are no alternatives. The Group minimises the use of animal models by cross-referring LentiVector platform data packages for regulatory authorities.

The Strategic report on pages 20 to 49 was approved by the Board of Directors on 14 March 2019 and was signed on its behalf by:

**John Dawson**  
Chief Executive Officer



- 1. Clinical trials**  
Our clinical studies are designed with patient safety as a paramount concern.
- 2. Animal testing**  
We minimise the use of animal models by cross-referring LentiVector platform data packages for regulatory authorities.





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Oxford Biomedica operates in the gene and cell therapy biotechnology sector which, by its nature, is relatively high risk compared with other industry sectors. Only a few gene and cell therapy products have been approved for commercial use so there are significant financial and development risks in the sector, and the regulatory authorities have shown caution in their regulation of such products. Risk assessment and evaluation is therefore an integral and well-established part of Oxford Biomedica’s management processes. The Group is exposed to a range of risks. Some of them are specific to Oxford Biomedica’s current operations, others are common to all development-stage biopharmaceutical companies. The Directors have carried out a robust assessment of the risks facing the company, including those which could threaten its business model and future performance.

Risk management framework

The Group’s risk management framework is as follows:

- Board of Directors – the Board has overall responsibility for risk management, determining the Group’s risk tolerance and for ensuring the maintenance of a sound system of internal control. The Board reviews key risks within the Group at each of its formal meetings, of which there at least six annually. However, twice a year in March and September a full presentation to the Board on Risk is expected. The risk management processes are the responsibility of the Senior Executive Team but the Audit Committee monitors the processes and their implementation as well as reviewing the Group’s internal financial controls and the internal control systems. The Audit Committee also monitors the integrity of the financial statements of Oxford Biomedica and any formal announcements relating to the Company’s financial performance, reviewing significant financial reporting judgements contained in them. During 2018, we received external assistance from PwC LLP to develop our risk framework appropriate for our larger Group.
- Senior Executive Team – the SET generally meets twice monthly to discuss current business issues and considers relevant risks on each occasion. At least four times a year, the SET meets with representatives from the Risk Management Committee to consider the operational risk management processes and risks identified.
- Key management committees – the Group currently has three key management sub-committees which meet monthly and through which much of the day-to-day business is managed. These are the extended Operational Leadership Team (incorporates the Quality and Manufacturing Operations Committee), the Product Development Committee and the Technical Development Committee. SET members attend these meetings and risk management is a key feature of each sub-committee.
- Risk Management Committee – Oxford Biomedica has a Risk Management Committee comprising senior managers from key areas of the business and chaired by the Director of Corporate Activities & Strategy. This Committee meets quarterly with a remit to identify and assess risks in the business and to consider mitigation and risk management steps that can be taken. The risk register is regularly reviewed by SET and key risks are highlighted to the Board at each formal meeting.
- Standard Operating Procedures – all areas of the business have well established Standard Operating Procedures which are required be followed in order to minimise the risks inherent in the business operations. Where these are required for GMP, GCP and GLP any deviations from the SOPs must be identified and investigated. Compliance with such SOPs are routinely subject to audit by the relevant regulators and customers. Other SOPs, such as financial processes, are also subject to audits.

Key risks specific to Oxford Biomedica’s current operations

Pharmaceutical product development risks

To develop a pharmaceutical product it is necessary to conduct pre-clinical studies and human clinical trials for product candidates to demonstrate safety and efficacy. The number of pre-clinical studies and clinical trials that will be required varies depending on the product candidate, the indication being evaluated, the trial results and the regulations applicable to the particular product candidate. In addition, the Group or its partners will need to obtain regulatory approvals to conduct clinical trials and bioprocess drugs before they can be marketed. This development process takes many years. The Group may fail to develop successfully a product candidate for many reasons, including:

- Failure to demonstrate long-term safety;
- Failure to demonstrate efficacy;
- Failure to develop technical solutions to achieve necessary dosing levels or acceptable delivery mechanisms;
- Failure to establish robust bioprocessing processes;
- Failure to obtain regulatory approvals to conduct clinical studies or, ultimately, to market the product; and
- Failure to recruit sufficient patients into clinical studies.

The failure of the Group to develop successfully a product candidate could adversely affect the future profitability of the Group. There is a risk that the failure of any one product candidate could have a significant and sustained adverse impact on the Group’s share price. There is also the risk that the failure of one product candidate in clinical development could have an adverse effect on the development of other product candidates, or on the Group’s ability to enter into collaborations in respect of product candidates.

(i) Safety risks

Safety issues may arise at any stage of the drug development process. An independent drug safety monitoring board (DSMB), the relevant regulatory authorities or the Group itself may suspend or terminate clinical trials at any time. There can be no assurances that any of the Group’s product candidates will ultimately prove to be safe for human use. Adverse or inconclusive results from pre-clinical testing or clinical trials may substantially delay, or halt, the development of product candidates, consequently affecting the Group’s timeline for profitability. The continuation of a particular study after review by the DSMB or review body does not necessarily indicate that all clinical trials will ultimately be successfully completed.

(ii) Efficacy risks

Human clinical studies are required to demonstrate efficacy in humans when compared against placebo and/or existing alternative therapies. The results of pre-clinical studies and initial clinical trials of the Group’s product candidates do not necessarily predict the results of later stage clinical trials. Unapproved product candidates in later stages of clinical trials may fail to show the desired efficacy despite having progressed through initial clinical trials. There can be no assurance that the efficacy data collected from the pre-clinical studies and clinical trials of the Group’s product candidates will be sufficient to satisfy the relevant regulatory authorities that the product should be given a marketing authorisation.

(iii) Technical risks

During the course of a product’s development, further technical development may be required to improve the product candidates characteristics such as the delivery mechanism or the bioprocessing process. There is no certainty that such technical improvements or solutions can be identified.



(iv) Bioprocessing process risk

There can be no assurance that the Group’s product candidates will be capable of being produced in commercial quantities at acceptable cost. The Group’s LentiVector platform product candidates use specialised bioprocessing processes for which there are only a few suitable bioprocessors including the Group itself. There can be no assurance that the Group will be able to bioprocess the Group’s product candidates at economic cost or that contractors who are currently able to bioprocess the Group’s product candidates will continue to make capacity available at economic prices, or that suitable new contractors will enter the market. Bioprocessing processes that are effective and practical at the small scale required by the early stages of clinical development may not be appropriate at the larger scale required for later stages of clinical development or for commercial supply. There can be no assurance that the Group will be able to adapt current processes or develop new processes suitable for the scale required by later stages of clinical development or commercial supply in a timely or cost-effective manner, nor that contract bioprocessors will be able to provide sufficient bioprocessing capacity when required.

(v) Regulatory risk

The clinical development and marketing approval of the Group’s product candidates, and the Group’s bioprocessing facility, are regulated by healthcare regulatory agencies, such as the FDA (USA), EMA (Europe), and MHRA (UK). During the development stage, regulatory reviews of clinical trial applications or amendments can prolong development timelines. Similarly, there can be no assurance of gaining the necessary marketing approvals to commercialise products in development. Regulatory authorities may impose restrictions on a product candidates use or may require additional data before granting approval. If regulatory approval is obtained, the product candidate and bioprocessor will be subject to continual review and there can be no assurance that such an approval will not be withdrawn or restricted. The Group’s laboratories, bioprocessing facility and conduct of clinical studies are also subject to regular audits by the MHRA and FDA to ensure that they comply with GMP, GCP and GLP standards. Failure to meet such standards could result in the laboratories or the bioprocessing site being closed or the clinical studies suspended until corrective actions have been implemented and accepted by the regulator.

(vi) Failure to recruit sufficient patients into clinical studies

Clinical trials are established under protocols which specify how the trials should be conducted. Protocols specify the number of patients to be recruited into the study and the characteristics of patients who can and cannot be accepted into the study. The risk exists that it proves difficult in practice to recruit the number of patients with the specified characteristics, potentially causing delays or even abandonment of the clinical study. This could be caused by a variety of reasons such as the specified characteristics being too tightly defined resulting in a very small population of suitable patients, or the emergence of a competing drug, either one that is approved or another drug in the clinical stage of development.

The threats from the above product development risks are inherent in the pharmaceutical industry and have not changed fundamentally over the last year. The Group aims to mitigate these risks by employing experienced staff and other external parties, such as Contract Research Organisations to plan, implement and monitor its product development activities and to review progress regularly in the Group’s Product Development Committee.

**Bioprocessing revenue risk**

The Group receives significant revenues from bioprocessing lentiviral vectors for third parties and in particular for Novartis. Bioprocessing of lentiviral vectors is complex and bioprocessing batches may fail to meet the required specification due to contamination or inadequate yield. Failure to deliver batches to the required specification may lead to loss of revenues.

Furthermore, the Group relies on third parties, in some cases sole suppliers, for the supply of raw materials and certain out-sourced services. If such suppliers perform in an unsatisfactory manner it could harm the Group’s business.

As the Group’s revenues from bioprocessing are growing the risk to the Group has increased in the last twelve months. The Group mitigates the risk of failing to meet required specifications by investing in high quality facilities, equipment and employees and, in particular, in quality management processes. The Group is also endeavouring to mitigate the risk of being overly reliant on Novartis by seeking bioprocessing contracts with other parties.

**Collaborator and partner risk**

The Group has entered several collaborations and partnerships, involving the development of product candidates by partners in which the Group has a financial interest through IP licenses. Failure of the partners to continue to develop the relevant product candidates for any reason could result in the Group losing potential revenues.

Business development

The Group is seeking to out-license or spin-out its in-house product development programmes into externally funded vehicles and may seek to arrange strategic partnerships for developing the Group’s other product candidates. The Group may not be successful in its efforts to build these third party relationships which may cause the development of the products to be delayed or curtailed.

The Group is building a revenue generating business by providing its LentiVector platform to third parties in return for revenues derived from process development, bioprocessing and future royalties. The Group may be unsuccessful in building this business for reasons including a) failing to maintain a leadership position in lentiviral vector technology, b) becoming uncompetitive from a pricing perspective, c) failure to provide an adequate service to business partners and collaborators. The Group is continuing to invest in the LentiVector platform in order to reduce this risk, and it also takes extremely seriously customer relationship management to ensure that customers and partners receive the service they expect.

Attraction and retention of highly skilled employees

The Group depends on recruiting and retaining highly skilled employees to deliver its objectives and meet its customers’ needs. The market for such employees is becoming increasingly competitive and the failure to recruit staff from the EU due to Brexit or to retain staff with the required skills and experience could adversely affect the Group’s performance. The Group mitigates this risk by creating an attractive working environment and ensuring that the remuneration package offered to employees is comparable with competing employers.

Broader business risks which are applicable to Oxford Biomedica

Gene and cell therapy risk

The Group’s commercial success, both from its own product development and from supporting other companies in the sector, will depend on the acceptance of gene and cell therapy by the medical community and the public for the prevention and/or treatment of diseases. To date only a limited number of gene therapy products have been approved in Europe, and only three in the USA. Furthermore, specific regulatory requirements, over and above those imposed on other products, apply to gene and cell therapies and there can be no assurance that additional requirements will not be imposed in the future. This may increase the cost and time required for successful development of gene and cell therapy products.

Rapid technical change

The gene and cell therapy sector is characterised by rapidly changing technologies and significant competition. Advances in other technologies in the sector could undermine the Group’s commercial prospects.

Longer-term commercialisation risks

In the longer term, the success of the Group’s product candidates and those of its partners will depend on the regulatory and commercial environment several years into the future. Future commercialisation risks include:

- The emergence of new and/or unexpected competitor products or technologies. The biotechnology and pharmaceutical industries are subject to rapid technological change which could affect the success of the Group’s product candidates or make them obsolete;
- Regulatory authorities becoming increasingly demanding regarding efficacy standards or risk averse regarding safety;
- Governments or other payers being unwilling to pay for/reimburse gene therapy products at a level which would justify the investment. Based on clinical studies to date, the Group’s LentiVector platform product candidates have the unique potential to provide permanent therapeutic benefit from a single administration. The pricing of these therapies will depend on assessments of their cost-benefit and cost effectiveness;
- The willingness of physicians and/or healthcare systems to adopt new treatment regimes.

Any or all of these risks could result in the Group’s future profitability being adversely affected as future royalties and milestones from commercial partners could be reduced.

Intellectual property and patent protection risk

The Group’s success depends, amongst other things, on maintaining proprietary rights to its products and technologies and the Board gives high priority to the strategic management of the Group’s intellectual property portfolio. However, there can be no guarantee that the Group’s product candidates and technologies are adequately protected by intellectual property. Furthermore, if the Group’s patents are challenged, the defence of such rights could involve substantial costs and an uncertain outcome.

Third party patents may emerge containing claims that impact the Group’s freedom to operate. There can be no assurance that the Group will be able to obtain licences to these patents at reasonable cost, if at all, or be able to develop or obtain alternative technology. Where copyright, design right and/or “know how” protect the Group’s product candidates or technology, there can be no assurance that a competitor or potential competitor will not independently develop the same or similar product candidates or technology.

Rights of ownership over, and rights to license and use, intellectual property depend on a number of factors, including the circumstances under which the intellectual property was created and the provisions of any agreements covering such intellectual property. There can be no assurance that changes to the terms within licence agreements will not affect the entitlement of the Group to the relevant intellectual property or to license the relevant intellectual property from others.



Financial risks

(a) Product liability and insurance risk

In carrying out its activities the Group potentially faces contractual and statutory claims, or other types of claim from customers, suppliers and/or investors. In addition, the Group is exposed to potential product liability risks that are inherent in the research, pre-clinical and clinical evaluation, bioprocessing, marketing and use of pharmaceutical products. While the Group is currently able to obtain insurance cover, there can be no assurance that any future necessary insurance cover will be available to the Group at an acceptable cost, if at all, or that, in the event of any claim, the level of insurance carried by the Group now or in the future will be adequate, or that a product liability or other claim would not have a material and adverse effect on the Group’s future profitability and financial condition.

(b) Foreign currency exposure

The Group records its transactions and prepares its financial statements in pounds sterling, but some of the Group’s income from collaborative agreements and patent licences is received in US dollars and the Group incurs a proportion of its expenditure in US dollars and the Euro. The Group’s cash balances are predominantly held in pounds sterling, although the Group’s Treasury Policy permits cash balances to be held in other currencies in order to hedge foreseen foreign currency expenses. The Group also has a US dollar loan facility provided by Oaktree Capital Management. Under that facility the Group is required to maintain \$2.5 million in a ring fenced bank account. To the extent that the Group’s foreign currency assets and liabilities in the longer term are not matched, fluctuations in exchange rates between pounds sterling, the US dollar and the Euro may result in realised and unrealised gains and losses on translation of the underlying currency into pounds sterling that may increase or decrease the Group’s results of operations and may adversely affect the Group’s financial condition, each stated in pounds sterling. In addition if the currencies in which the Group earns its revenues and/or holds its cash balances weaken against the currencies in which it incurs its expenses, this could adversely affect the Group’s future profitability.

(c) Interest rate exposure

The Group is exposed to interest rate movements, primarily arising on the Oaktree loan facility. the interest rate is 9.0% plus US\$ LIBOR, subject to a minimum of 1%. If 3 month LIBOR rises above 1% the Group’s interest payments may increase.

Financial position

The Directors have considered the cash position in the context of going concern and their conclusions are set out in the Financial review page 43, the Director’s report page 92 and in note 1 to the Consolidated financial statements (page 108).

Loan facility

The Group has a \$55 million loan facility provided by Oaktree Capital Management, secured on the Group’s assets. Failure to comply with the terms of the loan agreement could potentially place the Group in default, which could adversely affect the Group’s business operations, financial position and prospects.

UK departure from European Union (“Brexit”)

The impact of the UK’s decision to leave the European Union is not yet clear but it may significantly affect the fiscal, monetary and regulatory landscape in the UK, and could have a material impact on its economy and the future growth of its industries, including the pharmaceutical and biotechnology industries. Depending on the exit terms negotiated between EU Member States and the UK following Brexit, the UK could lose access to the single European Union market and to the global trade deals negotiated by the European Union on behalf of its members. Although it is not possible at this point in time to predict fully the effects of an exit of the UK from the European Union, we believe the impact would be minor on Oxford Biomedica with anticipated effects being managed. Key uncertainties relate to recruitment of individuals from the EU and impact on the regulatory relationships between the UK and the EU. Significant recruitment has taken place over the last year, to the extent the staff base can support growth over the short term. All EU Nationals currently employed will be able to stay in the UK under the “settled status” directive. Short term regulatory impacts include the requirement for QP certification to be performed in an EU member state and as such, we have undertaken steps to establish a subsidiary in Ireland.

Left to right:  
Andrew Heath, Martin Diggle, Lorenzo Tallarigo, John Dawson,  
Stuart Henderson, Heather Preston, Stuart Paynter



Dr. Lorenzo Tallarigo

Chairman

Dr. Lorenzo Tallarigo was appointed as Non-Executive Chairman of Oxford Biomedica in February 2016. He was previously Chairman of Intercept Pharmaceuticals where he led the company’s successful IPO. He was also Chief Executive Officer and remains a Board member of Genextra, a holding company focused on identifying life science research to create successful businesses that develop novel treatments and technologies. Previously, he worked at Eli Lilly, where he held various positions of increasing seniority in a number of areas including clinical research, product management, marketing and general management, and ultimately as President of International Operations. He has a Doctor of Medicine degree from the University of Pisa (Italy) and a PMD from Harvard Business School.

**Appointment:**  
— Appointed as Non-Executive Director and Chairman in February 2016

**Committee membership:**  
— Nomination Committee

Dr. Andrew Heath

Deputy Chairman and Senior Independent Director

Dr. Andrew Heath was appointed to Oxford Biomedica’s Board in January 2010 and became Deputy Chairman and Senior Independent Director in May 2011. Previously he was Chief Executive Officer of Protherics plc where he managed the company’s significant growth and eventual acquisition by BTG for £220 million and held senior positions at Astra AB and Astra USA, including Vice President Marketing & Sales, and at Glaxo Sweden as Associate Medical Director. He is a Non-Executive Director of Novacyt SA. He was previously a Director of the UK BioIndustry Association.

**Appointment:**  
— Appointed a Director in January 2010 and became Deputy Chairman and Senior Independent Director in May 2011

**Committee membership:**  
— Audit Committee  
— Remuneration Committee  
— Nomination Committee

Martin Diggle

Non-Executive Director

Martin Diggle was appointed to Oxford Biomedica’s Board in October 2012. He is a founder of Vulpes Investment Management which manages a number of funds, including the Vulpes Life Sciences Fund, Oxford Biomedica’s largest shareholder. He has over 30 years’ experience in investment banking and fund management, and has been an investor in life sciences and biotech for nearly 20 years. He is also an expert in emerging markets and Russia, in particular, where he was previously a partner and Director of UBS Brunswick. He holds a Master’s Degree in Philosophy, Politics and Economics from University of Oxford.

**Appointment:**  
— Appointed a Director in October 2012

**Committee membership:**  
— None

Stuart Henderson

Independent Non-Executive Director

Stuart Henderson was appointed a Non-Executive Director and Chair of the Audit Committee in June 2016. Previously, he was a partner at Deloitte, where he was Head of European Healthcare and Life Sciences. Prior to this he was a partner at Arthur Andersen, where he was Head of Emerging Biotechnology. He has extensive audit and transaction experience and has worked with life sciences businesses ranging from start-ups to multinationals, as well as acting as reporting accountant on numerous IPO and Class 1 transactions. As Audit Partner, he has reported to the audit committees of publicly quoted companies for over 20 years. He is a former Director of the Babraham Institute and currently sits as a Non-Executive Director on the Boards of OneNucleus (the Life Sciences trade body for Cambridge and London), the Cell Therapy Catapult Limited and BioCity Group Limited.

**Appointment:**  
— Appointed a Director in June 2016

**Committee membership:**  
— Audit Committee  
— Remuneration Committee  
— Nomination Committee

John Dawson

Chief Executive Officer

John Dawson joined Oxford Biomedica’s Board as a Non-Executive Director in August 2008, and was appointed Chief Executive Officer in October 2008. Previously he held senior management positions in the European operations of Cephalon Inc., including Chief Financial Officer and Head of Business Development Europe. While at Cephalon he led many deals building the European business to over 1,000 people, and to a turnover of several hundred million US dollars and in 2005 led the \$360 million acquisition of Zeneus by Cephalon. Prior to his time at Cephalon he was Director of Finance and Administration of Serono Laboratories (UK) Limited. He is currently a Non-Executive Director of Paion AG.

**Appointment:**  
— Appointed a Director in August 2008 and became Chief Executive Officer in October 2008

**Committee membership:**  
— None

Stuart Paynter

Chief Financial Officer

Stuart Paynter joined Oxford Biomedica and the Board in August 2017. He has 16 years’ experience in the pharmaceutical and healthcare sectors. He qualified as a chartered accountant with Haines Watts before moving to EDS. He subsequently joined Steris, and worked in a variety of roles within the healthcare and life sciences divisions prior to becoming the European Finance Director. He then moved to Shire Pharmaceuticals where he became the senior Director of finance business partnering for all business outside of the US. He then moved to a corporate finance role before becoming the global head of internal audit. Prior to joining Oxford Biomedica he was head of finance business partnering at De La Rue plc. He is a member of the Institute of Chartered Accountants in England and Wales.

**Appointment:**  
— Appointed a Director and Chief Financial Officer in August 2017

**Committee membership:**  
— None

Heather Preston

Independent Non-Executive Director

Dr. Heather Preston was appointed to Oxford Biomedica’s Board in March 2018. Dr. Preston is a Partner and Managing Director of TPG Biotech. She has over 25 years of experience in healthcare, as a scientist, physician and management consultant and she has been an investor in life sciences and Biotech for the last 16 years. She holds a degree in Medicine from the University of Oxford.

**Appointment:**  
— Appointed a Director in March 2018

**Committee membership:**  
— Audit Committee  
— Remuneration Committee (March 2019)  
— Nomination Committee



Dear Shareholder

I am pleased to present Oxford Biomedica’s Corporate Governance Report for 2018.

Good governance is essential for the long term success of the business and this is ultimately the responsibility of the Board and its committees. The Board comprises both Non-Executive and Executive Directors and provides the forum for external and independent review and challenge to the Executives.

There have been two changes to the Board during 2018. In March Dr. Heather Preston joined the Board as an Non-Executive Director. In July, Peter Nolan retired as a Board member and Executive Director. I wish to thank Peter Nolan for all his hard work for the Group over the last 20 years.

The Group has had a transformational year, with a substantial increase in the Group’s revenues during the year and being profitable for the first time. As the Group has grown substantially over the year, the corporate governance framework and committees are in the process of being reviewed in order to understand whether the current structure and committees are appropriate for a larger company. The final governance structure and committees have not yet been finalised and I look forward to reporting on these in the 2019 Annual report.

With this amount of change and activity the Board has paid particular attention to ensuring that the Group’s strategy remains appropriate and that management is focused on delivering the Group’s key priorities and managing the key risks facing the Group.

Between December 2018 and February 2019 we have had Deloitte LLP perform an external evaluation of the Board’s performance during 2018. The review process comprised the completion of a questionnaire covering the various aspects of Board activities, interviews with each Director individually by the external evaluator and an active observation of a Board meeting. The independent report is the process of being finalised. The Board will assess and implement appropriate changes based on the recommendations of the report.

The Financial Reporting Council (FRC) produced a revised UK Corporate Governance Code in July 2018 (Revised Code). The Board considers that it has been compliant with the 2016 UK Corporate Governance Code (2016 Code), while working towards implementing parts of the Revised Code as best practice.

The following pages set out in more detail the activities and major matters considered by the Board in 2018.

Lorenzo Tallarigo  
Chairman



Lorenzo Tallarigo was appointed as Non-Executive Director and Chairman in February 2016

Compliance with the 2016 UK Corporate Governance Code

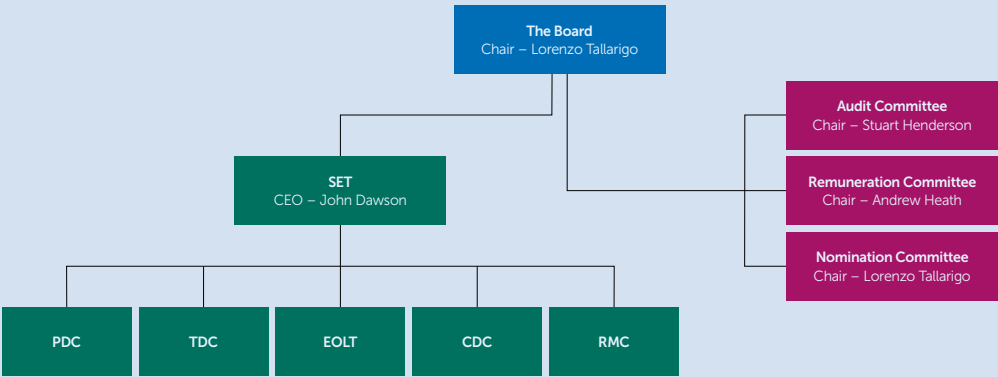
The table below sets out how the Group has applied the main principles in the 2016 Code during 2018:

UKCGC reference	Main Principle	Application
A.1	Every company should be headed by an effective Board which is collectively responsible for the long-term success of the company.	The Company’s Board comprises both Non-Executive Directors and Executive Directors. The Board met seven times during 2018 for regular board meetings as well as several other times for specific ad hoc matters.
A.2	There should be a clear division of responsibilities at the head of the company between the running of the Board and the Executive responsibility for the running of the company’s business. No one individual should have unfettered powers of decision.	There is a clear division of responsibilities between the Chairman and Chief Executive Officer.
A.3	The Chairman is responsible for leadership of the Board and ensuring its effectiveness on all aspects of its role.	The Chairman provides leadership to the Board and is responsible for setting the agenda for its meetings and for ensuring there is adequate time allowed for discussion.
A.4	As part of their role as members of a unitary Board, Non-Executive Directors should constructively challenge and help develop proposals on strategy.	All of the Non-Executive Directors participate at all Board meetings and also are involved in periodic strategic reviews.
B.1	The Board and its Committees should have the appropriate balance of skills, experience, independence and knowledge of the company to enable them to discharge their respective duties and responsibilities effectively.	The current Board members have a broad mix of experience including the Pharmaceutical industry, financing and investment, and UK corporate governance. The Audit and Remuneration Committees are comprised solely of independent Non-Executive Directors.
B.2	There should be a formal, rigorous and transparent procedure for the appointment of new Directors to the Board.	The process to appoint Dr. Heather Preston was led by the Chairman. A search firm was employed to help identify potential candidates. Short-listed candidates met most of the Directors as part of the selection process. The final selection decision was made by the Non-Executive Directors in consultation with the Chief Executive Officer.
B.3	All Directors should be able to allocate sufficient time to the company to discharge their responsibilities effectively.	All Directors have been able to participate at the majority of meetings held in 2018.
B.4	All Directors should receive induction on joining the board and should regularly update and refresh their skills and knowledge.	Dr. Heather Preston received induction during the year including meetings with investors, the Company’s auditors, lawyers, financial and other advisers and senior managers in the business.
B.5	The Board should be supplied in a timely manner with information in a form and of a quality appropriate to enable it to discharge its duties.	The Board meets formally at least six times per annum. The Chairman sets the agenda in consultation with the Chief Executive Officer and Company Secretary. Relevant papers are circulated to all Board members several days prior to each meeting.
B.6	The Board should undertake a formal and rigorous annual external evaluation of its own performance and that of its committees and individual Directors.	The Board conducts a performance evaluation annually. The most recent evaluation took place during December 2018 to February 2019.
B.7	All Directors should be submitted for re-election at regular intervals, subject to continued satisfactory performance.	All new Directors are required by the Company’s Articles of Association to submit themselves for election at the first Annual General Meeting after their appointment. The Articles also require that one-third of the Directors submit themselves for re-election by rotation each year. In 2019, in order to comply with the Revised Code all Directors will submit themselves for election every year.
C.1	The Board should present a fair, balanced and understandable assessment of the company’s position and prospects.	The Directors formally review the Annual report each year and make a statement in the report confirming that they consider the report to be fair, balanced and understandable.
C.2	The Board is responsible for determining the nature and extent of the principal risks it is willing to take in achieving its strategic objectives. The board should maintain sound risk management and internal control systems.	The Board’s remit includes risk management which is an agenda item at every formal meeting. A system of risk management has been established in the Company with advice given by PwC LLP and this is monitored by the Audit Committee. The Audit Committee also reviews the internal control systems.
C.3	The Board should establish formal and transparent arrangements for considering how they should apply the corporate reporting and risk management and internal control principles and for maintaining an appropriate relationship with the company’s auditor.	Corporate reporting, internal controls and relations with the Company’s auditors are the responsibility of the Audit Committee which provides feedback to the full board following Audit Committee meetings.
D.1	Executive Directors’ remuneration should be designed to promote the long-term success of the company. Performance-related elements should be transparent, stretching and rigorously applied.	Executive Directors’ remuneration is set in accordance with the remuneration policy which was approved by shareholders at the 2018 AGM.
D.2	There should be a formal and transparent procedure for developing policy on executive remuneration and for fixing the remuneration packages of individual Directors. No Director should be involved in deciding his or her own remuneration.	The remuneration policy was designed by the Remuneration Committee with advice from the compensation and benefits practice of Deloitte LLP. The current recommended policy was approved by shareholders at the 2018 Annual General Meeting. No Director is involved with setting his own remuneration.
E.1	There should be a dialogue with shareholders based on the mutual understanding of objectives. The Board as a whole has responsibility for ensuring that a satisfactory dialogue with shareholders takes place.	Vulpes Life Sciences Fund, the Company’s largest shareholder is represented on the Board by Martin Diggle which provides a clear line of communication. The Chairman, Chief Executive Officer and Chief Financial Officer meet periodically with the Company’s other large shareholders.
E.2	The Board should use the general meetings to communicate with investors and to encourage their participation.	All Board members endeavour to attend the Annual General Meeting in person and sufficient time is allowed for questioning by shareholders who attend the meeting.

The Board considers that it has complied throughout the year with the 2016 Code, while working towards implementing parts of the Revised Code as best practice.

Corporate Governance Framework

As the Group has grown substantially over the year, the corporate governance framework and committees are in the process of being reviewed in order to understand whether the structure and committees are fit for a larger company. The final structure and committees have not yet been finalised, so the current governance framework comprises the Board and the Senior Executive Team and their respective sub-committees as set out below:



- SET – Senior Executive Team  
PDC – Product Development Committee  
TDC – Technical Development Committee  
EOLT – Extended Operations Leadership Team (incorporates the Quality and Manufacturing Operations Committee)  
CDC – Commercial Development Committee  
RMC – Risk Management Committee

The Board

The Board is collectively responsible for promoting the success of the Group by directing and supervising the Group’s activities to create shareholder value. In doing so it ensures that there are robust corporate governance and risk management processes in place. Following changes during 2018 the Board comprises five Non-Executive Directors and two Executive Directors. The Chairman and Martin Diggle are considered not to be independent.

The Board’s powers and responsibilities are set out in the Company’s articles of association and it has a formal schedule of matters reserved for the Board’s approval which include:

- the Group’s strategy;
- the financial statements and accounting policies;
- acquisitions, disposals and capital expenditure;
- financing and capital structure;
- corporate governance;
- internal control and risk management;
- board membership and remuneration;
- appointment and remuneration of auditors.

The Board also takes a close interest in Quality, Health, Safety & Environment and Risk Management and has these as standing items on its meeting agendas.

The Chairman sets the agenda for the Board meeting in consultation with the Chief Executive Officer and the Company Secretary. Board papers covering the agenda items are circulated several days ahead of each meeting. Regular board papers cover Product and Technical Development, Production, Business Development, Finance, Investor Relations, HR, Quality, Safety, Health & Environment and Risk Management.

There is a clear division of responsibilities between the Chairman and Chief Executive Officer.

Certain responsibilities are delegated to three Board committees – the Audit, Nomination and Remuneration Committees. These Committees operate under clearly defined terms of reference which are disclosed on the Group’s website. Reports from the Audit and Nomination Committees are included in this section and the Directors’ remuneration report is on pages 69 to 89 incorporating the Remuneration Committee report.

The current Board members are set out on pages 60 to 61.

- Lorenzo Tallarigo is the Non-Executive Chairman. Dr Tallarigo met the independence criteria recommended by the UKCGC at the time of his appointment.
- Andrew Heath, the Senior Independent Director, is considered to be independent.
- Stuart Henderson is the chairman of the Audit Committee. He is considered to be independent.
- Heather Preston is considered to be independent.
- Martin Diggle is a founder of Vulpes Investment Management which, through its Vulpes Life Sciences Fund, is the Group’s largest investor and as such he is not considered independent under the 2016 Code.
- The Group therefore has been in compliance with provision B.1.2 of the 2016 Code which recommends that a small company, defined as one which is not in the FTSE350, should have at least two independent Non-Executive Directors excluding the Chairman.

Each Director is provided with an appropriate induction on appointment.

All Directors and the Board and its committees have access to advice and services of the Company Secretary, and also to external professional advisers as required. The appointment and removal of the Company Secretary is a matter for the Board as a whole to consider.

Board meetings

The Board meets regularly with meeting dates agreed for each year in advance. During 2018 there were seven regular Board meetings. The attendance of individual Directors at Board and Committee meetings was as follows:

	Regular Board		Audit Committee		Remuneration Committee		Nominations Committee	
	Possible	Attended	Possible	Attended	Possible	Attended	Possible	Attended
John Dawson	7	7						
Martin Diggle	7	5					1	1
Andrew Heath	7	7	3	3	9	9	1	1
Stuart Henderson	7	7	3	3	9	9	1	1
Peter Nolan	4	4						
Stuart Paynter	7	7						
Heather Preston <sup>1</sup>	5	5	2	2	0	0		
Lorenzo Tallarigo	7	7					1	1

1. Appointed to Remuneration Committee 12 March 2019.

In addition to the above regular meetings, the Board (or an appointed sub-committee of the Board) met on a number of other occasions to consider specific ad hoc matters including the approval of the 2017 financial statements and the interim 2018 financial results.

The Chairman holds meetings from time to time with Non-Executive Directors without the Executive Directors in attendance.



Board activity during 2018

Board matters during 2018 included:

- Routinely recurring items such as the approvals of the 2018 financial budget and objectives, the 2017 preliminary results and Annual report, and the 2018 interim results announcement.
- A review of the Group’s strategy, conducted in September.
- Monitoring the progress of the Group’s priority product development programmes.
- Reviewing business development opportunities including partnering and collaboration transactions.
- The appointment of Heather Preston as a Director.
- Ongoing reviews of the Group’s risk management processes and key risks.

Review of performance

Between December 2018 and February 2019, Deloitte LLP conducted an independent review of the Board’s performance during 2018. The review process comprised the completion by each Director of a comprehensive questionnaire covering all aspects of the Board’s performance, interview with each Director and an active observation of a Board meeting. The independent report is in the process of being finalised. The Board will assess and implement appropriate changes based on the recommendations of the report.

Retirement of Directors

In accordance with the articles of association, any Director who was appointed after the last Annual General Meeting (AGM) or has served for three years, and one third of the other Directors (or if their number is not a multiple of three the number nearest to but not exceeding one third) retire from office by rotation at each AGM. However, to ensure that we comply with the Revised Code all Directors will now be subject to annual re-election.

Accordingly, at the Annual General Meeting in 2019, and in line with the Revised Code, Lorenzo Tallarigo, Andrew Heath, Stuart Henderson, Martin Diggle, Heather Preston, John Dawson and Stuart Paynter all will retire and be subject to re-election. If re-elected to the Board at the AGM, Andrew Heath, will reach the 10th anniversary in January 2020 of his original appointment as a Non-Executive Director. Following an internal review, the Board is satisfied that Andrew Heath remains independent in thought and in action in terms of his participation in Board and Committee meetings, and has the full support of the other Board members in the activities he undertakes.

Communication with shareholders

The Board recognises the importance of effective communication with shareholders and potential investors. The primary points of contact are the Chief Executive Officer and Chief Financial Officer but the Chairman and Senior Independent Director are also available for meetings with investors if required. Vulpes Life Sciences Fund (“VLSF”), the Company’s second largest investor, is represented on the Board by Martin Diggle ensuring a clear channel of communication with VLSF. The Group has engaged with shareholders and potential investors through the various channels below:

Meetings with existing shareholders	John Dawson and Stuart Paynter met with major shareholders during 2018. Lorenzo Tallarigo has also met with major shareholders.
2018 Annual General Meeting	The 2018 AGM was held in London on 29 May 2018. Shareholders were invited to attend this meeting which lasted for about 1 hour and which, as well as the formal business, included a presentation by the Chief Executive Officer followed by a Q&A session and a chance to meet Directors after the meeting closed.
Meetings with potential investors	The Chief Executive Officer and Chief Financial Officer regularly make presentations and meet potential investors on a one-to-one basis at investor conferences in Europe and the USA. The company also conducts investor roadshows periodically which provide further opportunities to meet potential investors.
Results announcements and presentations	The Group announced its 2017 full year performance and financial results in March 2018, and its 2018 half year interim results in September 2018 through RNS announcements accompanied by analyst conference calls which are accessible to all shareholders and recordings of which are made available on the Group’s website.
2017 Annual report	The Group published its 2017 Annual report in April 2018.
Website	The Group’s website <a href="http://www.oxb.com">http://www.oxb.com</a> contains details of the Group’s activities as well as copies of regulatory announcements and press releases, copies of the Group’s financial statements, and terms of reference for the Board Committees. Investors and others can subscribe to an e-mail alert service which provides notifications of announcements.
Investor relations	The Group also endeavours to respond to all enquiries from shareholders and potential investors received through its enquiry inbox <a href="mailto:enquiries@oxb.com">enquiries@oxb.com</a> .
Social media	The Group uses Twitter to alert followers to relevant sector news which is relevant to the Group.

The Senior Executive Team (SET) and its committees

Operational management is conducted by the Executive Directors who, together with Lisa Giles, James Miskin, Kyriacos Mitrophanous, Nick Page, Jason Slingsby and Helen Stephenson-Ellis form the Senior Executive Team (SET). The Chief Executive Officer is John Dawson. The SET meets approximately every two weeks and its agenda covers the full range of activities of the Group, including financial performance, organisational and employment matters, risk management and Safety, Health & Environment.

There are three SET sub-committees covering the major business operational areas. These committees meet monthly and are attended by SET members and other relevant senior managers from the business. These sub-committees are:

- Product Development Committee (PDC) – covering the development of new gene and cell therapy products from initial concept through to clinical development.
- Technical Development Committee (TDC) – covering the development of new and improved assays and production and other processes, including cell and vector engineering.
- Extended Operational Leadership Team (eOLT) – incorporates the Quality and Manufacturing Operations Committee and covers quality, operational and manufacturing matters.

Within their area of responsibility these committees cover objective and target setting, monitoring performance against targets, ensuring compliance with GxP and other relevant requirements, monitoring expenditure against budget and risk management.

There are two other important committees:

- Commercial Development Committee (CDC) – which covers the external opportunities to out-licence and in-licence technology or product candidates, and also to generate partnership opportunities for manufacturing and product development.
- Risk Management Committee (RMC) – which comprises senior managers from all parts of the business, meets at least quarterly to identify and assess risks facing the business and to propose risk mitigation and management actions.

Important matters from all of these committees are referred to the SET.

Risk management

The Board is responsible for determining the nature and extent of the risks it is willing to take in achieving the objectives of the Group and it reviews current key risks at every Board meeting. The Audit Committee monitors the conduct of the risk management processes within the Group whilst the SET is accountable for those processes, identifying the risks facing the Group and formulating risk mitigation plans. The active involvement of the Executive Directors in the management sub-committees allows them to monitor and assess significant business, operational, financial, compliance and other risks.

Board committee reports

Audit Committee report

The Audit Committee comprises Stuart Henderson, Dr. Heather Preston and Dr. Andrew Heath.

Mr. Henderson, Dr. Preston and Dr. Heath all have relevant experience which qualifies them for membership of the Audit Committee and, in Mr. Henderson’s case, to be Chair of the Committee. Their experience is set out in their brief biographies on page 60 and 61.

The primary duties of the Audit Committee, as set out in its written terms of reference which is available on the Group’s website [www.oxb.com](http://www.oxb.com), are to:

- Keep under review the Group’s reporting and internal control policies and procedures;
- Oversee the relationship with the external auditors including their appointment, subject to approval by shareholders at the AGM, remuneration, independence, and the provision of non-audit services;
- Review and recommend to the Board the financial statements and associated announcements.

Provision C.3.5 of the 2016 Code states that the Audit Committee should review the effectiveness of the Group’s internal audit function. The Audit Committee considers that, given the size of the Group, it is unnecessary for it to have an internal audit function. However, the Committee regularly reviews this at its meetings and with the external auditors.

The Audit Committee met three times in 2018:

- 5 March 2018 – to review the 2017 audit and the auditors’ report; review specific accounting issues including revenue recognition, revaluation of equity instruments, accounting for the Oaktree loan and the adoption of IFRS 15; review the going concern and the viability assessment and their disclosure in the Annual report; review auditors’ opinion and representation letter and review the overall quality of the audit process. No major concerns had arisen in respect of the key audit risks identified but a number of areas required attention. Revenues from the Novartis contract had been recognised consistently with the methodology previously agreed, as was the revaluation of equity instruments. The auditors concurred with the accounting for the Oaktree loan facility and were comfortable with the proposed accounting treatments in line with IFRS 15. The auditors had also reviewed the going concern statement and associated disclosure in the Annual report. No significant audit adjustments had been identified by the auditors, and there were no material observations regarding the financial internal control procedures. The committee discussed and agreed the wording of the viability statement. The auditors’ opinion was reviewed and no issues or concerns were raised. The Committee reviewed a number of areas of the quality of the audit and no significant concerns arose.
- 16 August 2018 – to review progress to date for the six months’ financial results to 30 June 2018; identify any issues that require further attention and an update on risk. The Committee agreed with the interim review strategy. An update on the risk management process was presented relating to the PwC LLP assistance in developing our risk management system for the larger Group.
- 03 December 2018 – to review the full 2018 audit strategy; insurance strategy, tax strategy, risk process, treasury policy and financial control assessment. The Committee accepted the 2018 year-end audit strategy. The updated 2018/2019 insurance strategy was discussed and agreed. The Committee also agreed with the current tax strategy. An update on the risk management process was presented to the Committee. The Committee approved the current treasury policy and discussed the financial control assessment with the Group. The Committee agreed that a financial control assessment will be performed on an annual basis.

Internal control

The Directors are responsible for Oxford Biomedica’s system of internal control and for reviewing its effectiveness. The system is designed to manage, rather than eliminate, the risk of failure to achieve business objectives, and can only provide reasonable, and not absolute, assurance against material misstatement or loss. The Audit Committee annually reviews the effectiveness of all significant aspects of internal control, including financial, operational and compliance controls and risk management. The review for 2018 was prepared by the Chief Financial Officer and the Financial Controller and was reviewed at the March 2019 Audit Committee meeting.

The main features of the internal control and risk management processes which apply to the Group’s financial reporting processes include clear separation of duties within the financial processes such as approval of purchase orders, payroll and disbursements, and an organisation of the finance function such that monthly management results and externally reported financial statements are subject to thorough review by the Group Financial Controller and Chief Financial Officer. The financial results are also reviewed by the Senior Executive Team and the Board.

Nomination Committee report

The Nomination Committee leads the process for making appointments to the Board, and comprises all of the Non-Executive Directors.

The Nomination Committee met several times in 2018 on an ad hoc basis to consider the recruitment process and ultimate appointment of Dr. Heather Preston as a Non-Executive Director member of Board.

Share capital

The information about the share capital required by the Takeover Directive is in the Directors’ report on page 91.

Introduction

This report is on the activities of the Remuneration Committee. It is prepared in accordance with Schedule 8 to the Large and Medium-sized Companies and Groups (Accounts and Reports) Regulations 2008 (as amended in 2013). The report contains:

- The annual statement from the Remuneration Committee chair,
- The annual report on remuneration showing payments and awards made to the Directors and explaining the link between company performance and remuneration for the 2018 financial year,
- Extracts from the Directors’ remuneration policy (the "policy"), which was approved at the 2018 Annual General Meeting (AGM), and took binding effect from the close of that meeting.

The annual statement and the annual report on remuneration are subject to an advisory vote at the Company’s 2019 AGM.

The Companies Act 2006 requires the auditors to report to the shareholders on certain parts of the Directors’ remuneration report and to state whether, in their opinion, those parts of the report have been properly prepared in accordance with the relevant regulations. The parts of the report that are subject to audit are indicated. The statement from the chair of the Remuneration Committee and the policy report are not subject to audit.

Annual statement from the Remuneration Committee chair

Dear Shareholder

I am pleased to introduce our remuneration report for the 2018 financial year. The report is divided into two sections: the annual report on remuneration followed by extracts from our Directors’ remuneration policy ("the policy") approved at the 2018 AGM.

The Committee considers that the policy remains appropriate and, accordingly shareholder approval for a new policy will not be sought at the 2019 AGM. Although the relevant regulations do not require us to include the policy in the Directors’ remuneration report, we have included those parts we think shareholders will find most useful. The full new policy as approved by shareholders at the 2018 AGM is included in the Company’s 2018 annual report and accounts, which is available at [www.oxb.com](http://www.oxb.com).

The policy

The policy was approved by shareholders at the AGM on 29 May 2018, with over 97% of all votes cast in favour. We review the application of this policy regularly, to ensure it remains appropriate, linked to strategy and reflective of developing market practices.

2018 business performance and incentive impact

In February 2019 the Committee met to consider the achievement of 2018 objectives and the annual bonus award for 2018.

The performance of the business in 2018 is set out in detail in the Strategic report from pages 24 to 43 and the performance against corporate objectives is set out on page 75 of this remuneration report. Taking all of these factors into account the Committee decided to award John Dawson a bonus of 116% of salary and Stuart Paynter a bonus of 117% of salary. Peter Nolan was awarded a bonus of 118% of salary, which has been pro-rated to reflect his service in the year to the date of cessation of employment (1 July 2018). The 2018 bonuses earned by John Dawson and Stuart Paynter will be paid 50% in cash and 50% in deferred share awards. Reflecting his retirement from the business, Peter Nolan’s bonus earned during the year will be paid in cash, in line with the policy. Further details are provided on page 75 with regards to how performance under the annual bonus targets translated into bonus payment.



### Vesting of the 2015 LTIP award

LTIP awards were granted on 10 June 2015 to John Dawson, Peter Nolan and Tim Watts when the share price was 485p; the vesting conditions were as follows:

Average annual compound share price growth over the three year period starting with the date of grant	Percentage of the options granted that will vest
Less than 15%	0%
15% (i.e. 52.1% over 3 years)	25%
Between 15% and 25%	Calculated on a straight line basis between 25% and 100%
25% or more (i.e. 95.3% over 3 years)	100%

The 2015 LTIP awards vested during 2018. The share price was averaged across 20 business days prior to the end of the assessment period. In accordance with the rules of the scheme, the Committee considered and agreed a two week extension of the date of the performance assessment of the 2015 LTIP due to the Company being in a closed period. Details are provided on page 77.

The awards were also subject to a performance underpin, such that the awards would only vest to the extent that the Remuneration Committee considered that the overall performance of the business across the period justified it. The Remuneration Committee reviewed performance against this underpin and concluded the overall LTIP payments to be appropriate. Clawback and malus provisions will apply to the awards.

### Board changes

Peter Nolan resigned from the Board and retired from the Company on 1 July 2018. The remuneration arrangements in relation to Peter’s retirement from the Board have been determined in accordance with the shareholder approved Directors’ remuneration policy. In summary, Peter Nolan will receive a bonus of 118% of salary, pro-rated to reflect his service in the year to the date of cessation of employment, and will retain all vested LTIPs and deferred bonus awards made to date. Peter will also retain any unvested LTIPs previously granted, to the extent that these are assessed to have vested at the end of their three year performance periods. Further information is set out on page 79.

Heather Preston was appointed as a Non-Executive Director with effect from 15 March 2018. Details of Heather Preston’s remuneration received during the year are set out in the single figure table on page 76.

### Implementation of our policy in 2019

As discussed on page 69, the Remuneration Committee increased John Dawson’s salary by 7.9% to £410,000 and Stuart Paynter’s salary by 6.7% to £228,000. These increases recognise that our Executive Director salaries are significantly below market for companies of our size and complexity and that the rapid growth in staff in the organisation, from 321 in 2017 to more than 432 today, has resulted in an increase in the quality of individuals hired into senior management. Our success has been achieved by offering a competitive package in this highly competitive sector and these changes now need to be reflected in the compensation paid to our Executive Directors.

The maximum annual bonus opportunity for our Executive Directors will remain up to 125% of salary, in line with the opportunity for 2018. The performance measures are based on the Company’s strategic priorities, and further information is given on page 37.

The Committee has agreed that Executive Directors will be granted LTIP awards of up to 125% of salary in the case of the CEO and 100% in the case of the other Executive Directors. The Company has historically used share price growth as its primary measure for LTIP awards. However, it is the Committee’s view that as the business has grown, a mixture of financial measures and share price growth is considered to be more appropriate. The Committee believes that these measures will ensure significant value will continue to be delivered to shareholders. The proposed 2019 performance measures and targets are discussed on page 37.

### Other matters

The Committee recognises the expectations of our shareholders on executive pay and we were pleased that the 2017 Directors’ remuneration report received votes in favour in excess of 99% at the 2018 AGM. Shareholders will be invited to approve the 2018 annual remuneration report at the 2019 AGM.

Reflecting the introduction of the Revised Code, we are making some changes to the way we implement the policy, including:

- the introduction of a two year holding period for LTIP awards;
- the enhancement of recovery provisions applying to variable remuneration (enabling us to operate these provisions in the event of material corporate failure and serious reputational damage);
- an increase, with effect from 1 January 2019, to our share ownership guidelines for our Executive Directors from 150% of salary to 200% of salary; and
- the adoption of a post-cessation shareholding guideline.

Where relevant, we have described these changes later in this report – our approach will be formally enshrined in the policy when we next seek shareholder approval for it, which is currently intended to be at the 2021 AGM.

We have also included in this report a CEO pay ratio, comparing the remuneration of our CEO to that of the wider workforce. Although we are not required to include this until we publish our 2019 Directors’ remuneration report, we have done so on a voluntary basis; the detail is set out on page 81.

The Committee reviewed the Gender Pay Gap Report for 2018 and was pleased with the growth of the Company and the increase in representation of female employees at the more senior levels of the organisation over the past 12 months. This has had a positive impact on the Company’s gender pay gap. For full details of the report please visit our website at [www.oxb.com](http://www.oxb.com).

### Andrew Heath

Chair, Remuneration Committee



Andrew Heath was appointed a Director in January 2010 and became Deputy Chairman and Senior Independent Director in May 2011

Remuneration Committee role and members

The responsibilities of the Remuneration Committee are set out in its terms of reference which are available on the Group’s website and have been amended to reflect the revised Corporate Governance Code to include:

- Recommending to the Board the policy and framework for the remuneration of the Executive Directors and senior management (Senior Executive Team). The remuneration of the Non-Executive Directors is a matter for the Chairman.
- Approval of individual remuneration packages for Executive Directors and the Senior Executive Team.
- Approval of annual performance incentive plans and bonuses payable.
- Approval of the Group’s Long Term Incentive Plan (LTIP) for Executive Directors and senior management (Senior Executive Team), and awards granted under the plan.
- Approval of options granted to all employees under the Group’s share option plan.

The Remuneration Committee members are currently Andrew Heath (Chairman), Heather Preston (appointed 12 March 2019) and Stuart Henderson. Martin Diggle was a member of the Committee until 31 December 2016 but, as he is not considered to be independent for reasons explained in the Corporate Governance Report (page 67), he has stepped down from formal membership of the Committee. He retains “observer” status and therefore continues to receive all papers, and has a standing invitation to attend all meetings. Other Directors are invited to attend meetings on an agenda driven basis.

Remuneration Committee activities during 2018

During 2018 the Committee met nine times. The main activities and decisions were as follows:

- 09 February 2018 and 22 February 2018 – the Committee considered whether or not bonuses should be paid to the Executive Directors in respect of 2017 in light of the performance against the Group’s 2017 objectives, and also whether there should be salary increases for 2018. The outcome of these discussions was reported in the 2017 Annual report.
- 20 March 2018 – the Committee considered and agreed the proposed new 2018 Director’s Remuneration Policy.
- 10 May 2018 – the Committee considered and agreed a two week extension of the date of the performance assessment of the 2015 LTIP. This was permitted within the rules of the scheme, when the Company is in a closed period.
- 25 June 2018 – the Committee considered the extent to which the share price performance conditions for the June 2015 LTIP grant of options had been met. The outcome was that 79.7% of the options granted in 2015 would vest and the remaining 20.3% will lapse. The Committee also approved the vesting of Deferred Bonus Plan (DBP) options granted in 2015, 2016 and 2017. DBP options vest in three equal instalments on the first, second and third anniversaries of the grant.
- 06 August 2018 – the Committee considered the granting of options to employees under the Group’s Long Term Incentive Plan, Deferred Bonus Plan and Employee Share Option Scheme. The Committee approved the granting of the share options.
- 26 September 2018 and 10 October 2018 – in September the Committee approved an invitation to all employees to participate in the 2018 offer under the Company’s Save As You Earn Scheme. In October the Committee approved the grant of options under this offer.
- 01 October 2018 – the Committee considered and approved the proposal to award a non-pensionable additional allowance (car allowance) to members of the Senior Executive Team.

Annual report on remuneration

Summary of changes to executive remuneration for 2019

(subject to audit)

Under the remuneration policy Executive Directors’ base salaries are normally reviewed annually. The Remuneration Committee has carried out this review in February 2019 and has awarded the following base salary increases:

	Current salary	Percentage increase	Total of increase	New salary
John Dawson	£380,000	7.9%	£30,000	£410,000
Stuart Paynter	£213,725	6.7%	£14,275	£228,000

The Committee recognises that salaries for our CEO and CFO are significantly below market for companies of our size and complexity. With the rapid growth in staff in the organisation, from 321 in 2017 to more than 432 today, there has been an increase in the quality of individuals hired into senior management. Our success has been achieved by offering a competitive package in this highly competitive sector. These changes now need to be reflected in the compensation paid to our Executive Directors, and it is with this in mind that we increased John Dawson’s salary last year and have implemented these salary increases for 2019. Subject to continued strong performance by the company and the individuals, the Committee’s intention is to achieve a base salary of £450,000 for John Dawson and £260,000 for Stuart Paynter over two to three years.

Annual bonus

(subject to audit)

Performance objectives for the Group have been agreed by the Board and the extent to which Executive Directors’ bonuses for 2019 are earned will be determined by the Remuneration Committee early in 2020 in the light of performance against those objectives and in line with the remuneration policy. The performance measures are based on the Company’s strategic priorities, and further information is given on page 37.

LTIP

(subject to audit)

The Company has historically used share price growth as its primary measure for LTIP awards. However it is the Committee’s view that as the business has grown, a mixture of financial measures and share price growth is considered to be more appropriate. The Committee believes that these measures will ensure significant value will continue to be delivered to shareholders.

The Committee intends to grant LTIP options to the Executive Directors during 2019 of up to 125% of salary in the case of the CEO and 100% in the case of other Executive Directors in accordance with the approved remuneration policy. The proposed 2019 performance criteria will be equally weighted between share price growth (requiring 10% CAGR for threshold vesting and 17.5% CAGR or greater for maximum vesting) and revenue growth (requiring 15% CAGR for threshold vesting and 24% or greater for maximum vesting). There will be a performance underpin, such that the awards will only vest to the extent that the Committee considers that the overall performance of the business across the period justifies it. Share price growth will also be averaged across a three month period to avoid rewarding for short term spikes in performance.

As noted in the statement from the Committee’s Chairman, the awards will be subject to a two year holding period following the end of the performance period. Awards will vest following the end of the performance period but will not be released, so that the Executive Director is not entitled to acquire the vested shares until the end of the holding period.



Corporate governance  
**Directors’ remuneration report**

for the year ended 31 December 2018

**Single total figure of remuneration**

(subject to audit)

The following tables show a single total figure of remuneration for 2018 for each Director and comparative figures for 2017.

2018	Salary £'000	Benefits <sup>1</sup> £'000	Bonus £'000	LTIP <sup>2</sup> £'000	Pension <sup>3</sup> £'000	Total £'000
John Dawson	380	4	439	438	50	1,311
Stuart Paynter	214	4	251	–	32	501
Peter Nolan <sup>4</sup>	108	1	127	268	16	520
<b>Total</b>	<b>702</b>	<b>9</b>	<b>817</b>	<b>706</b>	<b>98</b>	<b>2,332</b>

2017	Salary £'000	Benefits £'000	Bonus £'000	LTIP £'000	Pension £'000	Total £'000
John Dawson	350	1	372	67	53	843
Stuart Paynter <sup>5</sup>	71	–	76	–	11	158
Peter Nolan	216	1	238	37	32	524
Tim Watts <sup>6</sup>	169	1	185	42	25	422
<b>Total</b>	<b>806</b>	<b>3</b>	<b>871</b>	<b>146</b>	<b>121</b>	<b>1,947</b>

1. Benefits comprise medical insurance and the provision of a car allowance.  
2. This comprises the LTIP awards granted in 2015 which vested in June 2018. The relevant performance criteria and the performance against them are set out on page 77. The values are calculated by reference to the share price at the last day of the period over which the share price was awarded to determine the extent of vesting.  
3. Pension contributions are made into the Group's defined contribution scheme, or at the election of the Director, as a cash allowance in lieu of a company pension contribution – Tim Watts and John Dawson had elected to receive such a cash allowance.  
4. Peter Nolan stepped down from the Board on 1 July 2018. His 2018 remuneration is in respect of the period to his retirement from the Board, including his 2018 bonus.  
5. Stuart Paynter was appointed CFO with effect from 29 August 2017. His 2017 remuneration is in respect of the period from his appointment to the Board.  
6. Tim Watts stepped down from the Board on 29 September 2017. His 2017 remuneration is in respect of the period to his retirement from the Board, including his 2017 bonus.

In February 2019 the Committee met to consider the achievement of the 2018 objectives and the annual bonus award for 2018. The performance of the business 2018 is set out in detail in the Strategic report from pages 32 to 36.

Performance against the Group objectives for 2018, on which the executives’ bonuses are based, was as follows:

Objective	Weighting	Performance assessed	Assessment against objective	% of bonus awarded
<b>Support partner portfolio advancement</b> Supporting our partners in order to gain approval and launch of key products in both US and EU, support the progress of programmes into the clinic and also deliver on our commitments to partners.	35%	We supported Novartis in the EU/US approvals and launch of Kymriah for paediatric ALL and DLBCL (7.5%). We also supported the progression of an undisclosed product into the clinic (5%) and ensured process submission documents were approved by Novartis (7.5%). Batches of material were also delivered to Novartis as scheduled/requested (10%). We were also successful in producing documents in order to support the suspension process approval. In terms of our collaboration with Orchard Therapeutics, we were also key in supporting the production of documents required for the BLA submission and the advancement of one of their products according to the schedule (5%).	Met in full	35%
<b>Progress action on implementing strategy</b> Achieving successful progression of key programmes against plan for a partner; to deliver new pre-clinical products to the Group and also, as previously announced to reduce the financial risk of clinical stage product development while retaining significant financial interest; look to complete the partnering or spin out of OXB-102 and ocular programmes.	20%	These goals were partially met. We successfully managed to out-licence OXB-102 (now AXO-Lenti-PD) for Parkinson's disease to Axovant for more than \$840 million (17.5%). However, our plan for spin out/out-licence of our ocular assets was put under review.	Partially met	17.5%
<b>Financial objectives</b> Confidential targets relating to the Group's financial performance.	15%	The goal to achieve an operating EBITDA target around £2.6 million as per the budget was met (5%) along with net cash inflow from operating activities of £6.6 million (5%). The re-finance of the Oaktree debt was not pursued.	Partially met	10%
<b>Business development</b> Secure further revenue and royalty generating partnership relationships and build further on those we already have.	25%	These goals were fully met as we signed an agreement with Bioerativ, now Sanofi, for haemophilia products in February 2018 and with Boehringer Ingelheim, the UK Cystic Fibrosis Gene Therapy Consortium and Imperial Innovations for development of a gene therapy product to treat cystic fibrosis in August 2018 (25%).	Met in full	25%
<b>Management structure</b> Further organisational improvement objectives were set.	5%	Transformation of the management structure (brought in three new SET members in 2018) and introduction of key individual training for senior managers to ensure all skill sets are covered for future growth.	Met in full	5%

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John Dawson’s bonus is entirely linked to the achievement of the corporate objectives. Bonuses for Peter Nolan and Stuart Paynter are 80% linked to corporate objectives and 20% linked to personal objectives.

The personal element of the bonus was assessed by reference to the achievement of clear personal objectives and targets which supported the strategic objectives of the business. The objectives and targets are considered by the Company to be commercially sensitive, as they will give our competitors insight into our strategic plans, and so are not disclosed below. However, the principal areas are summarised below for each Executive Director:

Stuart Paynter: Managed the finance team to achieve financial targets.

Peter Nolan: Managed the business development team to increase deal flow.

The Remuneration Committee undertook a robust assessment of the achievements of each Executive Director with respect to their personal objectives, and based on those objectives having been achieved in full, awarded bonuses equal to 20% of salary to each of Stuart Paynter and Peter Nolan.

In accordance with the S430(b) statement on the Group’s website, Peter will be eligible to receive an annual bonus in respect of the financial year ending on 31 December 2018 reflecting his period of employment with the Group to the date of retirement. The bonus will be assessed against the prescribed performance targets and may be paid fully in cash.

Accordingly, bonuses earned by the Executive Directors in respect of 2018 were:

- John Dawson: £439,000 (115% of salary);
- Stuart Paynter: £251,000 (117% of salary); and
- Peter Nolan: £127,000 (118% of salary, after pro-rating to reflect his period of service in the year).

The 2018 bonuses for John Dawson and Stuart Paynter will be paid 50% in cash and 50% in deferred share awards.

The deferred share awards are not subject to further performance targets and will vest in three equal instalments on the first three anniversary dates after the award date provided that the relevant participant remains employed at the first anniversary of the award. Reflecting his retirement from the business and in accordance with the policy, Peter Nolan’s bonus will be paid fully in cash. The Remuneration Committee reviewed performance against the annual bonus out-turn and concluded the overall bonus payments to be appropriate.

The single total figures of remuneration for Non-Executive Directors are shown in the table below:

Fees	2018 £’000	2017 £’000
Lorenzo Tallarigo	150	150
Andrew Heath	65	46
Stuart Henderson	65	53
Heather Preston	52	–
Total	332	249

Heather Preston was appointed as a Non-Executive Director with effect from 15 March 2018. Her 2018 remuneration is in respect of the period from her appointment to the Board.

Martin Diggle has elected to receive no fees for his services as a Director.

Aggregate Directors’ emoluments	2018 £’000	2017 £’000
Salaries	702	806
Benefits	9	3
Pension /cash alternative	98	121
LTIP	706	146
Bonuses	817	871
Non-Executive Directors fees	332	249
Total	2,664	2,196

LTIPs vesting during 2018

(subject to audit)

LTIP awards were granted on 10 June 2015 to John Dawson, Peter Nolan and Tim Watts when the share price was 485p, the vesting conditions were as follows:

Average annual compound share price growth over the three year period starting with the date of grant	Percentage of the options granted that will vest
Less than 15%	0%
15% (i.e. 52.1% over 3 years)	25%
Between 15% and 25%	Calculated on a straight line basis between 25% and 100%
25% or more (i.e. 95.3% over 3 years)	100%

The 2015 LTIP awards vested during 2018. The share price was averaged across 20 business days prior to the end of the assessment period. In accordance with the rules of the scheme, the Committee considered and agreed a two week extension of the date of the performance assessment of the 2015 LTIP due to the Company being in a closed period. The Committee considered the extent to which the share price performance conditions for the June 2015 LTIP grant of options had been met. Over the three year performance period from the date of grant, the annual compound share price growth was 83.6%.

The outcome was that 79.7% of the options granted in 2015 would vest and the remaining 20.3% will lapse.

The awards were also subject to a performance underpin, such that they would vest only to the extent that the Remuneration Committee considers that the overall performance of the business across the period justifies it. The Remuneration Committee reviewed performance against this underpin and concluded the overall LTIP payments to be appropriate. Clawback and malus provisions will apply to the awards.

The value of the awards vesting during 2018 are detailed below:

	Number of awards granted that vested²	Share price at the date on which the shares vest	Value of awards on vesting¹
John Dawson	43,824	1,000p	£438,230
Peter Nolan	26,817	1,000p	£268,167
Tim Watts	28,126	1,000p	£281,253

- 1. The values are calculated by reference to the share price of 1,000p on on the last day of the averaging period.
- 2. Number of shares post 30 May 2018 share consolidation.

LTIPs awarded during 2018

(subject to audit)

On 8 August 2018, the Executive Directors were awarded the following options under the Group’s LTIP scheme:

	Number of options granted	Face value of grant
John Dawson	52,555	£474,572
Stuart Paynter	23,647	£213,532

The number of options awarded in August 2018 was calculated by reference to 125% (John Dawson) and 100% (Stuart Paynter) of salary divided by the average share price of 904p in the five business days preceding the relevant award.

The awards are nil cost options and are subject to a three year vesting period. They are exercisable from the third anniversary of the award, subject to the achievement of the performance condition set out below:

Average annual compound share price growth over the three year period starting with the date of grant*	Percentage of the options granted that will vest
Less than 10%	0%
10% (i.e. 33% over 3 years)	20%
Between 10% and 17.5%	Calculated on a straight line basis between 17.5% and 100%
17.5% or more (i.e. 63% over 3 years)	100%

\* The starting share price for 8 August 2018 is 904p respectively, being the average share price over the five business days preceding the date of grant. The end share price shall be calculated as the average of the closing price for the three months period prior to 8 August 2021.



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There will also be a performance underpin, such that the awards will only vest to the extent that the Remuneration Committee considers that the overall performance of the business across the period justifies it. The Committee has always taken a prudent approach to LTIP awards, reflecting the share price at the time and the dilutive impact to shareholders, and to avoid the potential for windfall gains. The Committee agreed that there would be no scale back of LTIP for the 2018 award.

Stuart Paynter was also granted an award over an additional 7,235 shares (£65,404) under the Group’s LTIP scheme to rectify an error in the 2017 LTIP award granted on 25 September 2017.

Statement of Directors’ shareholding and share interests  
(subject to audit)

The Remuneration Committee has adopted a shareholding guideline for the Executive Directors, which specifies a shareholding equivalent to 150% of base salary as further described in the Remuneration policy. The Remuneration Committee has decided to increase, with effect from 1 January 2019, the shareholding guidelines requirement for our Executive Directors to 200% of salary.

The value of the shares as at 31 December 2018 has been determined based on a share price of 707.2p (being the prevailing closing share price on 31 December 2018). Under this criteria both John Dawson and Peter Nolan (as at the date of cessation) meet the shareholding guidelines, with Stuart Paynter working towards meeting this guideline.

The interests in shares of the Directors who served during the year as at 31 December 2018 (or, if earlier, the date of their retirement) were as follows:

	Shares held outright		Vested but unexercised options		Unvested deferred bonus plan		Unvested LTIP awards subject to performance conditions	
	2018	2017	2018	2017	2018	2017	2018	2017
Executive Directors								
John Dawson	88,468	78,514	356,313	305,586	45,455	51,773	172,006	174,436
Peter Nolan <sup>1</sup>	45,795	38,366	23,006	153,639	30,425	34,742	107,461	107,461
Stuart Paynter	1,753	–	–	–	4,354	–	88,762	57,880
Non-Executive Directors								
Lorenzo Tallarigo	47,942	43,462						
Martin Diggle <sup>2</sup>	11,640,177	11,620,177						
Andrew Heath	36,000	32,142						
Stuart Henderson	6,677	6,677						
Heather Preston <sup>3</sup>	–	–						

1. Peter Nolan stepped down from the Board on 1 July 2018. His share held outright is as at the date of stepping down from the Board.  
2. Includes the interest of Vulpes Life Science Fund, Vulpes Testudo Fund and other parties connected to Martin Diggle.  
3. Heather Preston was appointed to the Board as a Non-Executive Director with effect from 15 March 2018.

Reflecting best practice, the Remuneration Committee has adopted, with effect from 1 January 2019, a post-cessation shareholding guideline. This requires that an Executive Director must retain shares with a value (as at cessation) equal to 100% of base salary for two years following cessation. If the Executive Director holds fewer than the required number of shares, he or she must retain the shares held. The guideline does not apply to shares which the Executive Director has purchased. The Remuneration Committee retains discretion to vary the post-cessation shareholding guideline in appropriate circumstances and will continue to review the guideline in light of developing market practice before formally enshrining it in the next policy.

During 2018 the following options have vested and lapsed:

LTIP	Unvested at 1 January 2018 <sup>1</sup>	Vested during 2018 <sup>1</sup>	Lapsed during 2018 <sup>1</sup>	Awarded during 2018	Unvested at 31 December 2018 <sup>1</sup>
John Dawson	174,436	43,824	11,161	52,555	172,006
Stuart Paynter	57,880	–	–	30,882	88,762
Peter Nolan <sup>2</sup>	107,461	26,817	6,830	–	73,814

Deferred bonus	Unvested at 1 January 2018 <sup>1</sup>	Vested during 2018 <sup>1</sup>	Awarded during 2018	Unvested at 31 December 2018 <sup>1</sup>
John Dawson	51,773	26,904	20,586	45,455
Peter Nolan <sup>2</sup>	34,742	17,487	13,170	30,425
Stuart Paynter	–	–	4,354	4,354

Note 1: Quantities have been amended for 50 to 1 share consolidation on 30 May 2018.  
Note 2: Peter Nolan stepped down from the Board on 1 July 2018.

During 2018 John Dawson exercised 20,000 options which were due to expire during the year, realising a gain of £168,000.

On 18 May 2019 the performance criteria for the LTIP awards granted on 18 May 2016 will be assessed. The average share price for the five business days preceding 18 May 2016 was 275p and vesting conditions were set as follows:

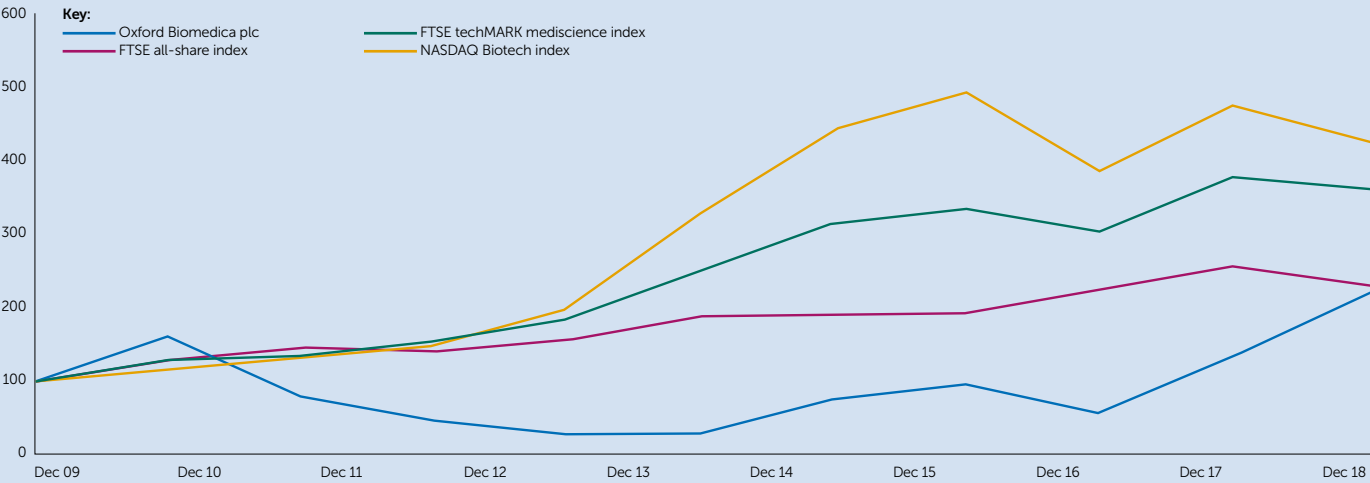
Average annual compound share price growth over the three year period starting with the date of grant	Percentage of the options granted that will vest
Less than 15%	0%
15% (i.e. 52.1% over 3 years)	25%
Between 15% and 25%	Calculated on a straight line basis between 25% and 100%
25% or more (i.e. 95.3% over 3 years)	100%

Payment to past Directors and payments for loss of office  
(subject to audit)

Peter Nolan stepped down from the Board and retired from the Group on 1 July 2018. His remuneration earned to that date and the bonus he has earned in respect of 2018 is included in the single figure table of remuneration on page 74. He will not receive any payment for loss of office or any other payments in relation to the cessation of his employment. Consistent with the terms of the Group’s remuneration policy and the rules of the LTIP, he will retain the unvested share awards made under the LTIP granted in 2016 and 2017, which will vest on their normal vesting dates, subject to the performance conditions. Peter will also retain the deferred bonus shares earned but not yet vested in respect of 2015, 2016 and 2017 bonuses. These will vest at the usual time.

Performance graph and comparison with CEO’s remuneration

The chart below illustrates the Company’s TSR performance since January 2009 relative to the FTSE all-share index and the FTSE techMARK MediScience index. The FTSE all-share index has been selected because it represents a broad-based measure of investment return from equities. The FTSE techMARK mediScience index, comprising biotech companies, provides a second benchmark that is a more specific comparator.



CEO’s remuneration in last ten years

Year		2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
CEO’s total single figure of remuneration		£’000	817 <sup>1</sup>	450	413	401	468	732	653	811	1,294
LTIP vesting		% of maximum	0%	0%	0%	40%	0%	100%	50%	25%	80%
Annual bonus		% of maximum	80%	42%	0%	17%	30%	42%	50%	85%	92%

1. On 1 September 2009 1,500,000 (consolidated to 30,000 shares) new Ordinary Shares were allotted to John Dawson. The shares were fully paid and were a one-off share based bonus payment in accordance with his contract of employment for successful achievement of certain transactions with Sanofi in April 2009. The value of the shares at the closing mid-market price on the trading day immediately prior to issue was £172,500 and the Company bore an additional cost of £120,000 required to gross up the value of the shares for income tax and National Insurance. Mr. Dawson also received a regular bonus of 80% of maximum.

Percentage change in CEO’s remuneration

The table below shows how the percentage change in the CEO’s salary, benefits and bonus between 2017 and 2018 compares with the equivalent changes in those components for a group of employees. As 2017 and 2018 have seen significant changes in headcount numbers, the Committee has chosen as the comparator group all those employees other than the CEO who were employed throughout the whole of both 2017 and 2018.

Year	Salary			Benefits			Bonus		
	2018	2017	% increase	2018	2017	% increase	2018	2017	% increase
John Dawson	380	350	8.6%	4	1	300%	439	372	18%
Comparator employee group	8,008	7,423	7.9%	88	93	(5.4%)	832	618	35%

The increase in the CEO’s benefits is due to the provision of a car allowance initiated during the year.

CEO’s pay ratio

The table below sets out the CEO pay ratio at the 25th, median and 75th percentile employee within the organisation. The Group used Option A as defined in The Companies (Miscellaneous Reporting) Regulations 2018, as this calculation methodology for the ratios was considered to be the most accurate method. The 25th, median and 75th percentile pay ratios were calculated using the full time equivalent remuneration for all UK employees as at the end of 2018. Employees’ involvement in the Group’s performance is encouraged, with all employees eligible to participate in the Share Option Scheme or the LTIP. Certain employees also participate in discretionary bonus schemes. The Group aims to provide a competitive remuneration package which is appropriate to promote the long-term success of the Group and to apply this policy fairly and consistently to attract and motivate staff. The Group considers the median pay ratio to be consistent with the Group’s wider policies on employee pay, reward and progression.

Financial year	Method	25th percentile pay ratio	Median pay ratio	75th percentile pay ratio
2018	Option A	1:48	1:37	1:27

Pay details for the individuals are set out below:

2018	CEO	25th percentile	Median	75th percentile
Salary (£’000)	£380	£25	£32	£44
Total remuneration (£’000)	£1,294	£27	£35	£48



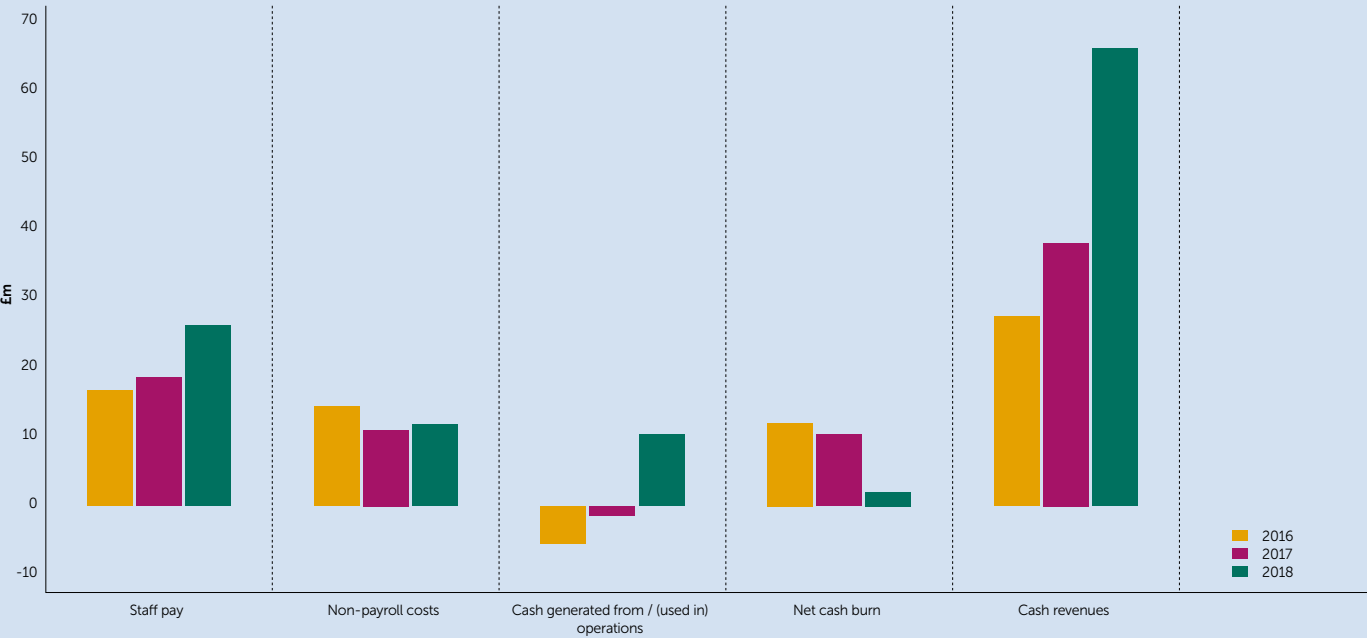
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**Relative importance of spend on pay**

The chart below illustrates the spend on employee remuneration compared with the Group’s key cash measures. Since the Group does not make dividend or other distributions, these have not been included in the table. The Group’s key cash measures were chosen by the Directors because they illustrate very clearly the importance of employee remuneration as a fundamental element of operational spend and our activities, as well as the continued investment of the business in its people. The key cash measure amounts were identified as being:

- Non-payroll costs
- Net cash used in operating activities
- Net cash burn
- Cash revenues



**Statement of voting at AGM**

At the 2018 AGM, the 2017 Directors’ remuneration report was approved by shareholders as follows:

Resolution	Votes for (including discretionary)	% for	Votes against	% against	Total votes cast (excluding votes withheld)	Votes withheld (abstentions)
Approval of the Directors’ remuneration report	1,989,086,555	99.7%	4,411,157	0.2%	1,993,497,712	1,733,366

At the 2018 AGM, the 2018 Directors’ remuneration policy was approved by shareholders as follows:

Resolution	Votes for (including discretionary)	% for	Votes against	% against	Total votes cast (excluding votes withheld)	Votes withheld (abstentions)
Approval of the Directors’ remuneration report	1,930,039,150	97.2%	56,288,698	2.8%	1,986,327,848	8,903,541

**Advisers to the Committee**

Deloitte LLP acted as adviser to the Committee during 2018. Deloitte is a founding member of the Remuneration Consultants Group and adheres to its Code of Conduct in relation to executive remuneration consulting in the UK. Deloitte’s fees for advice to the Committee during 2018 were £7,325 plus VAT. The advice received from Deloitte LLP was both objective and independent. Deloitte also advised the Group in relation to the operation of its share plans during 2018.

The Committee reviewed the potential conflicts of interest and the safeguards against them and is satisfied that Deloitte does not have any such interests or connections with the Group that may impair independence.

**Andrew Heath**  
Chair, Remuneration Committee  
14 March 2019

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Directors’ remuneration policy

Policy table

<b>Executive Directors</b>			
<b>Base salary</b> To provide a base salary which is sufficient to attract and retain executives of a suitable calibre.	Base salaries are initially set by reference to market information at the time of appointment and taking into account the experience and previous package of the new Director.  Base salaries are normally reviewed annually taking into account a number of factors which may include (but are not limited to): <ul style="list-style-type: none"><li>– underlying Group performance;</li><li>– role, experience and individual performance;</li><li>– competitive salary levels and market forces; and</li><li>– pay and conditions elsewhere in the Group.</li></ul> Any changes are normally effective from 1 January.	While there is no maximum salary, increases will normally be line with the level of salary increase awarded (in percentage of salary terms) to other employees in the Group.  Salary increases above this level may be awarded in certain circumstances, such as, but not limited to: <ul style="list-style-type: none"><li>– where an Executive Director has been promoted or has had a change in scope or responsibility;</li><li>– an individual's development or performance in role (e.g. to align a newly appointed Executive Director's salary with the market over time);</li><li>– where there has been a change in market practice; or</li><li>– where there has been a change in size and/or complexity of the business.</li></ul> Such increases may be implemented over such time period as the Committee deems appropriate.	While no formal performance conditions apply, an individual's performance in role is taken into account in determining any salary increase.
<b>Benefits</b> To provide benefits on a market competitive basis.	Benefits are provided in line with market practice and may include medical insurance, life assurance, permanent health insurance, provision of a company car or a car allowance and other appropriate benefits determined by the Committee. Additional benefits may be provided based on individual circumstances. These may include, for example, travel expenses.	There is no predetermined maximum but the totals are reviewed annually by the Remuneration Committee.	Not applicable.
<b>Retirement benefits</b> To provide funding for retirement.	The Group operates a defined contribution scheme for all employees including Executive Directors.  In appropriate circumstances, such as where contributions exceed the annual or lifetime allowance, Executive Directors may be permitted to take a cash supplement instead of some or all of the contributions to a pension plan.	15% of base salary.	Not applicable.
<b>Share ownership guidelines</b> To align Executives with Shareholders and provide an ongoing incentive for continued performance.	Shares which are fully owned with no outstanding vesting criteria count towards the shareholding guideline together with deferred annual bonus shares (on a net of tax basis).  Executive Directors will be required to retain half of any post-tax awards which vest under the long-term incentive plans, and deferred shares under the annual bonus, until the share ownership guideline has been satisfied.	Executive Directors are required to build and maintain 150% of salary minimum level of shareholding.	Not applicable.

Component and purpose	Operation	Maximum potential and payment at threshold	Performance targets and metrics
<b>Sharesave Scheme</b> To create alignment with the Group and promote a sense of ownership.	Executive Directors are entitled to participate in a tax qualifying all employee Sharesave Scheme under which they may make monthly savings contributions over a period of three or five years linked to the grant of an option over the Company's shares with an option price which can be at a discount of up to 20% to the market value of shares at grant (or such other discount as may be permitted by the applicable legislation from time to time).	Participation limits and the level of discount permitted in setting the exercise price are those set by the UK tax authorities from time to time.	Not subject to performance measures in line with HMRC practice.
<b>Annual bonus</b> To incentivise and reward delivery of the Group's objectives.  Delivery of 50% of any bonus payment via deferred shares aligns the incentive package with shareholders' interests.	Annual bonuses are determined by the Committee.  50% of the bonus is delivered as cash.  50% of the bonus is delivered through deferred shares which ordinarily vest in three equal instalments on the first, second and third anniversaries of the award. The deferred shares are not subject to further performance targets. Deferred share awards may be made under an HMRC EMI plan where appropriate. Bonus awards are discretionary and can be removed or adjusted at the Committee's discretion.  Dividend equivalents may be attached to the deferred shares over the deferral period. These dividend equivalents may be delivered in cash or shares and may assume the reinvestment of dividends into shares on a cumulative basis.  Recovery provisions apply as summarised at the foot of this table.	The maximum bonus opportunity will not exceed 125% of base salary.	The performance metrics and targets are decided annually by the Committee taking into account the strategic needs of the business.  Given the nature of the business, these objectives and metrics may change significantly each year.  There is no minimum bonus earned if threshold performance is not met.
<b>Long Term Incentive Plan (LTIP)</b> To augment shareholder alignment by providing Executive Directors with longer term interests in shares whilst requiring challenging performance before LTIP awards vest.	At the discretion of the Committee, annual grants of conditional nominal cost share options which vest subject to the achievement of specified performance targets, typically assessed over a three year performance period.  Awards granted under the LTIP may include dividend equivalents earned between the grant and vesting date. These dividend equivalents may be delivered in cash or shares and may assume the reinvestment of dividends into shares on a cumulative basis.  Awards have been made under an HMRC EMI plan where appropriate. Recovery provisions apply as summarised in the notes to the policy table on the next page.	The normal maximum award is 100% of base salary in respect of a financial year for Executive Directors, other than the CEO for whom the maximum award is 125% of base salary. Under the share plan rules the overall maximum opportunity that may be granted in respect of a financial year is 200% of base salary. The normal maximum award limit will only be exceeded in exceptional circumstances such as the recruitment of an Executive Director.	Performance conditions will be determined in advance of grant of awards and will be based on financial measures or the achievement of strategic objectives. Financial measures may include (but are not limited to) share price and revenue measures. For the achievement of growth performance in respect of a financial measure, no more than 25% of the award will vest for threshold performance and 100% of the award will vest for maximum performance; for below threshold performance, none of the award will vest.  For strategic measures, vesting will be determined between 0% and 100% depending upon the Committee's assessment of the extent to which the measure has been achieved.



Notes to the policy table

Recovery provisions

The annual bonus and LTIP are subject to malus and clawback provisions as follows:

Annual bonus:

For up to two years following the payment of an annual bonus award the Committee may require the repayment of some or all of the cash award in the relevant circumstances (clawback). Unvested deferred bonus awards may be cancelled or reduced in the relevant circumstances (malus). For up to one year following the vesting of the first instalment of deferred shares the Committee may require the repayment of some or all of the deferred shares in the relevant circumstances (clawback).

LTIP:

The Committee has the right to reduce, cancel or impose further conditions on unvested awards in the relevant circumstances (malus). For up to two years following the vesting of a LTIP award the Committee may require the repayment of some or all of the award in the relevant circumstances (clawback).

Malus may be applied in the event of:

- A material misstatement of the Group’s financial results;
- An error in the information or assumptions on which the award was granted or vests including an error in assessing any applicable performance conditions;
- A material failure of risk management by the Group;
- Serious reputational damage to the Group; or
- Material misconduct on the part of the participant.

Clawback may be applied in the event of:

- A material misstatement of the Group’s financial results;
- An error in the information or assumptions on which the award was granted or vests including an error in assessing any applicable performance conditions; or
- Material misconduct on the part of the participant.

Performance targets and metrics

Performance targets for the annual bonus are set by the Committee after taking into account the strategic needs of the business. A key component of the Group’s strategy is to develop gene and cell therapy products from pre-clinical proof of concept through to the end of Phase I or Phase II clinical studies before partnering or out-licensing. Targets for a particular year are therefore likely to include specific product development targets depending on the stage of development of each opportunity. The annual objectives are also likely to include targets related to generating recurring revenues such as manufacturing or development services to third parties.

The performance metrics for the LTIP are determined to ensure that the most appropriate targets are set for the Group’s situation at the time; awards to be granted in 2019 will be subject to measures based on share price growth and revenue.

The Committee retains the ability to adjust or set different performance measures if events occur (such as a change in strategy, a material acquisition and/or a divestment of a Group business, or a change in prevailing market conditions) which cause the Committee to determine that the measures are no longer appropriate and that amendment is required so that they achieve their original purpose.

Operation of share plans

Awards and options may be adjusted in the event of a variation of share capital or other relevant amendment in accordance with the rules of the Share Option Scheme, LTIP and Deferred Bonus Plan. The Company’s share plans may be operated in accordance with their terms, including that awards may be granted as cash based awards over a notional number of shares, and that share awards may be settled in cash at the election of the Committee; the Committee would only use these cash provisions for operational flexibility, for example if a regulatory restriction in any territory prevented the Company from offering shares to an Executive Director.

Component and purpose	Operation	Maximum potential and payment at threshold	Performance targets and metrics
Non-Executive Directors			
Non-Executive Directors’ fees To compensate Non-Executive Directors for their services to the Group.	Non-Executive Directors’ fees are determined by the Group’s Chairman at the time of appointment of a Director. The Chairman’s fees are set by the other Non-Executive Directors.  Non-Executive Directors may be eligible to receive benefits such as the use of secretarial support, travel costs or other benefits that may be appropriate.	There is no overall maximum, but fees are set taking into account the responsibilities of the role and expected time commitment.  Non-Executive Directors may receive a base fee and a supplementary fee for additional responsibilities such as chairing a Board committee.  Fees would normally be reviewed at the start of each three year period of appointment. However, increases in Non-Executive Directors’ fees may be made at other times.	Not applicable.

Corporate governance  
Directors’ remuneration report

for the year ended 31 December 2018

Service contracts and policy on payment for loss of office

Executive Directors’ service contracts are subject to 12 months’ notice from both the Group and from the Director. Directors may be required to work during the notice period or be paid in lieu of notice if not required to work for the full notice period.

The details of service contracts and letters of appointment of those who served as Directors during the year are:

Service contracts	Contract date	Unexpired term at 31 December 2018	Notice period
John Dawson	10 October 2008	N/A	12 months
Peter Nolan	1 May 2002	N/A	12 months
Stuart Paynter	29 August 2017	N/A	12 months

Letters of appointment	Date of appointment	Unexpired term at 31 December 2018	Notice period
Lorenzo Tallarigo	1 February 2016	1 month	3 months
Martin Diggle	4 October 2015	34 months	3 months
Andrew Heath	1 January 2016	0 months	3 months
Stuart Henderson	1 June 2016	5 months	3 months
Heather Preston	15 March 2018	27 months	3 months

All Directors are subject to election by shareholders at the first opportunity after their appointment, and in line with the revised Corporate Governance Code, thereafter, to re-election on an annual basis.

The principles on which the determination of payments for loss of office will be approached are set out below:

	Policy
Payment in lieu of notice	Contractual termination payments may not exceed the Director’s current salary and benefits (including pension contributions and any applicable salary supplement) for the notice period.
Annual Bonus	This will be at the discretion of the Committee on an individual basis and the decision as to whether or not to award a bonus in full or in part will be dependent on a number of factors, including the circumstances of the individual’s departure and their contribution to the business during the bonus period in question. Any bonus amounts paid will typically be pro-rated for time in service during the bonus period and will, subject to performance, be paid at the usual time (although the Committee retains discretion to pay the bonus earlier in appropriate circumstances). The Committee has discretion to pay the whole of any bonus earned for the year of departure and preceding year in cash.
Deferred Bonus Plan	The extent to which any unvested award will vest will be determined in accordance with the rules of the Deferred Bonus Plan.  Unvested awards will normally lapse on cessation of employment. However, if a participant leaves due to death, ill-health, injury, disability, the sale of his employer or any other reason, at the discretion of the Committee, the Committee shall determine whether the award will vest at cessation or at the normal vesting date. In either case, the extent of vesting will be determined by the Committee, taking into account, unless the Committee determines otherwise, the period of time elapsed from the date of grant to the date of cessation relative to the deferral period. Awards may then be exercised during such period as the Committee determines. Awards which have already vested at the date of cessation may be exercised for such period as the Committee determines.
LTIP	The extent to which any unvested award will vest will be determined in accordance with the rules of the LTIP.  Unvested awards will normally lapse on cessation of employment. However, if a participant leaves due to death, ill-health, injury, disability, the sale of his employer or any other reason at the discretion of the Committee, the Committee shall determine whether the award will vest at cessation or at the normal vesting date. In either case, the extent of vesting will be determined by the Committee taking into account the extent to which the performance condition is satisfied and, unless the Committee determines otherwise, the period of time elapsed from the date of grant to the date of cessation relative to the performance period. Awards may then be exercised during such period as the Committee determines. Awards which have already vested at the date of cessation may be exercised for such period as the Committee determines.
Change of control	The extent to which unvested awards under the Deferred Bonus Plan and LTIP will vest will be determined in accordance with the rules of the relevant plan.  Awards under the Deferred Bonus Plan will vest in full in the event of a takeover, merger or other relevant corporate event.  Awards under the LTIP will vest early on a takeover, merger or other relevant corporate event. The Committee will determine the level of vesting taking into account the extent to which the performance condition is satisfied and, unless the Committee determines otherwise, the period of time elapsed from the date of grant to the date of the relevant corporate event relative to the performance period.
Other payments	Payments may be made either in the event of a loss of office or a change of control under the Sharesave Scheme, which is governed by its rules and the legislation relating to such tax qualifying plans. There is no discretionary treatment for leavers or on a change of control under this scheme.  In appropriate circumstances, payments may also be made in respect of accrued holiday, outplacement and legal fees.  The Committee retains discretion to make additional exit payments where such payments are made in good faith in discharge of an existing legal obligation (or by way of damages for breach of such an obligation) or by way of settlement or compromise of any claim arising in connection with the termination of a Director’s office or employment.

By order of the Board

Andrew Heath  
Chair, Remuneration Committee

14 March 2019



The Directors present their Annual report and audited consolidated financial statements for the year ended 31 December 2018 as set out on pages 104 to 144. This report should be read in conjunction with the corporate governance report on pages 52 to 68.

Discussions regarding financial information contained in this Annual report may contain forward-looking statements with respect to certain of the plans, current goals and expectations relating to the future financial condition, business performance and results of the Group and Company. By their nature, all forward looking statements involve risk and uncertainty because they relate to future events and circumstances that are beyond the control of the Group and Company. Readers are cautioned that, as a result, the actual future financial condition, business performance and results of the Group may differ materially from the plans, goals and expectations expressed or implied in such forward looking statements.

**Strategic report**

The Strategic report including the outlook for 2019 on page 37, is on pages 20 to 49. The Directors consider that the Annual report and accounts, taken as a whole, are fair, balanced and understandable. In reaching this conclusion, the Audit Committee initially discussed the requirements with the Group’s auditors when discussing the strategy for the 2018 audit, and the full Board reviewed the contents of the report at its 12 March 2019 meeting. Since the Board met seven times for routine meetings in 2018 the Directors consider that they are sufficiently well informed to be able to make this judgement.

**Key financial performance indicators (KPIs)**

Key financial performance indicators are outlined in the Chief Financial Officer’s review on pages 38 to 43.

**Corporate governance**

The Group’s statement on corporate governance is included in the corporate governance report on pages 52 to 68.

**Risk management**

The Group’s exposure to risks is set out on pages 52 to 58 (principal risks and uncertainties) and on page 121 (note 3: financial risk management).

**Dividends**

The Directors do not recommend payment of a dividend (2017: Enil).

**Directors**

Details of the Directors of the Company who were in office during the year and up to the date of signing the financial statements are detailed on pages 60 to 61 and page 70. The contracts of employment of the Executive Directors are subject to a twelve months’ notice period. The Directors’ remuneration and their interests in the share capital of the Company at 31 December 2018 are disclosed in the Directors’ remuneration report on pages 69 to 89.

**Appointment and replacement of Directors**

Directors may be appointed by an ordinary resolution at any general meeting of shareholders, or may be appointed by the existing Directors, provided that any Director so appointed shall retire at the next annual general meeting (AGM) and may offer himself for re-election. In order to ensure that we comply with the revised Corporate Governance Code all Directors will retire at each annual general meeting and may offer themselves for re-election. A Director may be removed in the following ways: by an ordinary resolution at a general meeting; if he or she is prohibited by law from being a Director; in the event of bankruptcy; if he or she is suffering from specified mental disorders; if he or she is absent without consent for more than six months; or by request in writing by all the other Directors. Any Director may appoint another Director or another person approved by the other Directors as an alternate Director.

**Directors’ third party indemnity provision**

The Group maintains a qualifying third party indemnity insurance policy to provide cover for legal action against its Directors. This was in force throughout 2018 and up to the date of approval of the financial statements.

**Share capital**

**Structure of the Company’s capital**

The Company’s share capital comprises a single class of 1p ordinary shares, each carrying one vote and all ranking equally with each other. Following the adoption of new articles of association in 2010, the authorised share capital of the Company is unlimited.

On 30 May 2018, Oxford Biomedica consolidated its existing ordinary shares of 1 pence each to 65,701,073 new consolidated ordinary shares of 50 pence each. At 31 December 2018 the Company had 66,103,528 shares in issue, all allotted and fully paid. There are no restrictions on the transfer of shares in the Company or on voting rights. All shares are admitted to trading on the London Stock Exchange.

**Rights to issue and buy back shares**

Each year at the AGM the Directors seek rights to allot shares. The authority, when granted lasts for 15 months or until the conclusion of the next AGM if sooner. At the last AGM held on 29 May 2018, authority was given to allot up to 21,893,424 shares (that number being one third of total issued share capital of the Company at the time), subject to the normal pre-emption rights reserved to shareholders contained in the Companies Act 2006, and to allot up to a further 21,893,424 shares, solely in a rights issue. Authority was also given, subject to certain conditions, to waive pre-emption rights over up to 6,568,024 shares, being 10% of the shares then in issue. No rights have been granted to the Directors to buy back shares.

Substantial shareholdings

At 15 February 2019, the latest practical date prior to approval of the Directors’ report, the Company had been notified of the following shareholdings amounting to 3% or more of the ordinary share capital of the Company.

Shareholder	Number of ordinary shares	Percentage of issued share capital
Vulpes Investment Management	11,640,177	17.6%
M&G Investments	11,598,648	17.5%
Hargreaves Lansdown Asset Management	3,727,030	5.6%
Cannaccord Genuity Wealth Management	3,684,136	5.6%
Mr. S Shah	2,897,000	4.4%
Aviva Investors	2,811,681	4.3%
Interactive Investor Sharedealing	2,328,085	3.5%

No other person has reported an interest in the ordinary shares of the Company required to be notified to the Company. No person holds shares carrying special rights with regard to control of the Company.

Employees

In accordance with s172 of the Companies Act 2006, the Group communicates and consults regularly with employees throughout the year. Employees’ involvement in the Group’s performance is encouraged, with all employees eligible to participate in the share option scheme or the LTIP. Certain employees participate in discretionary bonus schemes.

The Group’s aim for all members of staff and applicants for employment is to fit the qualifications, aptitude and ability of each individual to the appropriate job, and to provide equal opportunity regardless of sex, religion or ethnic origin. The Group does all that is practicable to meet its responsibility towards the employment and training of disabled people.

Further details on employees, health and safety, environmental matters and corporate social responsibility are in the corporate responsibility statement on pages 44 to 49.

Employee share schemes

The Group has established an Employee Benefit Trust (EBT) to hold shares purchased in order to settle shares awarded to Executive Directors and other senior managers under the 2013 Deferred Bonus Plan. The EBT currently holds 116,724 shares on which all the related options have vested. See note 25 of the consolidated financial statements for further information.

Agreements that take effect, alter, or terminate because of a takeover bid or on change of control. There are no such agreements that the Directors consider are material. There are no agreements providing for compensation for loss of office for Directors or employees in the event of a takeover bid.

Going concern

The Group held £32.2 million of cash at the end of 2018. During 2018 the Group generated positive operational cash flows, and although the Group is making a further strategic investment in extending our bioprocessing capacity, the Group expects to generate sufficient operational cash flow to continue its growth strategy. Taking this into account, in conjunction with currently known and probable cash flows, the Directors consider that the Group has sufficient cash resources and cash inflows to continue its activities for at least twelve months from the date of these financial statements and have therefore prepared the financial statements on a going concern basis.

Although the UK’s decision to leave the European Union may significantly affect the fiscal, monetary and regulatory landscape in the UK,the Group has assessed the future impact of Brexit on its operations to be minor. Further details of our contingency planning is provided on page 58.

Viability statement

Assessment of prospects

In accordance with provision C.2.2 of the UK Corporate Governance Code, the Directors have assessed the prospects of the Group over the three years to December 2021. They believe three years to be appropriate due to the inherent significant uncertainties of forecasting beyond this time horizon given the nature of the business sector in which the Group operates. The assessment has been informed by the strategy adopted by the Board in 2016 and the evolution of the business over the last twelve months.

The Group’s strategy is to exploit its LentiVector platform to develop gene and cell therapy products in its own portfolio and to support the development of other companies’ products. The Group is generating growing revenues and other operating income from licensing its platform technology, generating upfront receipts and royalties, and from fees for providing process development and bioprocessing services to other companies. Over the three years to December 2021 the Directors believe that revenues from licensing its technology to third parties and from providing process development and bioprocessing services to its partners will be sufficient to create a sustainable Group.

Assessment of viability

The main area of risk to the viability of the Group within the three-year period to December 2021 is that the Group fails to generate sufficient revenue from the process development and bioprocessing services it provides to third parties to cover its operational spend and loan interest payments. In particular, should the commercial supply requirements of Novartis, in terms of the global roll-out of Kymriah fall substantially short of current expectations, this would have a materially negative impact on the Group. However, the Group has started to mitigate this risk by signing new commercial contracts with Axovant, Bioverativ (Sanofi) and the UK Cystic Fibrosis Gene Therapy consortium which will bolster our commercial development and bioprocessing pipelines. We continue to develop our technology so as to retain a leadership position within the field . Orchard Therapeutics has again grown in importance having IPO’d at the end of the year in anticipation of the commercial launch of its strategic product portfolio which we continue to support in a bioprocessing and commercial development capacity.

Although the loan is repayable in the viability period, the Directors are confident that the Group will be able to refinance the loan at the same or more favourable terms than those currently in place. The Directors have also assumed that regulatory approval for our bioprocessing facilities remains in place across the period.

The Directors anticipate that the Group has reasonable prospects for attracting further new customers and generating additional revenues in line with the increased revenues across the past five years. The Group’s financial forecasts developed reflect these assumptions and therefore the Directors have concluded that there is a reasonable expectation, although not a certainty, that the Group will be able to continue in operation and meet its liabilities as they fall due over the three-year period to December 2021. If additional revenues were to fall below the Director’s expectations, the Group might need to secure alternative sources of financing to continue to fund its operations.

Amendment of the Company’s articles of association

Amendment of the Company’s articles may be made by special resolution at a general meeting of shareholders.

Compliance with Listing Rule 9.8.4R

The Directors have reviewed the requirements of LR 9.8.4R. The majority of these do not apply to the Group but the following are applicable.

Listing Rule	Information required	Response
LR 9.8.4 (5) and (6)	Arrangement under which a Director has waived current or future emoluments.	Martin Diggle has elected to receive no fees for his services as Director (page 76).
LR 9.8.4 (7) and (8)	Allotment of shares other than to existing shareholders in proportion to holdings.	Allotment of shares on exercise of options by employees under approved share schemes (note 25, page 138).



Statement of Directors’ responsibilities in respect of the financial statements

The Directors are responsible for preparing the Annual report and the Group and parent Company financial statements in accordance with applicable law and regulations.

Company law requires the Directors to prepare Group and parent Company financial statements for each financial year. Under that law they are required to prepare the Group financial statements in accordance with International Financial Reporting Standards as adopted by the European Union (IFRSs as adopted by the EU) and applicable law and have elected to prepare the parent Company financial statements on the same basis.

Under company law the Directors must not approve the financial statements unless they are satisfied that they give a true and fair view of the state of affairs of the Group and parent Company and of their profit or loss for that period. In preparing each of the Group and parent Company financial statements, the Directors are required to:

- select suitable accounting policies and then apply them consistently;
- make judgements and estimates that are reasonable, relevant and reliable;
- state whether they have been prepared in accordance with IFRSs as adopted by the EU;
- assess the Group and parent Company’s ability to continue as a going concern, disclosing, as applicable, matters related to going concern; and
- use the going concern basis of accounting unless they either intend to liquidate the Group or the parent Company or to cease operations, or have no realistic alternative but to do so.

The Directors are responsible for keeping adequate accounting records that are sufficient to show and explain the parent Company’s transactions and disclose with reasonable accuracy at any time the financial position of the parent Company and enable them to ensure that its financial statements comply with the Companies Act 2006. They are responsible for such internal control as they determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error, and have general responsibility for taking such steps as are reasonably open to them to safeguard the assets of the Group and to prevent and detect fraud and other irregularities.

Under applicable law and regulations, the Directors are also responsible for preparing a Strategic Report, Directors’ Report, Directors’ Remuneration Report and Corporate Governance Statement that complies with that law and those regulations.

The Directors are responsible for the maintenance and integrity of the corporate and financial information included on the Group’s website. Legislation in the UK governing the preparation and dissemination of financial statements may differ from legislation in other jurisdictions.

Responsibility statement of the Directors in respect of the annual financial report

We confirm that to the best of our knowledge:

- the financial statements, prepared in accordance with the applicable set of accounting standards, give a true and fair view of the assets, liabilities, financial position and profit or loss of the Company and the undertakings included in the consolidation taken as a whole; and
- the Directors’ report includes a fair review of the development and performance of the business and the position of the issuer and the undertakings included in the consolidation taken as a whole, together with a description of the principal risks and uncertainties that they face.

We consider the annual report and accounts, taken as a whole, is fair, balanced and understandable and provides the information necessary for shareholders to assess the Group’s position and performance, business model and strategy.

Statement as to disclosure of information to auditors

In accordance with s418 of the Companies Act 2006, so far as each Director is aware, there is no relevant audit information of which the Group and Company’s auditors are unaware, and each Director has taken all the steps that he ought to have taken as a Director in order to make himself aware of any relevant audit information and to establish that the Group and Company’s auditors are aware of that information.

Independent auditors

During 2017 a tender process was completed with KPMG LLP being appointed as independent auditors. PricewaterhouseCoopers LLP continued in office until the release of the 2017 financial statements, after which KPMG LLP took up office.

Greenhouse gas emissions report

Details on greenhouse gas emissions are set out in the corporate social responsibility section on page 47.

Annual General Meeting

The Annual General Meeting will be held at 11:00 a.m. on Wednesday 29 May 2019 at the London offices of Covington & Burling LLP.

By order of the Board

Stuart Paynter

Company Secretary

14 March 2019

Company registered number: 03252665



Stuart Paynter was appointed a Director and Chief Financial Officer in August 2017

1. Our opinion is unmodified

We have audited the financial statements of Oxford Biomedica plc (“the Company”) for the year ended 31 December 2018 which comprise the consolidated statement of comprehensive income, the Group and parent Company balance sheets, the Group and parent Company statements of cash flows, the Group and parent Company statements of changes in equity attributable to owners of the parent, and the related notes, including the accounting policies in note 1.

In our opinion:

- the financial statements give a true and fair view of the state of the Group’s and of the parent Company’s affairs as at 31 December 2018 and of the Group’s profit for the year then ended;
- the Group financial statements have been properly prepared in accordance with International Financial Reporting Standards as adopted by the European Union (IFRSs as adopted by the EU);
- the parent Company financial statements have been properly prepared in accordance with IFRSs as adopted by the EU and as applied in accordance with the provisions of the Companies Act 2006; and
- the financial statements have been prepared in accordance with the requirements of the Companies Act 2006 and, as regards the Group financial statements, Article 4 of the IAS Regulation.

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (UK) (“ISAs (UK)”) and applicable law. Our responsibilities are described below. We believe that the audit evidence we have obtained is a sufficient and appropriate basis for our opinion. Our audit opinion is consistent with our report to the audit committee.

We were first appointed as auditor by the shareholders on 29 May 2018. The period of total uninterrupted engagement is for the financial year ended 31 December 2018. We have fulfilled our ethical responsibilities under, and we remain independent of the Group in accordance with, UK ethical requirements including the FRC Ethical Standard as applied to listed public interest entities. No non-audit services prohibited by that standard were provided.

Overview

- **Materiality:** Group financial statements as a whole: £570k, 0.85% of revenue.
- **Coverage:** 100.0% of Group revenue.
- **Key audit matters (recurring risks):**
  1. Revenue recognition.
  2. Recoverability of parent Company’s investment in and debt due from subsidiaries.

2. Key audit matters: including our assessment of risks of material misstatement

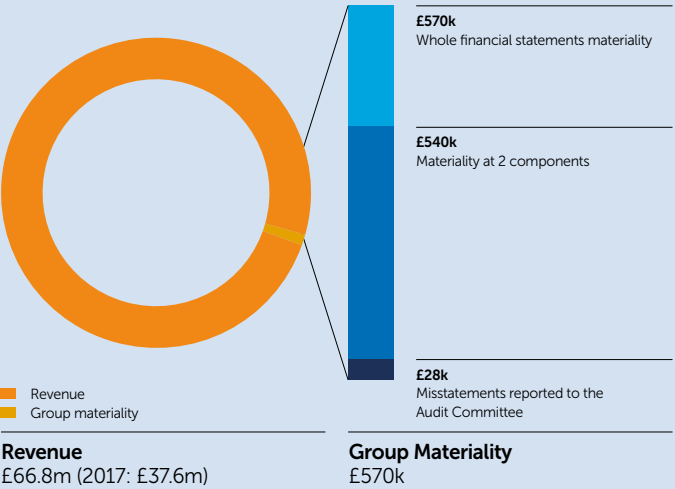
Key audit matters are those matters that, in our professional judgment, were of most significance in the audit of the financial statements and include the most significant assessed risks of material misstatement (whether or not due to fraud) identified by us, including those which had the greatest effect on: the overall audit strategy; the allocation of resources in the audit; and directing the efforts of the engagement team. We summarise below the key audit matters, in arriving at our audit opinion above, together with our key audit procedures to address those matters and, as required for public interest entities, our results from those procedures. These matters were addressed, and our results are based on procedures undertaken, in the context of, and solely for the purpose of, our audit of the financial statements as a whole, and in forming our opinion thereon, and consequently are incidental to that opinion, and we do not provide a separate opinion on these matters.

	The risk	Our response
<b>Revenue</b> Product and technology licenses, milestone receivables and payments and process development. <i>Refer to page 110 (accounting policy) and page 117 (critical accounting judgement).</i>	<b>Accounting treatment</b>  The Company enters into a number of multiple element contracts with differing terms. There are inherent judgements required to be made by the Group in the following areas: <ul style="list-style-type: none"><li>— Identification of performance obligations of the contract, primarily the license fees, milestones and commercial development work,</li><li>— Assessing the allocation of the total transaction price to each performance obligation with reference to their stand-alone selling price, including consideration of FTE rates applied, and</li><li>— Whether revenue for each performance obligation satisfies the criteria for recognition over time or at a point in time.</li></ul>	Our procedures included: <ul style="list-style-type: none"><li>— <b>Accounting analysis:</b> Evaluation of the Group’s revenue accounting policy against the accounting standard.</li><li>— <b>Testing application:</b> Assessing and challenging the Group’s judgements made, in line with accounting policies and with reference to significant contracts, including:<ul style="list-style-type: none"><li>— The identification of the goods or services promised in the contract and whether they are distinct and therefore separate performance obligations,</li><li>— The stand-alone selling prices of individual components through benchmarking across the Group’s other customer contracts, and</li><li>— The revenue recognition over time or point in time with reference to the contract terms, nature of goods and services being provided and Group’s accounting policy.</li></ul></li><li>— <b>Assessing transparency:</b> Assessing the adequacy of the Group’s disclosures about the judgements involved in the recognition of revenue.</li></ul> <b>Our results:</b> We found the Group’s revenue recognition and related disclosures of the judgements to be acceptable.
<b>Investments and loans</b> (£91.8 million). <i>Refer to page 115 (accounting policy) and page 129 (financial disclosures).</i>	<b>Recoverability of parent Company’s investment in and debt due from subsidiaries:</b>  Low risk, high value.  The carrying amount of the parent Company’s investment and loan in the sole trading subsidiary represents 98.8% of the Company’s total assets. Their recoverability is not at a high risk of significant misstatement or subject to significant judgement. However, due to their materiality in the context of the parent Company financial statements, this is considered to be the area that had the greatest effect on our overall parent Company audit.	Our procedures included: <ul style="list-style-type: none"><li>— <b>Comparing valuations:</b> Comparing the carrying amount of the investment and loans with the expected value of the business based on the market capitalisation of the Group.</li></ul> <b>Our results:</b> We found the Group’s assessment of the recoverability of the investment in and loan to subsidiaries to be acceptable.



3. Our application of materiality and an overview of the scope of our audit

Materiality for the Group financial statements as a whole was set at £570k, determined with reference to a benchmark of revenue (of which it represents 0.85%. We consider total revenue to be the most appropriate benchmark as it provides a more stable measure year on year than group profit before tax. Materiality for the parent Company financial statements as a whole was set at £540k, determined with reference to a benchmark of Company total assets, of which it represents 0.6%. We agreed to report to the Audit Committee any corrected or uncorrected identified misstatements exceeding £28k, in addition to other identified misstatements that warranted reporting on qualitative grounds. Of the group’s 3 components, we subjected 2 to full scope audits for group purposes. The components within the scope of our work accounted for 100% of group revenue, profit before tax and total assets. The Group team approved the component materialities, which were set at £540k for both inscope components. The work on all of the components, including the audit of the parent Company, was performed by the Group team.



4. We have nothing to report on going concern

The Directors have prepared the financial statements on the going concern basis as they do not intend to liquidate the Company or the Group or to cease their operations, and as they have concluded that the Company’s and the Group’s financial position means that this is realistic. They have also concluded that there are no material uncertainties that could have cast significant doubt over their ability to continue as a going concern for at least a year from the date of approval of the financial statements (“the going concern period”).

Our responsibility is to conclude on the appropriateness of the Directors’ conclusions and, had there been a material uncertainty related to going concern, to make reference to that in this audit report. However, as we cannot predict all future events or conditions and as subsequent events may result in outcomes that are inconsistent with judgements that were reasonable at the time they were made, the absence of reference to a material uncertainty in this auditor’s report is not a guarantee that the Group and the Company will continue in operation.

In our evaluation of the Directors’ conclusions, we considered the inherent risks to the Group’s and Company’s business model, including the impact of Brexit, and analysed how those risks might affect the Group’s and Company’s financial resources or ability to continue operations over the going concern period. The risks that we considered most likely to adversely affect the Company’s available financial resources over this period were:

- The reliance on future receipts from both current and new customers,
- Capital expenditure commitments, and
- Current covenant compliance and the ability to refinance.

As these were risks that could potentially cast significant doubt on the Company’s ability to continue as a going concern, we considered sensitivities over the level of available financial resources indicated by the Company’s financial forecasts taking account of reasonably possible (but not unrealistic) adverse effects that could arise from these risks individually and collectively and evaluated the achievability of the actions the Directors consider they would take to improve the position should the risks materialise. We also considered less predictable but realistic second order impacts, such as the impact of Brexit, which could result in a rapid reduction of available financial resources.

- Based on this work, we are required to report to you if:
- we have anything material to add or draw attention to in relation to the Directors’ statement in note 1 to the financial statements on the use of the going concern basis of accounting with no material uncertainties that may cast significant doubt over the Group and Company’s use of that basis for a period of at least twelve months from the date of approval of the financial statements; or
  - the related statement under the Listing Rules set out on page 92 is materially inconsistent with our audit knowledge.

We have nothing to report in these respects, and we did not identify going concern as a key audit matter.

5. We have nothing to report on the other information in the Annual report

The Directors are responsible for the other information presented in the Annual report together with the financial statements. Our opinion on the financial statements does not cover the other information and, accordingly, we do not express an audit opinion or, except as explicitly stated below, any form of assurance conclusion thereon. Our responsibility is to read the other information and, in doing so, consider whether, based on our financial statements audit work, the information therein is materially misstated or inconsistent with the financial statements or our audit knowledge. Based solely on that work we have not identified material misstatements in the other information.

Strategic report and Directors’ report

- Based solely on our work on the other information:
- we have not identified material misstatements in the strategic report and the Directors’ report;
  - in our opinion the information given in those reports for the financial year is consistent with the financial statements; and
  - in our opinion those reports have been prepared in accordance with the Companies Act 2006.

Directors’ remuneration report

In our opinion the part of the Directors’ Remuneration Report to be audited has been properly prepared in accordance with the Companies Act 2006.

Disclosures of principal risks and longer-term viability

- Based on the knowledge we acquired during our financial statements audit, we have nothing material to add or draw attention to in relation to:
- the Directors’ confirmation within the viability statement on page 93 that they have carried out a robust assessment of the principal risks facing the Group, including those that would threaten its business model, future performance, solvency and liquidity;
  - the Principal risks facing the business disclosures describing these risks and explaining how they are being managed and mitigated; and
  - the Directors’ explanation in the viability statement of how they have assessed the prospects of the Group, over what period they have done so and why they considered that period to be appropriate, and their statement as to whether they have a reasonable expectation that the Group will be able to continue in operation and meet its liabilities as they fall due over the period of their assessment, including any related disclosures drawing attention to any necessary qualifications or assumptions.

Under the Listing Rules we are required to review the viability statement. We have nothing to report in this respect.

Our work is limited to assessing these matters in the context of only the knowledge acquired during our financial statements audit. As we cannot predict all future events or conditions and as subsequent events may result in outcomes that are inconsistent with judgments that were reasonable at the time they were made, the absence of anything to report on these statements is not a guarantee as to the Group’s and Company’s longer-term viability.

Corporate governance disclosures

We are required to report to you if:

- we have identified material inconsistencies between the knowledge we acquired during our financial statements audit and the Directors’ statement that they consider that the annual report and financial statements taken as a whole is fair, balanced and understandable and provides the information necessary for shareholders to assess the Group’s position and performance, business model and strategy; or
- the section of the annual report describing the work of the Audit Committee does not appropriately address matters communicated by us to the Audit Committee. We are required to report to you if the Corporate Governance Statement does not properly disclose a departure from the eleven provisions of the UK Corporate Governance Code specified by the Listing Rules for our review.

We have nothing to report in these respects.

6. We have nothing to report on the other matters on which we are required to report by exception

Under the Companies Act 2006, we are required to report to you if, in our opinion:

- adequate accounting records have not been kept by the parent Company, or returns adequate for our audit have not been received from branches not visited by us; or
- the parent Company financial statements and the part of the Directors’ Remuneration Report to be audited are not in agreement with the accounting records and returns; or
- certain disclosures of Directors’ remuneration specified by law are not made; or
- we have not received all the information and explanations we require for our audit.

We have nothing to report in these respects.

7. Respective responsibilities

Directors’ responsibilities

As explained more fully in their statement set out on page 94, the Directors are responsible for: the preparation of the financial statements including being satisfied that they give a true and fair view; such internal control as they determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error; assessing the Group and parent Company’s ability to continue as a going concern, disclosing, as applicable, matters related to going concern; and using the going concern basis of accounting unless they either intend to liquidate the Group or the parent Company or to cease operations, or have no realistic alternative but to do so.

Auditor’s responsibilities

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or other irregularities (see below), or error, and to issue our opinion in an auditor’s report. Reasonable assurance is a high level of assurance, but does not guarantee that an audit conducted in accordance with ISAs (UK) will always detect a material misstatement when it exists. Misstatements can arise from fraud, other irregularities or error and are considered material if, individually or in aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the financial statements.

A fuller description of our responsibilities is provided on the FRC’s website at [www.frc.org.uk/auditorsresponsibilities](http://www.frc.org.uk/auditorsresponsibilities).

Irregularities – ability to detect

We identified areas of laws and regulations that could reasonably be expected to have a material effect on the financial statements from our general commercial and sector experience and through discussion with the Directors and other management (as required by auditing standards), and discussed with the Directors and other management the policies and procedures regarding compliance with laws and regulations. We communicated identified laws and regulations throughout our team and remained alert to any indications of non-compliance throughout the audit.

The potential effect of these laws and regulations on the financial statements varies considerably.

Firstly, the group is subject to laws and regulations that directly affect the financial statements including financial reporting legislation (including related companies legislation), distributable profits legislation and taxation legislation.

We assessed the extent of compliance with these laws and regulations as part of our procedures on the related financial statement items.

Secondly, the group is subject to many other laws and regulations where the consequences of non-compliance could have a material effect on amounts or disclosures in the financial statements, for instance through the imposition of fines or litigation or the loss of the group’s licence to operate. We identified the following areas as those most likely to have such an effect: those related to the pharmaceutical industry imposed by the Food and Drug Administration (FDA) and Medicines and Healthcare products Regulatory Agency (MHRA) recognising the regulated nature of the Group’s activities. Auditing standards limit the required audit procedures to identify non-compliance with these laws and regulations to enquiry of the Directors and other management and inspection of regulatory and legal correspondence, if any.

These limited procedures did not identify actual or suspected non-compliance.

Owing to the inherent limitations of an audit, there is an unavoidable risk that we may not have detected some material misstatements in the financial statements, even though we have properly planned and performed our audit in accordance with auditing standards. For example, the further removed non-compliance with laws and regulations (irregularities) is from the events and transactions reflected in the financial statements, the less likely the inherently limited procedures required by auditing standards would identify it. In addition, as with any audit, there remained a higher risk of non-detection of irregularities, as these may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal controls. We are not responsible for preventing non-compliance and cannot be expected to detect non-compliance with all laws and regulations.

8. The purpose of our audit work and to whom we owe our responsibilities

This report is made solely to the Company’s members, as a body, in accordance with Chapter 3 of Part 16 of the Companies Act 2006. Our audit work has been undertaken so that we might state to the Company’s members those matters we are required to state to them in an auditor’s report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the Company and the Company’s members, as a body, for our audit work, for this report, or for the opinions we have formed.

Charles le Strange Meakin (Senior Statutory Auditor)  
for and on behalf of KPMG LLP, Statutory Auditor

Chartered Accountants

Botanic House  
98-100 Hills Rd  
Cambridge  
CB2 1JZ

14 March 2019





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Group financial statements  
**Consolidated statement of comprehensive income**

for the year ended 31 December 2018

		2018	2017
Continuing operations	Note	£'000	£'000
Revenue	4	66,778	37,590
Cost of sales		(22,763)	(18,442)
Gross profit		44,015	19,148
Research, development and bioprocessing costs		(29,714)	(21,611)
Administrative expenses		(7,433)	(7,276)
Other operating income	4	1,064	1,774
Revaluation of investments	13	5,983	2,297
Operating profit/(loss)	4	13,915	(5,668)
Finance income	6	71	38
Finance costs	6	(8,972)	(6,131)
Profit/(loss) before tax		5,014	(11,761)
Taxation	8	2,527	2,744
Profit/(loss) and total comprehensive income/(expense) for the year	27	7,541	(9,017)
Basic earnings/(loss) per ordinary share	9	11.57p	(14.50p)
Diluted earnings/(loss) per ordinary share	9	10.89p	(14.50p)

There was no other comprehensive income or loss in either year.

The loss for the year is attributable to the owners of the parent.

Group financial statements  
**Balance sheets**

as at 31 December 2018

		Group		Company	
	Note	2018	2017	2018	2017
		£'000	£'000	£'000	£'000
<b>Assets</b>					
<b>Non-current assets</b>					
Intangible assets	11	117	97	–	–
Property, plant and equipment	12	31,791	25,370	–	–
Investments and loans	13	10,966	2,954	91,786	72,350
Deferred tax assets	22	–	–	1,129	–
		42,874	28,421	92,915	72,350
<b>Current assets</b>					
Inventories	14	4,251	3,332	–	–
Trade and other receivables	15	30,585	17,088	–	9
Current tax assets	8	2,446	2,232	–	–
Cash and cash equivalents	16	32,244	14,329	11	31
		69,526	36,981	11	40
<b>Current liabilities</b>					
Trade and other payables	17	11,422	8,690	164	81
Contract liabilities and deferred income	18	17,084	13,072	–	–
		28,506	21,762	164	81
Net current assets/(liabilities)		41,020	15,219	( 153 )	(41)
<b>Non-current liabilities</b>					
Loans	19	41,153	36,864	–	–
Provisions	20	1,287	630	–	–
Contract liabilities and deferred income	18	6,434	–	–	–
Deferred tax liability	22	279	–	–	–
		49,153	37,494	–	–
Net assets		34,741	6,146	92,762	72,309
<b>Equity attributable to owners of the parent</b>					
Ordinary share capital	23	33,034	31,076	33,034	31,076
Share premium account	24	172,074	154,224	172,074	154,224
Other reserves	28	3,509	3,509	10,731	9,599
Accumulated losses	27	(173,876)	(182,663)	( 123,077 )	(122,590)
Total equity		34,741	6,146	92,762	72,309

The Company’s registered number is 03252665.

The Company made a loss for the year of £446,000 (2017: £1,207,000).

The financial statements on pages 108 to 144 were approved by the Board of Directors on 14 March 2019 and were signed on its behalf by:

**John Dawson**  
Chief Executive Officer



## Group financial statements

### Statements of cash flows

for the year ended 31 December 2018

		Group		Company	
		2018	2017	2018	2017
	Note	£'000	£'000	£'000	£'000
<b>Cash flows from operating activities</b>					
Cash generated from/(used in) operations	29	9,214	(1,533)	(1,483)	(1,308)
Tax credit received		3,654	4,530	–	–
Overseas tax paid		–	(18)	–	–
Net cash generated from/(used in) operating activities		12,868	2,979	(1,483)	(1,308)
<b>Cash flows from investing activities</b>					
Loan to subsidiary		–	–	(18,304)	(4,575)
Purchases of property, plant and equipment	12	(10,103)	(1,969)	–	–
Purchases of intangible assets	11	(45)	–	–	–
Interest received		52	38	–	–
Net cash used in investing activities		(10,096)	(1,931)	(18,304)	(4,575)
<b>Cash flows from financing activities</b>					
Proceeds from issue of ordinary share capital	23, 24	21,184	385	21,143	385
Costs of share issues	24	(1,376)	–	(1,376)	–
Interest paid		(4,665)	(10,800)	–	–
Loans received	19	–	38,897	–	–
Loans repaid		–	(30,536)	–	–
Net cash generated from/(used in) financing activities		15,143	(2,054)	19,767	385
<b>Net increase/(decrease) in cash and cash equivalents</b>					
		17,915	(1,006)	(20)	(5,498)
Cash and cash equivalents at 1 January		14,329	15,335	31	5,529
<b>Cash and cash equivalents at 31 December</b>	16	<b>32,244</b>	<b>14,329</b>	<b>11</b>	<b>31</b>

## Group financial statements

### Statements of changes in equity attributable to owners of the parent

for the year ended 31 December 2018

Group	Notes	Ordinary shares £'000	Share premium account £'000	Reserves			Accumulated losses £'000	Total equity £'000
				Merger £'000	Treasury £'000	Warrant £'000		
At 1 January 2017		30,879	154,036	2,291	(102)	–	(174,489)	12,615
Year ended 31 December 2017:								
Loss for the year		–	–	–	–	–	(9,017)	(9,017)
Total comprehensive expense for the year		–	–	–	–	–	(9,017)	(9,017)
Transactions with owners:								
Share options								
Proceeds from shares issued	23, 24	197	188	–	–	–	–	385
Value of employee services	27	–	–	–	–	–	945	945
Issue of warrants	28	–	–	–	–	1,218	–	1,218
Vesting of deferred share award	27	–	–	–	102	–	(102)	–
<b>At 31 December 2017</b>		<b>31,076</b>	<b>154,224</b>	<b>2,291</b>	<b>–</b>	<b>1,218</b>	<b>(182,663)</b>	<b>6,146</b>

#### Year ended 31 December 2018:

<b>Income for the year</b>		–	–	–	–	–	7,541	7,541
<b>Total comprehensive income for the year</b>		–	–	–	–	–	7,541	7,541
Transactions with owners:								
Share options								
Proceeds from shares issued	23, 24	246	478	–	–	–	–	724
Value of employee services	27	–	–	–	–	–	1,246	1,246
<b>Issue of shares excluding options</b>	28	<b>1,712</b>	<b>18,748</b>	–	–	–	–	<b>20,460</b>
<b>Cost of share issues</b>	24	<b>–</b>	<b>(1,376)</b>	–	–	–	–	<b>(1,376)</b>
<b>At 31 December 2018</b>		<b>33,034</b>	<b>172,074</b>	<b>2,291</b>	<b>–</b>	<b>1,218</b>	<b>(173,876)</b>	<b>34,741</b>

Company	Notes	Ordinary shares £'000	Share premium account £'000	Reserves			Accumulated losses £'000	Total equity £'000
				Merger £'000	Warrant £'000	Other £'000		
At 1 January 2017		30,875	154,036	1,580	–	6,052	(121,383)	71,164
Year ended 31 December 2017:								
Loss for the year		–	–	–	–	–	(1,207)	(1,207)
Total comprehensive expense for the year	10	–	–	–	–	–	(1,207)	(1,207)
Transactions with owners:								
Share options								
Proceeds from shares issued	23, 24	197	188	–	–	–	–	385
Credit in relation to employee share schemes	26, 28	–	–	–	–	749	–	749
Issue of warrants	23, 24	–	–	–	1,218	–	–	1,218
<b>At 31 December 2017</b>		<b>31,076</b>	<b>154,224</b>	<b>1,580</b>	<b>1,218</b>	<b>6,801</b>	<b>(122,590)</b>	<b>72,309</b>

#### Year ended 31 December 2018:

<b>Loss for the year</b>		–	–	–	–	–	(446)	(446)
<b>Total comprehensive expense for the year</b>	10	–	–	–	–	–	(446)	(446)
Share options								
Proceeds from shares issued	23, 24	246	478	–	–	–	–	724
Credit in relation to employee share schemes	26, 28	–	–	–	–	1,132	(41)	1,091
<b>Issue of shares excluding options</b>	28	<b>1,712</b>	<b>18,748</b>	–	–	–	–	<b>20,460</b>
<b>Cost of share issues</b>	24	<b>–</b>	<b>(1,376)</b>	–	–	–	–	<b>(1,376)</b>
<b>At 31 December 2018</b>		<b>33,034</b>	<b>172,074</b>	<b>1,580</b>	<b>1,218</b>	<b>7,933</b>	<b>(123,077)</b>	<b>92,762</b>

**1. Accounting policies**

Oxford Biomedica plc (the Company) is a public company limited by shares, incorporated and domiciled in England, and listed on the London Stock Exchange. The consolidated financial statements for the year ended 31 December 2018 comprise the results of the Company and its subsidiary undertakings (together referred to as the Group).

The Company’s principal subsidiary is Oxford Biomedica (UK) Limited.

The Group is a gene and cell therapy research and development business which is also building a revenue-generating business providing bioprocessing and process development services to third parties. The Group currently has no marketed pharmaceutical products.

**Basis of preparation**

The principal accounting policies adopted in the preparation of these financial statements are set out below. These policies have been consistently applied to all the financial years presented, unless otherwise stated.

The financial statements have been prepared in accordance with International Financial Reporting Standards (‘IFRS’) and IFRS Interpretations Committee (‘IFRS IC’) interpretations as adopted by the European Union and with the Companies Act 2006 as applicable to companies reporting under IFRS. The financial statements have been prepared under the historic cost convention as modified by the revaluation of financial assets at fair value through profit and loss.

As more fully explained in the Directors’ report on pages 90 to 95 and below, the going concern basis has been adopted in preparing the financial statements.

A summary of the more important Group accounting policies are set out below.

The preparation of the financial statements in conformity with IFRS requires the use of certain critical accounting estimates. It also requires management to exercise its judgement in the process of applying the Group’s accounting policies. The areas involving a higher degree of judgement or complexity, or where assumptions and estimates are significant to the financial statements, are disclosed in note 2.

**Going concern**

The Group held £32.2 million of cash at the end of 2018. During 2018 the Group generated positive operational cash flows, and although the Group is making a further strategic investment in extending our bioprocessing capacity, the Group expects to generate sufficient operational cash flow to continue its growth strategy. Taking this into account, in conjunction with currently known and probable cash flows, the Directors consider that the Group has sufficient cash resources and cash inflows to continue its activities for at least twelve months from the date of these financial statements and have therefore prepared the financial statements on a going concern basis.

Although the UK’s decision to leave the European Union may significantly affect the fiscal, monetary and regulatory landscape in the UK,the Group has assessed the future impact of Brexit on its operations to be minor. Further details of our contingency planning is provided on page 58.

**Accounting developments**

The Group has adopted the following IFRSs in these financial statements.

- IFRIC 22 Foreign Currency Transactions and Advance Consideration (non material impact).
- IFRS 9 Financial Instruments (non material impact).
- Amendments to IFRS 2: Classification and Measurement of Share-based Payment Transactions Contracts (non material impact).
- IFRS 15 Revenue from Contracts with Customers (note 2).

The following new IFRSs have been endorsed but are not yet effective:

- IFRS 16 Leases (note 1).
- IFRIC 23 Uncertainty over Income Tax Treatments.
- Amendments to IFRS 9 Financial Instruments.

Standards issued but not yet effective

A number of new standards are effective for the annual period beginning after 1 January 2019 and earlier application is permitted; however the Group has not early adopted the new or amended standards in preparing these consolidated financial statements.

Of those standards that are not yet effective, IFRS 16 is expected to have a material impact on the Group financial statements in the period of initial application.

IFRS 16 ‘Leases’

The Group is required to adopt IFRS 16 ‘Leases’ from 1 January 2019. The Group has assessed the estimated impact that initial application of IFRS 16 will have on its consolidated financial statements, as described below. The actual impacts of adopting the standard on 1 January 2019 may change because the new accounting policies are subject to change until the Group presents its first financial statements that include the date of initial application.

IFRS 16 introduces a single, on-balance sheet lease accounting model for lessees. A lessee recognises a right-of-use asset representing its right to use the underlying asset and a lease liability representing it obligation to make lease payments. There are recognition exemptions for the short-term leases and low-value items. Lessor accounting remains similar to the current standard – i.e. lessors continue to classify leases as either a finance or operating lease.

IFRS 16 replaces existing leases guidance, including IAS 17 ‘Leases’, IFRIC 4 ‘Determining whether an Arrangement contains a Lease’, SIC-15 ‘Operating Leases – Incentives’ and SIC-27 ‘Evaluating the Substance of Transactions involving the Legal Form of a Lease’.

*Leases in which the Group is a Lessee*

The Group will recognise new assets and liabilities for its operating leases of laboratory office facilities and equipment (see note 31). The nature of expenses related to those leases will now change because the Group will recognise a depreciation charge for right-of-use assets and interest expense on lease liabilities.

Previously, the Group recognised operating lease expenses on a straight-line basis over the term of the lease, and recognised assets and liabilities only to the extent that there was a timing difference between actual lease payments and the expense recognised.

Based on information currently available, the Group estimates that it will recognise additional lease liabilities of £10,057,760 and right of use assets of £9,820,408 with a retained earnings impact of £237,352 at 1 January 2019.



Transition

The Group plans to apply IFRS 16 initially on 1 January 2019, using the modified retrospective approach. Therefore, the cumulative effect of adopting IFRS 16 will be recognised as an adjustment to the opening balance of retained earnings at 1 January 2019, with no restatement of comparative information.

The Group plans to apply the practical expedients to grandfather the definition of a lease on transition. This means that it will apply IFRS 16 to all contracts entered into before 1 January 2019 and identified as leases in accordance with IAS 17 and IFRIC 4.

Basis of consolidation

The consolidated financial statements comprise the Company and its subsidiary undertakings for the year to 31 December each year. Subsidiaries are entities that are directly or indirectly controlled by the Group. Subsidiaries are consolidated from the date at which control is transferred to the Group. Control exists where the Group has the power to govern the financial and operating policies of the entity so as to obtain benefits from its activities. The Group does not currently have any associates.

All intragroup transactions and balances are eliminated on consolidation.

Business combinations are accounted for using the acquisition method. The cost of an acquisition is measured as the fair value of the assets transferred, equity instruments issued, and liabilities incurred or assumed at the date of exchange.

Identifiable assets acquired, and liabilities and contingent liabilities assumed in a business combination are measured initially at their fair values at the acquisition date, irrespective of the extent of any minority interest. Any excess of the cost of the acquisition over the fair value of the Group’s share of the identifiable net assets acquired is recorded as goodwill. If the cost of acquisition is less than the fair value of the net assets of the subsidiary acquired, the difference is recognised directly in the statement of comprehensive income. Where necessary, adjustments are made to the financial statements of subsidiaries to bring accounting policies used into line with those of the Group.

The Group and Company have elected not to apply IFRS 3 ‘Business combinations’ retrospectively to business combinations which took place prior to 1 January 2004, namely the acquisition in 1996 of 100% of the issued share capital of Oxford Biomedica (UK) Limited that has been accounted for by the merger accounting method.

Foreign currencies

Transactions in foreign currencies are translated into sterling at the rate of exchange ruling at the transaction date. Assets and liabilities in foreign currencies are retranslated into sterling at the rates of exchange ruling at the balance sheet date. Differences arising due to exchange rate fluctuations are taken to the statement of comprehensive income in the period in which they arise.

Revenue

Revenue comprises income derived from bioprocessing of clinical product for partners, fees charged for providing development services to partners, product and technology licence transactions, royalties, options, and funded research and development programmes.

Platform

Bioprocessing of clinical/commercial product for partners is recognised on a percentage of completion basis over time as the processes are carried out. Progress is determined based on the achievement of verifiable stages of the process. The gross amount due from customers on all partnerships in progress for which costs incurred plus recognised profits exceed progress billings is presented as a contract asset separately on the balance sheet. Consideration received in excess of the stage of completion will be deferred until such time as it is appropriate to recognise the revenue.

Revenues for providing process development activities to partners are recognised during the period in which the service is rendered on a percentage of completion basis.

Technology licences that have been established by the group have all been determined as “right to use” licences, rather than “right to access” licences. As such, the revenue from these licences is recognised at the point in time at which the licence transfers to the customer.

Milestones relating to bioprocessing or process development activities have been identified as separate performance obligations as they involve the transfer of a distinct good or service, determined with reference to conditions stipulated in the relevant agreements or contracts. Each milestone is determined as either binary or non-binary.

Milestones that are considered to be binary relate to the achievement of specific events rather than the provision of, for example, support. Incentives related to the achievement of specific deliverables are considered to be binary incentives and will be recognised in full once it is deemed highly probable that the obligation will be met.

Milestones related to the provision of support services are considered to be non-binary incentives and are recognised on a percentage of completion basis, but taking into account the likelihood of achievement of the deliverable. Amounts receivable on delivery of a milestone performance obligation represents variable consideration and have been allocated to the relevant performance obligation.

Options to technology licences are recognised when the customer exercises the option to obtain that licence.

Non-cash revenues are recognised at fair value through profit and loss.

Product

Product licences that have been established by the Group have all been determined as “right to use” licences, rather than “right to access” licences. As such, the revenue from these licences is recognised at the point in time at which the licence transfers to the customer.

Amounts receivable in respect of milestone payments are considered to be separate performance obligations which are binary and will be recognised in full once it is deemed highly probable that the specific performance obligations stipulated in the licence agreement have been met. Payments linked to “success” such as regulatory filing or approval, or achievement of specified sales volumes, are recognised in full when the relevant event has occurred.

Non-binary milestones are recognised on a percentage of completion basis in the period in which related costs are incurred, or over the estimated period to completion of the relevant phase of development or associated clinical trials. Amounts receivable on delivery of a milestone performance obligation represents variable consideration and have been allocated to the relevant performance obligation.

Royalty revenue is recognised as the underlying sales occur.

Research and development revenue and associated costs are recognised over time. Progress is determined based on the cost-to-cost method.

Cost of sales

Cost of sales comprises the cost of bioprocessing clinical product for partners and royalties arising on partners’ licences.

The cost of bioprocessing clinical product for partners includes the raw materials, labour costs, overheads and other directly attributable costs. Costs are recognised on a percentage of completion basis dependent on the stage of completion of the contract. Costs incurred in excess of the stage of completion are recognised as work in progress until such time as it is appropriate to recognise the cost.

The Group’s products and technologies include technology elements that are licensed from third parties. Royalties arising from such partners’ licences are treated as cost of sales. Where royalties due have not been paid they are included in accruals. Where revenue is spread over a number of accounting periods, the royalty attributable to the deferred revenue is included in prepayments.

**Research, development and bioprocessing**

Research, development and bioprocessing expenditure is charged to the statement of comprehensive income in the period in which it is incurred.

Expenditure incurred on development projects is recognised as an intangible asset when it is probable that the project will generate future economic benefits, considering factors including its commercial and technological feasibility, status of regulatory approval, and the ability to measure costs reliably. Development expenditure which has been capitalised and has a finite useful life is amortised from the commencement of the commercial production of the product on a straight-line basis over the period of its expected benefit. No such costs have been capitalised to date as there was insufficient certainty about the recognition criteria having been met at the point the expenditure had been incurred. Other development expenditure is recognised as an expense when incurred.

**Employee benefit costs**

Employee benefit costs, notably holiday pay and contributions to the Group’s defined contribution pension plan, are charged to the statement of comprehensive income on an accruals basis. The assets of the pension scheme are held separately from those of the Group in independently administered funds. The Group does not offer any other post-retirement benefits.

**Share based payments**

The Group’s employee share option schemes, long term incentive plans, save as you earn scheme and deferred bonus plans allow group employees to acquire shares of the Company subject to certain criteria. The fair value of options granted is recognised as an expense of employment in the statement of comprehensive income with a corresponding increase in equity. The fair value is measured at the date of grant and spread over the period during which the employees become unconditionally entitled to the options. The fair value of options granted under the share option schemes and share save scheme is measured using the Black-Scholes model. The fair value of options granted under the LTIP schemes, which includes market condition performance criteria, is measured using a Monte Carlo model taking into account the performance conditions under which the options were granted. The fair value of options granted under the deferred bonus plan is based on the market value at the date of grant of these options.

At each financial year end, the Group revises its estimate of the number of options that are expected to become exercisable based on forfeiture such that at the end of the vesting period the cumulative charge reflects the actual options that have vested, with no charge for those options which were forfeit prior to vesting. When share options are exercised the proceeds received are credited to equity.

**Leases**

Leases are classified as finance leases whenever the terms of the lease transfer substantially all the risks and rewards of ownership to the lessee. No leases have been classified as finance leases. All other leases are classified as operating leases. Costs in respect of operating leases are charged to the statement of comprehensive income on a straight-line basis over the lease term.

**Grants**

Income from government and other grants is recognised over the period necessary to match them with the related costs which they are intended to compensate. Grant income is included as other operating income within the statement of comprehensive income, and the related costs are included within research, development and bioprocessing costs, and administrative expenses. Where grant income received exceeds grant income recognised, it is included within deferred income on the balance sheet, whilst where grant income recognised exceeds grant income received, it is included within other receivables on the balance sheet.

**Revaluation of equity instruments**

Gains and losses on the revaluation of equity instruments are recognised at fair value in the statement of comprehensive income.

**Finance income and costs**

Finance income and costs comprise interest income and interest payable during the year, calculated using the effective interest rate method. It also includes the revaluation of external loans denominated in a foreign currency.

**Taxation**

The Group is entitled to claim tax credits in the United Kingdom for certain research and development expenditure. The credit is paid in arrears once tax returns have been filed and agreed. The tax credit earned in the period, based on an assessment of likely receipt, is recognised in the statement of comprehensive income with the corresponding asset included within current assets in the balance sheet until such time as it is received.

The Group also receives a Research and Development Expenditure Credit (‘RDEC’) which is accounted for as a reduction in research, development and bioprocessing costs in the statement of comprehensive income, and within trade and other receivables in the balance sheet.

Current tax, including UK corporation tax and foreign tax, is provided at amounts expected to be paid (or recovered) using the tax rates and laws that have been enacted, or substantially enacted, by the balance sheet date.

Deferred tax is calculated in respect of all temporary differences identified at the balance sheet date. Temporary differences are differences between the carrying amount of the Group’s assets and liabilities and their tax base. Deferred tax liabilities may be offset against deferred tax assets within the same taxable entity or qualifying local tax group. Any remaining deferred tax asset is recognised only when, on the basis of all available evidence, it can be regarded as probable that there will be suitable taxable profits within the same jurisdiction in the foreseeable future against which the deductible temporary difference can be utilised.

Deferred tax is measured at the average tax rates that are expected to apply in the periods in which the asset is realised or liability settled, based on tax rates and laws that have been enacted or substantially enacted by the balance sheet date.

Measurement of deferred tax liabilities and assets reflects the tax consequence expected to fall from the manner in which the asset or liability is recovered or settled.



Intangible assets

Initial recognition

Intellectual property and in-process research and development acquired through business combinations are recognised as intangible assets at fair value. Other acquired intangible assets are initially recognised at cost.

Amortisation

Where the intangible asset has a finite life, amortisation is charged on a straight-line basis over the remaining useful economic life from the time they become available for use. Where the useful life of the intangible asset cannot be determined, the asset is carried at cost but tested annually for impairment. Intangible assets are amortised over the length of the patent life; current lives range from 5 to 19 years.

Impairment

The carrying value of non-financial assets is reviewed annually for impairment or earlier if an indication of impairment occurs and provision made where appropriate. Charges or credits for impairment are passed through the statement of comprehensive income.

For the purposes of assessing impairments, assets are grouped at the lowest levels for which there are separately identifiable cash flows or cash-generating units. Impairment losses are recognised for the amount by which each asset’s carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset’s fair value less costs to sell, and value in use. Where the asset is no longer being developed by the Group fair value less costs of disposal is used as the recoverable amount. Value in use is calculated using estimated discounted future cash flows. Key assumptions in the discounted cash flow calculations are whether:

- The product is developed by a collaborative partner who funds all future development costs and markets the product.
- The Group receives an initial licence fee, milestone payments and royalties on sales.
- The cash flow projections include estimates for selling price, royalty rates, population growth, disease incidence and market penetration.
- The resulting cash receipts are discounted at an appropriate discount rate.
- The cash flow projections are a long-term view, based on the expected patent life. Due to the length of the development cycle for innovative medicines, this period is significantly longer than five years.

The key assumptions are management estimates, based where possible on available information for similar products. Due to the novelty and early stage of development of the Group’s products, it is not possible to benchmark these assumptions against past experience.

Impairment and amortisation charges are included within research, development and bioprocessing costs in the statement of comprehensive income.

Intellectual property rights comprise third party patent rights that have been purchased by the Group. No in-house research and development or patent costs are included in intangible assets.

Property, plant and equipment

Property, plant and equipment are carried at cost, together with any incidental expenses of acquisition, less depreciation. Cost includes the original purchase price of the asset and any costs attributable to bringing the asset to its working condition for its intended use.

Depreciation is calculated to write off the cost of property, plant and equipment less their estimated residual values on a straight-line basis over the expected useful economic lives of the assets concerned. Depreciation of an asset begins when it is available for use. The principal annual rates used for this purpose are:

Freehold property	10%
Leasehold improvements	10% (or the remaining lease term if shorter)
Office equipment and computers	20 – 33%
Bioprocessing and laboratory equipment	20%

The assets’ residual values and useful lives are reviewed annually.

The bioprocessing plants are reviewed annually for impairment triggers and, where necessary, a full impairment review is performed.

Provisions for the anticipated cost of restoring the leasehold properties to their original condition are recognised as leasehold improvements within fixed assets.

Investments in subsidiaries

Investments are carried at cost less any provision made for impairment. Options over the Company’s shares have been awarded to employees of subsidiary companies. In accordance with IFRS2, the Company treats the value of these awards as a capital contribution to the subsidiaries, resulting in an increase in the cost of investment.

Investments in subsidiary undertakings, including shares and loans, are carried at cost less any impairment provision. Such investments are subject to review, and any impairment is charged to the statement of comprehensive income.

At each year end the Directors review the carrying value of the Company’s investment in subsidiaries. Where the review performed concludes that there is a material and sustained shortfall in the market capitalisation, or a significant and sustained change in the business resulting in a decrease in market capitalisation, the Directors consider this to be a trigger of an impairment review as set out in IAS 36, and the carrying value of the Company’s investments in subsidiaries is adjusted. The Directors consider that reference to the market capitalisation of the Group is an appropriate external measure of the value of the Company’s subsidiaries for this purpose.

At year end the Directors will assess the requirement to write back a portion or all of any impairment previously recognised on its investment in subsidiaries. Factors which will be taken into account with regards to this decision will be the Groups track record of improved financial results across the last three to four years, as well as the expectation of future impairments being required after a write back was accounted for.

Financial assets

Investments

Other investments held by the Group are classified as fair value through profit and loss.

Bank deposits

Bank deposits with original maturities between three months and twelve months are included in current assets and are classified as available for sale financial assets. After initial recognition, available for sale investments are measured at their fair value.

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**Inventories**

Inventories are stated at the lower of cost and net realisable value. Cost is determined using the weighted average method. The cost of finished goods and work in progress comprises raw materials, direct labour, other direct costs and related production overheads (based on normal operating capacity). It excludes borrowing costs. Net realisable value is the estimated selling price in the ordinary course of business, less applicable variable selling expenses.

**Trade receivables**

Trade receivables are recognised initially at the transaction price as these assets do not have significant financing components and are subsequently measured at amortised cost. The Group recognises loss allowances for trade receivables under the expected credit loss model as established by evidence that the Group will not be able to collect all amounts due according to the original terms of the receivables.

**Contract assets**

Contract assets relates to the Group’s rights to consideration for work completed but not billed at the reporting date for commercial development work and bioprocessing batches. The contract assets are transferred to trade receivables when the rights become unconditional. This usually occurs when the Group issues an invoice to the customer.

**Cash and cash equivalents**

Cash and cash equivalents include cash in hand, bank deposits repayable on demand, and other short term highly liquid investments with original maturities of three months or less.

**Deposits**

Deposits consists of amounts held in escrow and is included within other receivables within the Balance Sheet until such time as the restrictions relating to these items have been lifted.

**Trade payables**

Trade payables are recognised initially at fair value and subsequently measured at amortised cost using the effective interest method. Trade payables are classified as current liabilities if payment is due within one year or less. If not, they are presented as non-current liabilities.

**Contract liabilities and deferred Income**

The contract liabilities primarily relate to the advance consideration received from the customers for commercial development work and bioprocessing batches, as well as options, grants and funded research and development activities.

**Financial liability: loans**

On initial recognition, external loans are measured at fair value plus directly attributable transaction costs.

On subsequent measurement, external loans are measured at amortised cost under the effective interest rate method. The effective interest rate method is a method of calculating the amortised cost of a financial liability and allocating the interest expense over the relevant period. The calculation of the effective interest rate takes into account the estimated cash flows which consider all the contractual terms of the financial instrument, including any embedded derivatives which are not subject to separation.

If the Group assesses that a loan has elements of both a liability and an equity component, the Group will account for the loan as a compound financial instrument separating out the individual elements into financial liabilities or equity instruments. The liability and the equity components should be presented separately on the balance sheet. On initial recognition, the issuer of a compound instrument first measures the liability component at its fair value. The equity component is measured as the residual amount that results from deducting the fair value of the liability component from the initial carrying amount of the instrument as a whole. This method is consistent with the requirements for initial measurement of a financial liability in IFRS 9, and the definitions in IAS 32, and the framework of an equity instrument as a residual interest.

**Provisions**

Provisions for the anticipated cost of restoring the leasehold properties to their original condition are recognised when the Group has a present legal or constructive obligation as a result of past events; it is probable that an outflow of resources will be required to settle the obligation; and the amount has been reliably estimated.

Provisions are not recognised for future operating losses. Provisions are measured at the present value of the expenditure expected to be required to settle the obligation using a pre-tax discount rate that reflects the current market assessments of the time value of money and the risks specific to the obligations. The increase in the provision due to the passage of time is recognised as finance costs.

**Share capital**

Ordinary shares are classified as equity. Costs of share issues are charged to the share premium account.

**Merger reserve**

A merger reserve is used where more than 90% of the shares in a subsidiary are acquired and the consideration includes the issue of new shares by the Company, thereby attracting merger relief under s612 and s613 of the Companies Act 2006.

**Warrant reserve**

The warrant reserve comprises warrants exercisable on the enlarged Group’s share capital which have been fair valued and are exercisable over a period of time.

**2. Critical accounting judgements and estimates**

In applying the Group’s accounting policies, management is required to make judgements and assumptions concerning the future in a number of areas. Actual results may be different from those estimated using these judgements and assumptions. We do not believe that there are any key sources of estimation uncertainty. The critical accounting judgements are set out below.

**IFRS 15**

The Group has implemented a new accounting standard, IFRS 15 ‘Revenue from contracts with customers’, from 1 January 2018.

The new standard provides a single principles-based approach to the recognition of revenue from all contracts with customers and requires revenue to be recognised when or as performance obligations in a contract are performed.

The Group has adopted IFRS 15 applying the modified retrospective approach. No cumulative adjustment to equity was required at 1 January 2018 as there was no change in the way performance obligations have been recognised due to the implementation of IFRS 15, other than as identified below. In accordance with the requirements of the Standard, where the modified retrospective approach is adopted, prior year results are not restated.

In application of the standard the Group has identified three key areas of judgement within the existing collaboration agreements, firstly in relation to the number of distinct performance obligations contained within each collaboration agreement which include a licence, bioprocessing and process development activities within a single contract, secondly the appropriate allocation of revenue to each performance obligation to represent the stand-alone selling price of the obligation, and thirdly the appropriate recognition at a point-in-time or over time. The sales royalties contained within the collaboration agreements qualify for the royalty exemption available under IFRS 15 and will continue to be recognised as the underlying sales are made.

As part of the IFRS 15 revenue analysis performed, the Group is planning to recognise partially funded research and development incomes, previously recognised within other operating income in the statement of comprehensive income, within revenue in this statement, in line with the development of this service within the business. In 2018, the Group recognised £0.2 million (2017: £0.5 million) of this type of income. There are not expected to be any other material impacts on reported revenue, and the prior period will not be restated.



Revenue recognition

During 2018 the Group entered into a collaboration and license agreement with Bioverativ (Sanofi). As part of this agreement, the Group has recognised revenues as follows:

- £4.0 million upon granting of a license to our Lentivector technology,
- The provision of process development services and scale-up activities for its lentiviral vector haemophilia products which have been recognised as the work is completed.

As part of the collaboration the Group is entitled to recognise future revenues in terms of:

- The provision of process development services and scale-up activities for its lentiviral vector haemophilia products as the work is completed,
- Process development, technology transfer, product, regulatory and sales milestones which will be recognised upon achievement of the milestone,
- Bioprocessing income on a percentage of completion basis as the manufacturing is completed,
- Royalties based on underlying sales and technology access fees over the period in which the technology is provided.

During 2018 the Group entered into a license agreement with Axovant. As part of this agreement, the Group has recognised revenues as follows:

- £4.1 million upon granting of a license to our Lentivector technology,
- £10.2 million upon granting of an exclusive license to our OXB-102 (now AXO-LENTI-PD) and ProSavin products,
- The transfer of know-how and ongoing clinical development as the work is completed,
- The provision of process development services and scale-up activities for its lentiviral vector OXB-102 (AXO-LENTI-PD) product which have been recognised as the work is completed,
- Provision of existing stock of OXB-102 as that stock has been made available to Axovant.

As part of the license agreement the Group is entitled to recognise future revenues in terms of:

- The transfer of know-how and ongoing clinical development as the work is completed,
- The provision of process development services, scale-up activities, and technology transfer activities for its lentiviral vector OXB-102 (AXO-LENTI-PD) product as the work is completed,
- Manufacturing and process development, diligence, product, regulatory and sales milestones which will be recognised upon achievement of the milestone,
- Bioprocessing income on a percentage of completion basis as the manufacturing is completed,
- Royalties based on underlying sales.

During 2018 the Group entered into a process development collaboration agreement with the UK Cystic Fibrosis Gene Therapy Consortium (GTC) and Imperial Innovations to develop a long-term therapy for patients with cystic fibrosis (CF). Concurrently with this, a separate option and license agreement has been signed between Oxford Biomedica and Boehringer Ingelheim. As part of these agreements, the Group has recognised revenues as follows:

- The provision of process development services and scale-up activities for its lentiviral vector cystic fibrosis product which have been recognised as the work is completed.

As part of the license agreement the Group is entitled to recognise future revenues in terms of:

- The granting of a license to our Lentivector technology,
- The provision of process development services, scale-up activities, and technology transfer activities for its lentiviral vector cystic fibrosis product as the work is completed,
- Product development, technology transfer, regulatory and sales milestones which will be recognised upon achievement of the milestone,
- Bioprocessing income on a percentage of completion basis as the manufacturing is completed,
- Royalties based on underlying sales.

In 2018 the Group received £0.5 million from our insurer with regards to a loss suffered due to a temperature excursion on a customer stock shipment included within revenues in 2017.

Under the 2017 Novartis contract an up-front fee of \$10 million was due for a three year minimum capacity reservation covering the period from 2017 to 2019. The Group have determined that this revenue should be recognised over the capacity reservation term based on the number of batches completed per year, capped at the minimum capacity requirement per year per the contract. In 2018 the Group have therefore recognised revenues of £2.8 million (2017: £2.0 million) with regards to this item.

In 2017 the Group recognised a contractually agreed milestone for \$1.8 million for the provision of support to Novartis in preparation of their suspension process clinical submission. Although the milestone was formally agreed by Novartis in January 2018, the Group concluded that the criteria for revenue recognition had been met on the basis that they had completed the procedures and the submission had been through the first levels of review with Novartis. Accordingly, a total of \$1.8 million (£1.3 million) was recognised as revenue in 2017.

In 2017 the Group was due a contractually agreed step milestone from Novartis based on the increased scale-up of their suspension process. Dependent on productivity the Group could be awarded up to \$4 million. \$250,000 was recognised in 2016. During 2017 the Group achieved the target scale up and submitted documents supporting this. This was formally accepted by Novartis in January 2018. The Group concluded that the criteria for revenue recognition had been met on the basis that they had achieved the scale up, and the submission had been through the first levels of review with Novartis. Accordingly, the remaining \$3.8 million (£2.8 million) of revenue was recognised in 2017.

Contract balances

The following table provides information about receivables, contract assets and contract liabilities from contracts with customers.

	2018 £'000	2017 £'000
Trade Receivables	15,408	5,705
Contract Assets	8,886	8,681
Contract Liabilities	(18,485)	(13,072)

The contract assets relates to the Group’s rights to consideration for work completed but not billed at the reporting date for commercial development work and bioprocessing batches. The contract assets are transferred to receivables when the rights become unconditional. This usually occurs when the Group issues an invoice to the customer.

The contract liabilities primarily relate to the advance consideration received from the customers for commercial development work and bioprocessing batches, for which revenues are recognised on a percentage of completion basis.

No revenue was recognised in 2018 for performance obligations satisfied in previous periods.

No information is provided about remaining performance obligations at 31 December 2018 that have an original expected duration of one year or less, as allowed by IFRS 15.

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Performance obligations and revenue policies

Revenue is measured based on the consideration specified in a contract with a customer.

The following table provides information about the nature and timing of the satisfaction of performance obligations in contracts with customers, including significant payment terms, and the related revenue recognition policies. For services set out below, payment terms are negotiated on a customer by customer basis, however this is typically between 30 and 60 days.

Nature and timing of satisfaction of performance obligations	Revenue recognition under IFRS 15	Revenue recognition under IAS 18
Bioprocessing of clinical and commercial product for partners.  The Group has determined that for the bioprocessing of product, the customer controls all of the work in progress as the product is being manufactured. This is because those products are made under exclusive licence.	Revenue and associated costs are recognised over time as the processes are carried out. Progress is determined based on the achievement of verifiable stages of the process.  Un-invoiced amounts are presented as contract assets.	Revenue was recognised on a 'percentage of completion' basis dependent on the stage of completion of the process at the reporting date.
Revenues for providing process development activities to partners.	Revenue is recognised over time as the services are provided on a percentage of completion basis.	Revenue was recognised during the period in which the service is rendered on a percentage of completion basis.
Milestone receivables relating to bioprocessing or process development activities.  Milestones are determined by specific conditions stipulated in the relevant agreements or contracts.	When a contract with a customer is identified, each milestone is determined as either binary or non-binary. Milestones that are considered to be binary relate to the achievement of specific events rather than the provision of, for example, support:  A binary milestone will be recognised in full once it is deemed highly probable that the obligation will be met.  Non-binary milestones are recognised on a percentage of completion basis.	Milestones related to the achievement of specific deliverables were recognised on a probability adjusted basis once most of the work or identifiable deliverables have been completed and when there is a high probability that the incentive will be received.  Milestones related to the provision of support services are recognised on a percentage of completion basis, but taking into account the likelihood of achievement of the deliverable.
Product and technology licences.  The licences establish rights to the intellectual property and know-how of the Group.	The licences that have been established by the Group have all been determined as "right to use" licences, rather than "right to access" licences.  As such, the revenue from these licences is recognised at the point in time at which the licence transfers to the customer.	Where the amount received was non-refundable and there were no ongoing commitments from the Group and the licence had no fixed end date, the Group recognised revenue in full on execution of the licence.
Milestone payments relating to product licences.  Milestones are determined by specific conditions stipulated in the relevant agreements or contracts.	When a contract with a customer is identified, each milestone is determined as either binary or non-binary. Milestones that are considered to be binary relate to the achievement of specific events rather than the provision of, for example, support:  A binary milestone will be recognised in full once it is deemed highly probable that the obligation will be met.  Non-binary milestones are recognised on a percentage of completion basis.	Milestone payments were recognised as revenue when the specific conditions stipulated in the licence agreement have been met.  Payments linked to "success" such as regulatory filing or approval, or achievement of specified sales volumes, are recognised in full when the relevant event occurred.  Otherwise, amounts receivable were recognised in the period in which related costs incurred, or over the estimated period to completion of the relevant phase of development or associated clinical trials.
Royalties.	Recognised as the underlying sales occur.	Recognised as the underlying sales occur.
Research and development funding.	Revenue and associated costs are recognised over time. Progress is determined based on the cost-to-cost method.	Other income was recognised over a period that corresponds with the performance of the funded research and development activities.

Going concern

Management and the Directors have had to make estimates and important judgements when assessing the going concern status of the Group. The conclusions of these estimates and judgements are reported in several places in this annual report including the Directors Report (page 90) and note 1 to the financial statements (page 108).

3. Financial risk management

Financial risk factors

The Group has a simple corporate structure with the Company and its only operating subsidiary both being UK domiciled. Monitoring of financial risk is part of the Board's ongoing risk management, the effectiveness of which is reviewed annually. The Group's agreed policies are implemented by the Chief Financial Officer, who submits reports at each board meeting. The Group does not use financial derivatives, and it is the Group's policy not to undertake any trading in financial instruments.

(a) Foreign exchange risk

In 2018 the Group's revenues were mostly receivable in Sterling and US Dollars, and certain of its expenditures were payable in Euros and US Dollars. The majority of operating costs are denominated in Sterling but most of the finance costs and any related future repayment of capital will be in Dollars (please refer to Interest rate risk for further details with regards to the Oaktree loan). A 10% difference in the £/\$ exchange rate would have had an impact of approximately £3,054,000 (2017: £336,000) on net revenue over the year and would lead to an unrealised foreign exchange gain/loss of £4.1 million (2017: £3.3 million) on the outstanding loan balance.

The Group also has exposure to the £/€ exchange rate due to the need to fund expenditure denominated in Euros. Had the pound been 10% weaker in relation to the Euro, the increased cost in 2018 would have been approximately £156,000 (2017: £37,000). The Group's policy is to hold the majority of its funds in Sterling and US Dollars. No other hedging of foreign currency cash flows is undertaken.

(b) Interest rate risk

On 29 June 2017 the Group established a \$55 million loan facility with Oaktree Capital Management. \$50 million of the facility was drawn down as at 30 June 2017 while the remaining \$5 million of the loan facility was drawn down in July 2017. The fair value of the loan net of capitalised legal and associated finance costs at 31 December 2018 is accounted for as a £41.2 million (2017: £36.9 million) balance within loans, and the fair value of the warrants of £1.2 million is accounted for as equity.

The Group's policy is to maximise interest receivable on deposits, subject to maintaining access to sufficient liquid funds to meet day to day operational requirements and preserving the security of invested funds. With the current low level of bank interest rates, interest receivable on bank deposits in 2018 was just £71,000 (2017: £38,000).

If interest rates had been 1% higher in 2018 the impact on cash interest paid would have been £555,000 (2017: £403,000).

(c) Credit risks

Cash balances are mainly held on short and medium-term deposits with financial institutions with a credit rating of at least A, in line with the Group's policy to minimise the risk of loss.

Trade debtors are monitored to minimise the risk of loss (note 15).

Derivative financial instruments and hedging

There were no material derivatives at 31 December 2018 or 31 December 2017 which have required separation, and hedge accounting has not been used.

Fair value estimates

The fair value of short term deposits with a maturity of one year or less is assumed to be the book value.



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Capital Management

The Group’s objectives when managing capital are to safeguard the Group’s ability to continue as a going concern in order to provide returns to shareholders and benefits for other stakeholders, and to maintain an optimal capital structure to minimise the cost of capital. There have been no covenant breaches in relation to the loan agreements in place during the year.

Group	2018 £’000	2017 £’000
Net debt	8,909	22,535
Equity	34,741	6,146
Debt/equity	26%	367%

4. Segmental analysis

The chief operating decision-makers have been identified as the Senior Executive Team (SET), comprising the Executive Directors, Chief Project and Development Officer, Chief Technical Officer, Chief Scientific Officer, Chief Business Officer, Chief Operations Officer and Chief People Officer. The SET monitors the performance of the Group in two business segments:

- (i) Platform – this segment consists of the revenue generating bioprocessing and process development activities undertaken for third parties. It also includes internal technology developments and technical intellectual property.
- (ii) Product – this segment consists of the clinical and preclinical development of in vivo and ex vivo gene and cell therapy products which are owned by the Group, or out-licensed to customers.

During 2017 a change was made to the business segments monitored by SET to better reflect the way the business is being managed. Internal technology projects to develop new potentially saleable technology, improve our current processes and bring development & manufacturing costs down is now included within the newly named ‘Platform’ segment (previously ‘Partnering’), rather than forming part of the “Product” segment (previously ‘R&D’).

Revenues, Operating EBITDA and Operating profit/(loss) by segment

Revenues, Operating EBITDA and Operating profit/(loss) represent our measures of segment profit & loss as they are a primary measure used for the purpose of making decisions about allocating resources and assessing performance of segments.

2018	Platform £’000	Product £’000	Total £’000
Revenue	55,004	11,774	66,778
Other operating income	645	419	1,064
Operating EBITDA <sup>1</sup>	9,743	3,637	13,380
Depreciation, amortisation and share based payment	(4,358)	(1,090)	(5,448)
Revaluation of investments	5,983	–	5,983
Operating profit	11,368	2,547	13,915
Net finance cost			(8,901)
Profit before tax			5,014

2017	Platform £’000	Product £’000	Total £’000
Revenue	37,590	–	37,590
Other operating income	1,774	–	1,774
Operating EBITDA <sup>1</sup>	2,917	(4,786)	(1,869)
Depreciation, amortisation and share based payment	(5,035)	(1,061)	(6,096)
Revaluation of investments	2,297	–	2,297
Operating profit/(loss)	179	(5,847)	(5,668)
Net finance cost			(6,093)
Loss before tax			(11,761)

1. Operating EBITDA, being earnings before interest, tax, depreciation, amortisation, revaluation of investments and the share based payment charge, is considered by the Directors to give a fairer view of the year-on-year comparison of trading performance.

Other operating income of £1.1 million (2017: £1.8 million) includes grant income of £0.4 million (2017: £0.8 million) which is used to fund clinical and pre-clinical development and is included within the Product segment. Grant income to develop our supply chain capabilities of £0.5 million (2017: £0.2 million) is included within the Platform segment. 2018 includes £0.2 million (2017: £0.8 million) of partially funded development income.

Costs are allocated to the segments on a specific basis as far as possible. Costs which cannot readily be allocated specifically are apportioned between the segments using relevant metrics such as headcount or direct costs.

A geographical split of operating loss is not provided because this information is not received or reviewed by the chief operating decision-maker and the origin of all revenues is the United Kingdom.

A segmental or geographical split of assets and liabilities is not provided because this information is not received or reviewed by the chief operating decision-maker. All assets are located within the United Kingdom.

Disaggregation of revenue

Revenue is disaggregated by the type of revenue which is generated by the commercial arrangement. Revenue shown in the table below is denominated in GBP and is generated in the UK.

2018	Platform £’000	Product £’000	Total £’000
Bioprocessing/Commercial development	39,034	1,470	40,504
Licence fees & Milestones	15,970	10,304	26,274
Total	55,004	11,774	66,778

2017	Platform £’000	Product £’000	Total £’000
Bioprocessing/Commercial development	31,849	–	31,849
Licence fees & Milestones	5,741	–	5,741
Total	37,590	–	37,590

Our customer base includes Novartis, Axovant, Bioverativ (Sanofi) and Orchard Therapeutics which each generated more than 10% of the Group’s revenue in 2018.

Revenue by geographical location

The Group’s revenue derives wholly from assets located in the United Kingdom. Analysed by location the Group’s revenues derive predominantly from Europe with a large increase in rest of world (United States) revenues in 2018:

Revenue by customer location	2018 £’000	2017 £’000
Europe	41,542	36,398
Rest of world	25,236	1,192
Total revenue	66,778	37,590

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5. Employees and Directors

The monthly average number of persons (including Executive Directors) employed by the Group during the year was:

By activity	2018	2017
	Number	Number
Office and management	27	24
Research, development and bioprocessing	350	271
Total	377	295

Employee benefit costs	2018	2017
	£'000	£'000
Wages and salaries	20,444	14,771
Social security costs	2,411	1,616
Other pension costs (note 30)	1,277	958
Share based payments (note 26)	1,091	749
Total employee benefit costs	25,233	18,094

Key management compensation	2018	2017
	£'000	£'000
Wages and salaries	3,267	2,334
Social security costs	788	395
Other pension costs	186	158
Share based payments	572	420
Total	4,814	3,307

The key management figures above include Executive and Non-Executive Directors and the other members of the Senior Executive Team. Further information about the remuneration of individual Directors, including the highest paid Director, is provided in the audited part of the Directors’ remuneration report on page 74 which forms part of these financial statements.

The Company had no employees during the year (2017: zero).

6. Finance income and costs

Group	2018	2017
	£'000	£'000
Finance income:		
Bank interest receivable	71	38
Total finance income	71	38
Finance costs:		
Unwinding of discount in provisions (note 20)	(8)	(8)
Revaluation of liabilities in foreign currency	(2,744)	3,291
Interest payable	(6,220)	(9,414)
Total finance costs	(8,972)	(6,131)
Net finance income	(8,901)	(6,093)

Up to 29 June 2017, interest payable consisted of the cash interest paid on the Oberland loan facility at 10.5%, as well as the remaining 4.5% previously accrued to provide a return of 15% per annum to Oberland. The Group also incurred a loss on early extinguishment of the Oberland facility of £3.9 million included within interest payable of £9.4 million.

On 29 June 2017 the Group re-financed its loan facility at a lower cash cost with a new \$55.0 million facility with Oaktree Capital Management. The new facility provides for increased funding together with a lower interest rate of 9% plus US\$ three month LIBOR. The loan balance has increased from £36.9 million at 31 December 2017 to £41.2 million at 31 December 2018 due to the devaluation of sterling against the dollar, and interest accrued on the capitalised balance.

7. Expenses by nature

	Notes	Group	2017	Company	2017
		2018		2018	
		£'000	£'000	£'000	£'000
Employee benefit costs	5	25,223	18,094	365	280
Depreciation of property, plant and equipment	12	4,332	4,113	–	–
Amortisation	11	25	262	–	–
Impairment of intangible assets	11	–	971	–	–
Raw materials and consumables used in bioprocessing		9,825	7,833	–	–
Operating lease payments		30	143	–	–
Net (profit)/loss on foreign exchange		(1,305)	287	–	–

Company employee benefit costs of £365,000 (2017: £280,000) relates to Non-Executive costs paid by Oxford Biomedica UK Ltd and recharged to the Company.

Depreciation is charged to research, development and bioprocessing costs in the statement of comprehensive income.

During the year the Group (including its subsidiaries) obtained services from the Group’s auditors and their associates as detailed below:

Services provided by the Group's current auditors	Group	2017
	2018	£'000
Fees payable for the audit of the parent company and consolidated financial statements	25	–
Fees payable for other services:		
The audit of the Company's subsidiaries	125	–
Review of interim results	20	–
Other services	8	–
Total	178	–

Services provided by the Group's previous auditors	Group	2017
	2018	£'000
Fees payable for the audit of the parent company and consolidated financial statements	–	25
Fees payable for other services:		
The audit of the Company's subsidiaries	–	120
Additional fees relating to prior year audit	25	15
Other services	14	35
Tax compliance services	–	5
Total	39	200



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8. Taxation

The Group is entitled to claim tax credits in the United Kingdom for certain research and development expenditure. The amount included in the statement of comprehensive income for the year ended 31 December 2018 comprises the credit receivable by the Group for the year less overseas tax paid in the year. The United Kingdom corporation tax research and development credit is paid in arrears once tax returns have been filed and agreed. The tax credit recognised in the financial statements but not yet received is included in current tax assets in the balance sheet. The amounts for 2018 have not yet been agreed with the relevant tax authorities.

	Group	
	2018 £'000	2017 £'000
Current tax		
United Kingdom corporation tax research and development credit	(2,278)	(2,232)
Overseas taxation	–	18
	(2,278)	(2,214)
Adjustments in respect of prior periods:		
United Kingdom corporation tax research and development credit	(528)	(530)
Current tax	(2,806)	(2,744)
Deferred tax		
Relating to the origination of timing allowances	312	–
Adjustments in respect of prior periods	(33)	–
Deferred tax	279	–
Taxation Credit	(2,527)	(2,744)

The adjustment of current tax in respect of prior year of £528,000 (2017: £530,000) relates to a higher than anticipated tax receipt.

The Company has no tax liability, nor is it entitled to tax credits (2017: £nil).

The tax credit for the year is higher (2017: higher) than the standard rate of corporation tax in the UK. The differences are explained below:

	Group		Company	
	2018 £'000	2017 £'000	2018 £'000	2017 £'000
Profit/(Loss) on ordinary activities before tax	5,014	(11,761)	(1,575)	(1,207)
Profit/(Loss) on ordinary activities before tax multiplied by the standard rate of corporation tax in the UK of 19.00% (2017: 19.25%)	953	(2,264)	(299)	(232)
Effects of:				
Expenses not deductible for tax purposes	264	645	–	–
R&D relief mark-up on expenses	(1,880)	(1,333)	–	–
Income not taxable	(32)	(442)	–	–
Tax deduction for share options less than share option accounting charge	(387)	(134)	–	–
Recognition of previously unrecognised tax losses	(963)	–	(963)	–
Tax rate changes	(33)	–	133	–
Deferred tax not recognised	(358)	–	–	–
Overseas tax	–	14	–	–
Tax losses carried forward to future periods	–	1,326	–	232
Adjustments in respect of prior periods	(91)	(556)	–	–
Total tax credit for the year	(2,527)	(2,744)	(1,129)	–

At 31 December 2018, the Group had tax losses to be carried forward of approximately £91.1 million (2017: £89.5 million). Of the Group tax losses, £91.1 million (2017: £89.5 million) arose in the United Kingdom.

9. Basic earnings/(loss) and diluted earnings per ordinary share

The basic earnings/(loss) per share of 11.57p (2017: 14.50p loss) has been calculated by dividing the earnings/(loss) for the period by the weighted average number of shares in issue during the year ended 31 December 2018 (65,188,414; 2017: 61,913,343 adjusted for share consolidation (note 23)).

The diluted earnings per share of 10.89p has been calculated by dividing the earnings for the period by the weighted average number of shares in issue during the period after adjusting for the dilutive effect of the share options and warrants outstanding at 31 December 2018 (69,242,901).

There were no potentially dilutive options in the prior period. There is therefore no difference between the basic loss per ordinary share and the diluted loss per ordinary share in the prior period.

10. Loss for the financial year

As permitted by section 408 of the Companies Act 2006, the Company’s statement of comprehensive income has not been included in these financial statements. The Company’s loss for the year was £446,000 (2017: £1,207,000).

11. Intangible assets

Intangible assets comprise intellectual property rights.

	2018 £'000	2017 £'000
Cost at 1 January	5,591	5,591
Additions	45	–
Cost at 31 December	5,636	5,591
Accumulated amortisation and impairment		
At 1 January	5,494	4,261
Amortisation charge for the year	25	262
Impairment charge for the year	–	971
At 31 December	5,519	5,494
Net book amount at 31 December	117	97

During 2017, there was a write down of the Prime Boost technology and poxvirus patent intangible asset after Bavarian Nordic’s Prostavac product failed in its phase III study.

During 2018, the Group purchased a domain name for £45,000.

For intangible assets regarded as having a finite useful life amortisation commences when products underpinned by the intellectual property rights become available for use. Amortisation is calculated on a straight-line basis over the remaining patent life of the asset. Amortisation of £25,000 (2017: £262,000) is included in ‘Research, development and bioprocessing costs’ in the statement of comprehensive income.

An intangible asset is regarded as having an indefinite useful life when, based on an analysis of all of the relevant factors, there is no foreseeable limit to the period over which the asset is expected to generate net cash inflows for the entity. There are currently no assets with indefinite useful lives.

The Company had no intangible assets at 31 December 2018 or 31 December 2017.

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12. Property, plant and equipment

	Freehold property £'000	Leasehold improvements £'000	Office equipment and computers £'000	Bioprocessing and laboratory equipment £'000	Total £'000
<b>Cost</b>					
At 1 January 2018	21,171	4,689	3,179	6,651	35,690
Additions at cost	112	3,046 <sup>1</sup>	1,909	5,686	10,753
<b>At 31 December 2018</b>	<b>21,283</b>	<b>7,735</b>	<b>5,088</b>	<b>12,337</b>	<b>46,443</b>
<b>Accumulated depreciation</b>					
At 1 January 2018	4,306	978	1,862	3,174	10,320
Charge for the year	2,018	472	554	1,288	4,332
<b>At 31 December 2018</b>	<b>6,324</b>	<b>1,450</b>	<b>2,416</b>	<b>4,462</b>	<b>14,652</b>
<b>Net book amount at 31 December 2018</b>	<b>14,959</b>	<b>6,285</b>	<b>2,672</b>	<b>7,875</b>	<b>31,791</b>

1. Included within additions to leasehold improvements is £2,396,000 of assets under construction, representing ongoing construction works at the OxBox bioprocessing facility.

	Freehold property £'000	Leasehold improvements £'000	Office equipment and computers £'000	Bioprocessing and laboratory equipment £'000	Total £'000
<b>Cost</b>					
At 1 January 2017	20,902	6,970	1,651	6,488	36,011
Additions at cost	269	9	1,528	163	1,969
Disposals	–	(2,290)	–	–	(2,290)
<b>At 31 December 2017</b>	<b>21,171</b>	<b>4,689</b>	<b>3,179</b>	<b>6,651</b>	<b>35,690</b>
<b>Accumulated depreciation</b>					
At 1 January 2017	2,306	2,798	877	2,516	8,497
Charge for the year	2,000	470	985	658	4,113
Disposals	–	(2,290)	–	–	(2,290)
<b>At 31 December 2017</b>	<b>4,306</b>	<b>978</b>	<b>1,862</b>	<b>3,174</b>	<b>10,320</b>
<b>Net book amount at 31 December 2017</b>	<b>16,865</b>	<b>3,711</b>	<b>1,317</b>	<b>3,477</b>	<b>25,370</b>

The Company had no property, plant and equipment at 31 December 2018 or 31 December 2017.

13. Investments and loans

Investments: Group

On 29 November 2016, as part of a strategic alliance with Orchard Therapeutics, the Group received 735,000 ordinary shares in Orchard Therapeutics as consideration for the licenses granted under the agreement.

Additional shares valued at £2.0 million were awarded to the Group on the achievement of certain milestones, being 188,462 ordinary shares in February 2018 and a further 188,462 ordinary shares in August 2018. These shares awarded were recognised as revenue during the year upon achievement of the milestones. As Orchard Therapeutics was a private company at the time, the shares awarded were not valued based on observable market data, but rather the value of the most recent placing of shares by Orchard Therapeutics prior to the milestone being achieved.

Additional ordinary shares may be issued to Oxford Biomedica should the Group achieve the remaining milestones.

In November 2018, Orchard Therapeutics converted each of its shares of capital stock into 0.8003 shares. These were then re-designated as Ordinary shares, resulting in the number of shares owned by Oxford Biomedica being adjusted from 1,111,924 to 889,872. Subsequently, in November 2018, Orchard Therapeutics floated on Nasdaq.

At year end the investment was revalued based on the 31 December 2018 share price of \$15.73, and a gain of £6.0 million (2017: £2.3 million) was recognised during the year. The aggregate fair value of the equity investment in Orchard Therapeutics is £11.0 million (2017: £3.0 million).

	2018 £'000	2017 £'000
At 1 January	2,954	657
Recognition of milestones	2,029	–
Revaluation of investments	5,983	2,297
<b>At 31 December</b>	<b>10,966</b>	<b>2,954</b>

Investments & Loans: Company

	2018 £'000	2017 £'000
<b>Shares in group undertakings</b>		
<b>At 1 January and 31 December</b>	<b>15,182</b>	<b>15,182</b>

Financial assets: Loans to group undertakings

At 1 January	176,432	170,639
Loan advanced in the year	18,304	5,793
<b>At 31 December</b>	<b>194,736</b>	<b>176,432</b>
<b>Total investments in shares and loans to group undertakings</b>	<b>209,918</b>	<b>191,614</b>

Accumulated impairment

<b>At 1 January and 31 December</b>	<b>126,065</b>	<b>126,065</b>
<b>Net book amount at 31 December</b>	<b>83,853</b>	<b>65,549</b>

Capital contribution in respect of employee share schemes

At 1 January	6,801	6,052
Additions in the year (note 26)	1,132	749
<b>At 31 December</b>	<b>7,933</b>	<b>6,801</b>

<b>Total investments and loans</b>	<b>91,786</b>	<b>72,350</b>
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The application of the expected credit loss model has had no significant impact on the level of impairment of the loan to group undertakings as the market value of the Group, of which OxfordBiomedica (UK) Ltd as the operational company makes up almost all of the value, considerably exceeds the value of the loan and investment made by the parent company.

The loan to Oxford Biomedica (UK) has no fixed terms of repayment.

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Interests in subsidiary undertakings

	Country of incorporation	Description of shares held	Proportion of nominal value of issued shares held by the Group and Company	Nature of business
Oxford Biomedica (UK) Limited	Great Britain	1p ordinary shares	100%	Gene therapy research and development
Oxxon Therapeutics Limited	Great Britain	1p ordinary shares	100%	Dormant

The registered office of both subsidiaries is Windrush Court, Transport Way, Oxford, OX4 6LT.

In addition, during 2014, the Group set up the Oxford Biomedica Employee Benefit Trust (EBT) to hold market-purchased shares to settle the 2013 deferred bonus share awards made to Executive Directors and employees (note 25).

All of the above subsidiaries have been consolidated in these financial statements.

At each year end the Directors review the carrying value of the Company’s investment in subsidiaries. Where there is a material and sustained shortfall in the market capitalisation, or a significant and sustained change in the business resulting in a decrease in market capitalisation, the Directors consider this to be a trigger of an impairment review as set out in IAS 36. Where the impairment review performed concludes that the carrying value of the investment in subsidiaries is too high, it is adjusted. The Directors consider that reference to the market capitalisation of the Group is an appropriate external measure of the value of the Group for this purpose. Following an impairment review at 31 December 2018 no impairment charge was assessed to be required. Cumulative impairment of £126.1 million has been recognised up to 31 December 2018.

14. Inventories

Group	2018 £’000	2017 £’000
Raw Materials	2,422	1,895
Work-in-progress	1,829	1,437
Total inventory	4,251	3,332

Inventories are raw materials held for commercial bioprocessing purposes and work-in-progress inventory related to contractual bioprocessing obligations.

During 2018, the Group wrote off £233,000 (2017: £53,000) of inventory which is not expected to be used in production or sold onwards. The Company holds no inventories.

15. Trade and other receivables

	Group		Company	
	2018 £’000	2017 £’000	2018 £’000	2017 £’000
Trade receivables	15,408	5,705	–	–
Contract assets	8,886	8,681	–	–
Other receivables	4,307	23	–	–
Other tax receivable	1,144	1,288	–	–
Prepayments	840	1,391	–	9
Total trade and other receivables	30,585	17,088	–	9

The fair value of trade and other receivables is the current book values. The application of the expected credit loss model has had no significant impact on the level of impairment of receivables.

Included in the Group’s trade receivables balance are debtors with a carrying amount of £1,768,000 (2017: £65,000) which were past due at the reporting date, all of which have since been received.

Other receivables have increased due to £4.0 million of deposits held in escrow as part of the new discovery and innovation facility and OxBox lease arrangements.

Ageing of past due but not impaired trade receivables:

	2018 £’000	2017 £’000
0–30 days	–	65
30–60 days	–	–
60+ days	1,768	–
	1,768	65

Contract assets of £8.9 million (2017: £8.7 million) arises where work has been undertaken which is recoverable from third parties, but which has not yet been invoiced. The balance mainly relates to commercial development milestones which have been accrued as the specific conditions stipulated in the license agreement have been met, and commercial development work orders accrued on a percentage complete basis which will be invoiced as the related work package completes.

The carrying amounts of the Group’s trade and other receivables are denominated in the following currencies:

	2018 £’000	2017 £’000
Sterling	28,098	16,684
US Dollar	2,487	404
	30,585	17,088

The Company’s receivables are all denominated in Sterling.

The maximum exposure to credit risk at the reporting date is the fair value of each class of receivable above. The Group does not hold any collateral as security.

16. Cash and cash equivalents

The Group is required under the Oaktree Facility to maintain cash and cash equivalents of not less than \$2.5 million (£2.0 million) while the Oaktree Facility is outstanding (2017: \$5 million, £3.7 million).



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**17. Trade and other payables**

	Group		Company	
	2018 £'000	2017 £'000	2018 £'000	2017 £'000
Trade payables	3,746	3,682	–	–
Other taxation and social security	770	579	–	–
Accruals	6,906	4,429	164	81
<b>Total trade and other payables</b>	<b>11,422</b>	<b>8,690</b>	<b>164</b>	<b>81</b>

Accruals have increased significantly from the prior year as a result of purchases of equipment and leasehold improvements for the new OxBox facility.

**18. Contract liabilities and deferred income**

Contract liabilities arises when the Group has received payment for services in excess of the stage of completion of the services being provided.

Contract liabilities has increased from £13.1 million at the end of 2017 to £18.5 million (of which £1.8 million is Non-current) at the end of 2018 due to £0.5 million of options and £5.0 million of process development income from new customers.

Contract liabilities consists primarily of deferred bioprocessing and process development revenue, and is expected to be released as the related performance obligations are satisfied over the period as described below:

Years	0-1 £'000	0-3 £'000	0-5 £'000	0-10 £'000	Total
<b>Contract liabilities</b>					
Bioprocessing income	9,074	1,504	–	–	<b>10,578</b>
Process development income	–	7,085	–	–	<b>7,085</b>
Licence fees, options and milestones	168	–	500	154	<b>822</b>
<b>Deferred income</b>					
Lease incentives	–	–	–	2,250	<b>2,250</b>
Grant	–	–	–	2,783	<b>2,783</b>
<b>Total</b>	<b>9,242</b>	<b>8,589</b>	<b>500</b>	<b>5,187</b>	<b>23,518</b>

**19. Loans**

The Oberland Facility was fully repaid on 29 June 2017 at a cost of £36.3 million including the accrued interest and loss on early extinguishment of £5.3 million.

On 29 June 2017 the Group completed a new \$55 million debt facility with Oaktree Capital Management ("Oaktree"). The facility has been used to redeem the debt facility with Oberland Capital Healthcare.

The Oaktree loan is repayable no later than 29 June 2020 although it may be repaid, at the Group's discretion, at any time subject to early prepayment fees and an exit fee. The loan carries an interest rate of 9.0% plus US\$ three month LIBOR, subject to a minimum of 1%. Subject to achieving certain conditions, the interest rate could reduce by 0.25% in the second year and a further 0.25% in the third year. The loan was issued at an original discount of 2.5%, and under the agreement the Company has issued 2,687,025 (post consolidation) warrants to Oaktree (note 28). The terms also include financial covenants relating to the achievement of revenue targets and a requirement to hold a minimum of \$2.5 million (2017: \$5 million) cash at all times.

On initial recognition, the Oaktree loan, net of the expenses incurred in the refinancing which are treated as prepaid expenses, was fair valued at £37.7 million. The loan balance has increased to £41.2 million due to accrued interest and the impact of foreign exchange movements.

The Oaktree facility is secured by a pledge over substantially all of the Group's assets.

**20. Provisions**

Group	2018 £'000	2017 £'000
At 1 January	630	622
Unwinding of discount	8	8
Utilisation of provision	–	–
Additional provision recognised	649	–
<b>At 31 December</b>	<b>1,287</b>	<b>630</b>
	2018 £'000	2017 £'000
Current	–	–
Non-current	1,287	630
<b>Total provisions</b>	<b>1,287</b>	<b>630</b>

The dilapidations provisions relate to the anticipated costs of restoring the leasehold Yarnton and new discovery and innovation facility properties in Oxford, UK to their original condition at the end of the lease terms in 2024 and 2028 respectively, discounted using the rate per the Bank of England nominal yield curve. The equivalent rate was used in 2017. The provisions will be utilised at the end of the leases if they are not renewed.

The Group has signed a lease on a new facility in Oxford, UK (OxBox) that is near its Windrush laboratories. The new facility is 84,000 sq. ft (7,800 sqm). The Group's planned Phase I and Phase 2 expansion will fit out around 45,000 sq. ft (4,200 sqm) for four GMP clean room suites and two fill and finish suites as well as offices, warehousing and QC laboratories, with space available for future expansion. This new facility is still under construction and therefore it is not currently possible to accurately estimate the restoration costs.

The Company had no provisions at 31 December 2018 or 31 December 2017.

**21. Financial instruments**

The Group and Company's financial instruments comprise cash and cash equivalents, trade and other receivables, loans, and trade and other payables. Additional disclosures are set out in the corporate governance statement and in note 3 relating to risk management.

The Group had the following financial instruments at 31 December each year:

	Financial assets at fair value through profit & loss		Loans & receivables	Amortised costs, loans & other liabilities	
	2018 £'000	2017 £'000		2018 £'000	2017 £'000
Cash and cash equivalents (note 16)	–	–	32,244	14,329	–
Trade receivables and other receivables (note 15)	–	–	29,281	14,409	–
Investments (note 13)	10,966	2,954	–	–	–
Trade and other payables excluding tax (note 17)	–	–	–	–	10,652
Loans (note 19)	–	–	–	–	41,153
	10,966	2,954	61,525	28,738	52,108

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Floating rate instant access deposits earned interest at prevailing bank rates.

	2018	2017
	Year average	Year average
	Weighted average rate	Weighted average rate
Sterling	0.48%	0.49%
US Dollars	1.45%	0.66%

In accordance with IFRS 9 'Financial instruments: the Group has reviewed all contracts for embedded derivatives that are required to be separately accounted for if they meet certain requirements set out in the standard. There were no such derivatives identified at 31 December 2018 or 31 December 2017.

Fair value

The Directors consider that the fair values of the Group’s financial instruments do not differ significantly from their book values.

The carrying amounts of the Group’s cash and cash equivalents are denominated in the following currencies:

	2018	2017
	£'000	£'000
Sterling	3,560	3,843
US Dollar	28,684	10,486
	32,244	14,329

Financial assets classified as level 1 in hierarchy

The investment in Orchard Therapeutics is classified as at fair value through profit and loss. Please refer to note 13 for further information.

There has been a change in the valuation level of the investment in Orchard Therapeutics from level 3 to level 1 prior to the year end due to the company having IPO’d in November 2018.

Maturity analysis of the Group’s financial liabilities

The following table analyses the contractual undiscounted cash flows payable, as well as the carrying value and fair value of Group borrowings at the date of the statement of financial position. Contractual cash flows in respect of interest payments are calculated using interest rates applicable at the date of the statement of financial position.

The Group also has short-term receivables and payables that arise in the normal course of business and these are not included in the following table. Any cash flows based on floating interest rates are based on interest rates prevailing at 31 December:

	Due within 1 year £'000	Due between 1 and 2 years £'000	Due between 2 and 3 years £'000	Total payments to maturity £'000	Carrying value £'000
2018					
Oaktree Capital Management					
Interest	4,354	2,111	–	6,465	–
Capital	–	43,886	–	43,886	41,153
	4,354	45,997	–	50,351	41,153

	Due within 1 year £'000	Due between 1 and 2 years £'000	Due between 2 and 3 years £'000	Total payments to maturity £'000	Carrying value £'000
2017					
Oaktree Capital Management					
Interest	4,144	4,043	1,996	10,183	–
Capital	–	–	41,494	41,494	36,864
	4,144	4,043	43,490	51,677	36,864

All contractual payments are in US dollars. Interest payments are floating rate payments whilst the capital repayment at the end of the term is fixed.

Reconciliation in liabilities from financing activities

	2018 £'000	2017 £'000
At 1 January	36,864	34,389
Interest payable	6,210	9,414
Foreign exchange movement	2,744	(3,282)
Cash interest paid	(4,665)	(10,800)
Oberland loan repayment	–	(30,536)
Oaktree facility drawn down	–	38,897
Warrants recognised separately (note 28)	–	(1,218)
At 31 December 2018 (note 19)	41,153	36,864

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22. Deferred taxation

The Company and the Group have recognised deferred tax balances as at 31 December 2018 (2017: £nil). In light of the Group's history of losses, recovery of the whole deferred tax asset is not sufficiently certain, and therefore only a portion of the asset has been recognised.

The main rate of corporation tax in the UK reduced from 20% to 19% with effect from 1 April 2017 and will reduce further to 17% with effect from 1 April 2020.

Group – recognised	Tax losses	Revaluation of investments	Total
Deferred tax (assets)/liabilities	£'000	£'000	£'000
At 1 January 2018	–	–	–
Origination and reversal of temporary differences	(1,129)	1,408	279
At 31 December 2018	(1,129)	1,408	279

At 1 January 2017	–	–	–
Origination and reversal of temporary differences	–	–	–
At 31 December 2017	–	–	–

Company – recognised	Tax losses	Revaluation of investments	Total
Deferred tax (assets)/liabilities	£'000	£'000	£'000
At 1 January 2018	–	–	–
Origination and reversal of temporary differences	(1,129)	–	(1,129)
At 31 December 2018	(1,129)	–	(1,129)

At 1 January 2017	–	–	–
Origination and reversal of temporary differences	–	–	–
At 31 December 2017	–	–	–

Group – not recognised	Tax depreciation	Provisions	Tax losses	Share options	Total
Deferred tax (assets)/liabilities – not recognised	£'000	£'000	£'000	£'000	£'000
At 1 January 2018	(1,071)	(133)	(16,378)	(148)	(17,730)
Origination and reversal of temporary differences	285	(5)	(150)	(1,564)	(1,434)
At 31 December 2018	(786)	(138)	(16,528)	(1,712)	(19,164)
At 1 January 2017	(1,281)	(255)	(16,025)	(288)	(17,849)
Origination and reversal of temporary differences	210	122	(353)	140	119
At 31 December 2017	(1,071)	(133)	(16,378)	(148)	(17,730)

23. Ordinary share capital

Group and Company	2018	2017
Issued and fully paid	£'000	£'000
Ordinary shares of 1p each		
At 1 January – 3,107,704,224 (2017: 3,088,047,310) shares	31,076	30,879
Allotted for cash in placing and subscription – 174,346,817 (2017: nil) shares	1,712	–
Share consolidation (3,285,053,650 1p shares converted to 65,701,073 50 p shares)	–	–
Allotted on exercise of share options – 462,507 (2017: 393,138 adjusted for consolidation) shares	246	197
At 31 December – 66,103,528 (2017: 62,154,084 adjusted for consolidation) shares	33,034	31,076

In March 2018 the Company raised £20.5 million gross proceeds by way of a placing of 174,346,817 ordinary shares at a price of 11.7 pence per share. Net proceeds after expenses were £19.1 million.

On 30 May 2018, Oxford Biomedica consolidated its existing ordinary shares of 1 pence each to 65,701,073 new consolidated ordinary shares of 50 pence each.

24. Share premium account

Group and Company	2018	2017
	£'000	£'000
At 1 January	154,224	154,036
Premium on shares issued for cash in placing and subscription	18,748	–
Premium on exercise of share options	478	188
Costs associated with the issue of shares	(1,376)	–
At 31 December	172,074	154,224



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25. Options over shares of Oxford Biomedica plc

The Company has outstanding share options that were issued under the following schemes:

- The 2007 Share Option Scheme (approved February 2007).
- The 2015 Executive Share Option Scheme (approved May 2015).
- The 2007 Long Term Incentive Plan (LTIP) (approved February 2007).
- The 2015 Long Term Incentive Plan (LTIP) (approved May 2015).
- The 2013 Deferred Bonus Plan (approved February 2014).
- The 2015 Deferred Bonus Plan (approved May 2015).
- The 2015 Save As You Earn Scheme (approved May 2015).

Share options are granted to Executive Directors and selected senior managers under the Company’s Long Term Incentive Plans (LTIP) and Deferred Bonus Plan, and to other employees under the Share Option Schemes and Save as You Earn Scheme. All option grants are at the discretion of the Remuneration Committee.

Options granted under the 2007 and 2015 LTIPs to Directors and other senior managers are subject to market condition performance criteria and will vest only if, at the third anniversary of the grant, the performance criteria have been met. Failure to meet the minimum performance criteria by the third anniversary results in all the granted options lapsing.

The performance criteria are described in the Directors’ remuneration report. LTIP awards made to date are exercisable at either par or a nil cost on the third anniversary of the date of grant, and lapse 10 years after being granted.

Options granted under the 2007 Share Option Scheme have fixed exercise prices based on the market price at the date of grant. They are not subject to market condition performance criteria and the lives of the options are ten years, after which the options expire. Options granted prior to 2012 cannot normally be exercised before the third anniversary of the date of grant. Options granted under the 2007 Scheme during 2012 to 2014, with one exception, vest in tranches of 25% from the first to fourth anniversaries of the grant dates.

Options granted under the 2015 Executive Share Option Scheme have fixed exercise prices based on the market price at the date of grant. They are not subject to market condition performance criteria and the lives of the options are ten years, after which the options expire. Options granted under the 2015 Scheme cannot normally be exercised before the third anniversary of the date of grant.

Options granted under the 2015 Save As You Earn Scheme have fixed exercise prices based on the market price at the date of grant. They are not subject to market condition performance criteria and the lives of the options are ten years, after which the options expire. Options cannot be exercised before the third anniversary of the date of grant.

Share options outstanding at 31 December 2018 have the following expiry date and exercise prices:

Options granted to employees under the Oxford Biomedica 2007 and 2015 Share Option Schemes

2018 Number of shares	2017 Number of shares <sup>1</sup>	Exercise price per share	Date from which exercisable	Expiry date
–	6,000	290p	Vested	13/10/18
–	2,051	305p	Vested	25/03/19
12,211	23,139	270p to 290p	Vested	15/03/21 to 04/10/21
22,406	38,126	115p to 155p	Vested	08/05/22 to 21/12/22
40,314	65,426	80p to 140p	Vested	22/05/23 to 19/11/23
47,114	80,308	100p to 200p	Vested	03/06/24 to 17/10/24
101,757 <sup>2</sup>	175,859 <sup>2</sup>	490p	13/03/18 to 01/06/18	13/03/25 to 10/06/25
221,256 <sup>2</sup>	236,105 <sup>2</sup>	275p	16/05/19 to 13/10/19	16/05/26 to 13/10/26
340,995 <sup>2</sup>	379,110 <sup>2</sup>	495p	13/07/20	13/07/27
271,506 <sup>2</sup>	–	904p	07/08/21	07/08/28
1,057,559	1,006,124			

Note 1 – Restated following 50 to 1 share consolidation.  
Note 2 – Options granted under the 2015 Executive share option scheme.

Options granted to employees under the Oxford Biomedica 2015 Save As You Earn Scheme

2018 Number of shares	2017 Number of shares <sup>1</sup>	Exercise price per share	Date from which exercisable	Expiry date
27,078	67,022	310p	01/10/18	01/10/25
144,466	152,054	145p	13/10/19	13/10/26
77,283	80,001	330p	12/10/20	12/10/27
114,731	–	725p	10/10/21	10/10/28
363,558	299,077			

Note 1 – Restated following 50 to 1 share consolidation.

Options granted under the Oxford Biomedica 2007 and 2015 Long Term Incentive Plans

2018 Number of shares	2017 Number of shares <sup>3</sup>	Exercise price per share	Date from which exercisable	Expiry date
–	20,000	50p	Vested	13/10/18
142,000	217,600	50p	Vested	30/06/22
72,679	127,170	50p	Vested	12/06/23
93,349	107,339	50p	Vested	20/6/24 to 17/10/24
113,158 <sup>2</sup>	210,915 <sup>2</sup>	0p	Vested	10/01/25
178,909 <sup>1,2</sup>	178,911 <sup>1,2</sup>	0p	16/05/19	16/05/26
231,256 <sup>1,2</sup>	224,025 <sup>1,2</sup>	0p	17/07/20 to 25/09/20	17/07/27 to 25/09/27
196,912	–	0p	04/08/21	04/08/28
1,028,263	1,085,960			
2,449,380	2,391,161			

Note 1 – These LTIP awards will vest provided that performance conditions specified in the Directors’ remuneration report are met.  
Note 2 – Options granted under the 2015 LTIP.  
Note 3 – Restated following 50 to 1 share consolidation.

Deferred Share Awards

The Executive Directors and certain other senior managers have been awarded deferred bonuses in the form of share options. These options will vest provided that the managers are still employed by the Group on certain specified future dates and are exercisable at nil p on either the first three anniversaries of the grant or the third anniversary of the grant dependent on the option conditions. Options with a value of £267,000 vested during 2018 (2017: £314,000).

The options granted under the 2013 Deferred Bonus Plan will be satisfied by market-purchased shares held by the Oxford Biomedica Employee Benefit Trust (EBT). As at 31 December 2018, all shares held by the EBT had vested. The EBT is consolidated at year end with the shares held in trust accounted for as part of the treasury reserve within equity (note 28). During the year no shares (2017: 1,325,035) from the EBT were exercised.

The options granted under the 2015 Deferred Bonus Plan will be satisfied by new issue shares at the time of exercise.

Options granted to employees under the Oxford Biomedica 2013 and 2015 Deferred Bonus Plan

2018 Number of shares	2017 Number of shares <sup>1</sup>	Exercise price per share	Date from which exercisable	Expiry date
116,723	116,724	0p	Vested	15/06/24 & 14/10/24
78,907	99,966	0p	Vested	04/05/25
81,257	103,484	0p	14/05/17 to 14/05/19	14/05/26
53,900	63,808	0p	11/07/18 to 11/07/20	11/07/27
48,422	–	0p	04/08/19 to 04/08/21	04/08/28
379,209	383,982			

Note 1 – Restated following 50 to 1 share consolidation.

National Insurance liability

Certain options granted to UK employees could give rise to a national insurance (NI) liability on exercise. A provision of £437,000 (2017: £168,000) is included in accruals for the potential NI liability accrued to 31 December on exercisable options that were above water, based on the year-end share price of 707.20p (2017: 8.85p pre-consolidation) per share.

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26. Share based payments

The fair values of options granted during the year were calculated using the following assumptions:

Share options (Model used: Black Scholes)	Options awarded 7 August 2018
Share price at grant date	888.1p
Exercise price	903.8p
Vesting period (years)	3
Total number of shares under option	270.553
Expected volatility (weighted average)	58%
Expected life (years)	3
Risk free rate (weighted average)	0.81%
Fair value per option	342.06p

Save As You Earn scheme awards (Model used: Black Scholes)	Options awarded 10 October 2018
Share price at grant date	805.20p
Exercise price	724.66p
Vesting period (years)	3
Total number of shares under option	115,476
Expected volatility (weighted average)	57%
Expected life (years)	3
Risk free rate (weighted average)	1.04%
Fair value per option	338.43p

LTIP awards (Model used: Monte Carlo)	LTIPs awarded 7 August 2018
Share price at grant date	888.10p
Exercise price	0.0p
Vesting period (years)	3
Total number of shares under option	204,147
Expected volatility (weighted average)	58%
Expected life (years)	3
Risk free rate (weighted average)	0.81%
Fair value per option	505.86p

The tables below show the movements in the Share Option Scheme, Save As You Earn Scheme and the LTIP during the year, together with the related weighted average exercise prices.

Excluding the LTIP & Deferred Bonus awards which are exercisable at par/nil value, the weighted average exercise price for options granted during the year was 850.1p (2017: 470p).

462,507 options were exercised in 2018 (2017: 393,138), including 53,174 of deferred bonus options (2017: 56,316).

The total charge for the year relating to employee share-based payment plans was £1,132,000 (2017: £749,000), all of which related to equity-settled share based payment transactions.

	2018		2017	
Share options excluding LTIP	Number	Weighted average exercise price	Number	Weighted average exercise price
Outstanding at 1 January	65,260,044	6.7p	50,841,737	5.1p
Forfeited	(2,174,134)	8.0p	–	–
Granted	166,857	10.5p	–	–
Cancelled	(180,674)	5.8p	–	–
Exercised	(2,056,185)	3.3p	–	–
Share consolidation	(59,795,959)	6.8p	–	–
Granted	386,029	633.4p	24,120,663	9.4p
Forfeited	(28,985)	474.9p	(4,202,453)	6.7p
Exercised	(149,191)	337.7p	(4,439,429)	2.8p
Cancelled	(6,685)	156.1p	(1,060,474)	5.0p
Outstanding at 31 December	1,421,117	419.2p	65,260,044	6.7p
Exercisable at 31 December	250,880	299.7p	9,478,677	3.0p
Exercisable and where market price exceeds exercise price at 31 December	250,880	299.7p	9,478,677	3.0p

LTIP awards (options exercisable at par value 1p or nil cost)	2018 Number	2017 Number
Outstanding at 1 January	54,297,969	70,826,153
Exercised	(300,000)	–
Share consolidation	(52,918,024)	–
Granted	204,147	11,201,233
Expired	(42,811)	(14,002,687)
Exercised	(213,018)	(13,726,730)
Outstanding at 31 December	1,028,263	54,297,969
Exercisable at 31 December	421,186	23,605,450

	2018			2017		
Range of exercise prices	Weighted average exercise price	Number of shares	Weighted average remaining life (years) Contractual	Weighted average exercise price <sup>1</sup>	Number of shares <sup>1</sup>	Weighted average remaining life (years) Contractual
LTIP:						
Exercisable at par or at nil cost	15p	1,028,263	8.1	20p	1,085,960	7.0
Deferred bonus:						
Exercisable at par or at nil cost	0p	379,209	6.9	0p	383,982	7.6
Options:						
50p to 150p	132p	215,881	6.8	125p	270,270	7.5
150p to 250p	175p	38,419	4.4	175p	65,644	5.4
250p to 350p	290p	337,828	7.5	285p	414,318	8.1
350p+	659p	828,989	8.8	495p	554,969	8.9
	2,828,589			2,775,143		

Note 1 – Restated following 50 to 1 share consolidation.

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27. Accumulated losses

	Group		Company	
	2018 £'000	2017 £'000	2018 £'000	2017 £'000
At 1 January	(182,663)	(174,489)	(122,590)	(121,383)
Profit/(Loss) for the year	7,541	(9,017)	(446)	(1,207)
Share based payments	1,246 <sup>1</sup>	945	(41)	–
Vesting of deferred share award	–	(102)	–	–
At 31 December	(173,876)	(182,663)	(123,077)	(122,590)

Note 1 – The credit to accumulated losses is made up out of the charge for the year relating to employee share-based payment plans of £1,132,000 (2017: £749,000) (note 26), £267,000 (2017: £314,000) related to the vesting of deferred share awards made to Executive Directors and senior managers, less £153,000 (2017: 118,000) in relation to the exercise of 53,174 (2017: 56,316 post consolidation) of these deferred share awards (note 25).

Neither the Company nor its subsidiary undertakings had reserves available for distribution at 31 December 2018 or 31 December 2017.

28. Other reserves

Group	Warrant reserve £'000	Merger reserve £'000	Treasury reserve £'000	Total £'000
At 1 January 2018 and 31 December 2018	1,218	2,291	–	3,509

Group	Warrant reserve £'000	Merger reserve £'000	Treasury reserve £'000	Total £'000
At 1 January 2017	–	2,291	(102)	2,189
Issue of warrants	1,218	–	102	1,320
At 31 December 2017	1,218	2,291	–	3,509

The Group merger reserve at 31 December 2018 and 2017 comprised £711,000 arising from the consolidation of Oxford Biomedica (UK) Ltd using the merger method of accounting in 1996, and £1,580,000 from the application of merger relief to the purchase of Oxxon Therapeutics Limited in 2007.

All shares previously held in the treasury reserve have now vested leaving a balance of nil (2017: nil) (note 25).

Under the Oaktree loan agreement the Company has issued 2,687,025 warrants (post consolidation) to Oaktree, equivalent to 4.4% of the enlarged Group’s share capital. The warrants are exercisable at the nominal share price of 1p and may be exercised at any time over the next ten years. The warrants have been fair valued at £1.2 million net of related expenses and this amount has been credited to the warrant reserve.

Company	Warrant reserve £'000	Merger reserve £'000	Share Scheme Reserve £'000	Total £'000
At 1 January 2018	1,218	1,580	6,801	9,599
Credit in relation to employee share schemes	–	–	1,132	1,132
At 31 December 2018	1,218	1,580	7,933	10,751
At 1 January 2017	–	1,580	6,052	7,632
Credit in relation to employee share schemes	–	–	749	749
Issue of warrants	1,218	–	–	1,218
At 31 December 2017	1,218	1,580	6,801	9,599

Options over the Company’s shares have been awarded to employees of subsidiary companies. In accordance with IFRS 2 ‘Share-based Payment’ the expense in respect of these awards is recognised in the subsidiaries’ financial statements (see note 26). In accordance with IFRS 2 the Company has treated the awards as a capital contribution to the subsidiaries, resulting in an increase in the cost of investment of £1,132,000 (2017: £749,000) (see note 13) and a corresponding credit to reserves.

29. Cash flows from operating activities

	Group		Company	
	2018 £'000	2017 £'000	2018 £'000	2017 £'000
Continuing operations				
Operating profit/(loss)	13,915	(5,668)	(1,575)	(1,207)
Adjustment for:				
Depreciation	4,332	4,113	–	–
Amortisation of intangible assets	25	262	–	–
Charge for impairment	–	971	–	–
Charge in relation to employee share schemes	1,246	945	–	–
Non-cash gains	(8,012)	(2,297)	–	–
Changes in working capital:				
(Increase)/decrease in trade and other receivables	(14,559)	(11,183)	9	(6)
Increase/(decrease) in trade and other payables	2,732	2,687	83	(95)
Increase in contract liabilities and deferred income	10,446	9,759	–	–
Increase/(decrease) in provisions	8	8	–	–
Increase in inventory	(919)	(1,130)	–	–
Net cash used in operations	9,214	(1,533)	(1,483)	(1,308)

Non cash gains include equity stakes in Orchard Therapeutics granted on completion of milestones (£2.0 million), and a gain of £6.0 million (2017: £2.3 million) on the revaluation of the equity investment at the end of the year.

30. Pension commitments

The Group operates a defined contribution pension scheme for its Directors and employees. The assets of the scheme are held in independently administered funds. The pension cost charge of £1,277,000 (2017: £958,000) represents amounts payable by the Group to the scheme. Contributions of £186,000 (2017: £138,000), included in accruals, were payable to the scheme at the year-end.

31. Operating lease commitments – minimum lease payments

The future aggregate minimum lease payments under non-cancellable operating leases are as follows:

Group	2018 £'000	2017 £'000
Not later than one year	842	94
Later than one year and not later than five years	4,532	330
Over five years	8,532	144
Total lease commitments	13,906	568

The Group leases equipment under non-cancellable operating lease agreements. The Group continues to lease the manufacturing site at Yarnton, Oxford under a non-cancellable operating lease agreement. The Group entered into a lease for the new discovery and innovation facility property and a lease on a new facility (Oxbox) that is near to its Windrush laboratories in Oxford, UK. The leases have various terms, escalation clauses and renewal rights.

The Company had no operating lease commitments during the year (2017: none).



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**32. Contingent liabilities and capital commitments**

The Group had commitments of £15,723,000 for capital expenditure for leasehold improvements, plant and equipment not provided for in the financial statements at 31 December 2018 (2017: £850,000). The largest part of the 2018 commitment relates to the leasehold improvements, and plant and equipment of the new OxBox bioprocessing facility.

**33. Related party transactions**

**Identity of related parties**

The Group consists of a parent, Oxford Biomedica plc, one wholly-owned trading subsidiary (Oxford Biomedica (UK) Limited), the principal trading company, and one dormant subsidiary (Oxxon Therapeutics Limited), which was acquired and became dormant in 2007 when its assets and trade were transferred to Oxford Biomedica (UK) Limited. The registered address for the Company and all of its subsidiaries is Windrush Court, Transport Way, Oxford OX4 6LT.

During the year, OcQuila (UK) Ltd was incorporated as a wholly-owned subsidiary of the parent company. In November 2018 it was sold. It remained dormant from incorporation to date of sale.

The parent company is responsible for financing and setting group strategy. Oxford Biomedica (UK) Limited carries out the Group strategy, employs all the UK staff including the Directors, and owns and manages all of the Group’s intellectual property. The proceeds from the issue of shares by the parent are passed from Oxford Biomedica plc to Oxford Biomedica (UK) Limited as a loan, and Oxford Biomedica (UK) Limited manages group funds and makes payments, including the expenses of the parent company.

	2018 £’000	2017 £’000
<b>Company: transactions with subsidiaries</b>		
<b>Purchases:</b>		
Parent company expenses paid by subsidiary	(1,370)	(976)
<b>Warrants:</b>		
Issue of warrants for shares as part of consideration for loan obtained by subsidiary	–	1,218
<b>Cash management:</b>		
Cash loaned by parent to subsidiary	19,674	5,551

The loan from Oxford Biomedica plc to Oxford Biomedica (UK) Limited is unsecured and interest free. The loan has no fixed repayment terms and is not expected to be repaid within 12 months of the year end. The year-end balance on the loan was:

	2018 £’000	2017 £’000
<b>Company: year-end balance of loan</b>		
Loan to subsidiary	194,736	176,432

The investment in the subsidiary, of which the loan forms part, has been impaired by £126 million (note 13) in previous years.

In addition to the transactions above, options over the Company’s shares have been awarded to employees of subsidiary companies. In accordance with IFRS 2, the Company has treated the awards as a capital contribution to the subsidiaries, resulting in a cumulative increase in the cost of investment of £7,892,000 (2017: £6,801,000).

There were no transactions (2017: none) with Oxxon Therapeutics Limited.

**Company: transactions with related parties**

There is an outstanding balance of £10,767 (2017: £5,000) owed to Lorenzo Tallarigo at year end. This was paid in January 2019. There were no other outstanding balances in respect of transactions with Directors and connected persons at 31 December 2018 (2017: none). Key person remuneration can be seen in note 5 of the financial statements.

Other matters  
**Glossary**

**Oxford Biomedica specific terminology**

**LentiVector platform**

Oxford Biomedica’s LentiVector platform technology is an advanced lentiviral vector based gene delivery system which is designed to overcome the safety and delivery problems associated with earlier generations of vector systems. The technology can stably deliver genes into cells with up to 100% efficiency and can integrate genes into non-dividing cells including neurons in the brain and retinal cells in the eye. In such cell types, studies suggest that gene expression could be maintained indefinitely. The LentiVector platform technology also has a larger capacity than most other vector systems and can accommodate multiple therapeutic genes.

**OXB-102: Parkinson’s disease**

OXB-102 is a gene-based treatment for Parkinson’s disease, a progressive movement disorder caused by the degeneration of dopamine producing nerve cells in the brain. OXB-102 uses the Company’s LentiVector platform technology to deliver the genes for three enzymes that are required for the synthesis of dopamine. The product is administered locally to the region of the brain called the striatum, converting cells into a replacement dopamine factory within the brain, thus replacing the patient’s own lost source of the neurotransmitter.

**OXB-201: “wet” age-related macular degeneration**

OXB-201 is a gene-based treatment for neovascular “wet” age-related macular degeneration (AMD) and diabetic retinopathy (DR). OXB-201 aims to preserve and improve the vision of patients through anti-angiogenesis; blocking the formation of new blood vessels. The product uses the Company’s LentiVector platform technology to deliver two anti-angiogenic genes, endostatin and angiostatin, directly to the retina.

**SAR 422459: Stargardt disease**

SAR 422459 is a gene-based therapy for the treatment of Stargardt disease. The disease is caused by a mutation of the ABCR gene which leads to the degeneration of photoreceptors in the retina and vision loss. SAR 422459 uses the Company’s LentiVector platform technology to deliver a corrected version of the ABCR gene. A single administration of the product directly to the retina could provide long-term or potentially permanent correction.

**SAR 421869: Usher syndrome type 1B**

SAR 421869 is a gene-based therapy for the treatment of Usher syndrome 1B. The disease is caused by a mutation of the gene encoding myosin VIIA (MYO7A), which leads to progressive retinitis pigmentosa combined with a congenital hearing defect. SAR 421869 intends to address vision loss due to retinitis pigmentosa by using the Company’s LentiVector platform technology to deliver a corrected version of the MYO7A gene. A single administration of the product could provide long-term or potentially permanent correction.

**OXB-202: corneal graft rejection**

OXB-202 is a gene-based treatment for the prevention of corneal graft rejection. Corneal grafting arises from a need to remove and replace pathology arising in the cornea causing ‘clouding’. Although one of the most successfully transplanted tissues, a significant number of grafts are rejected due to vascularisation. OXB-202 uses the Company’s LentiVector platform technology to deliver endostatin and angiostatin ex vivo to donor corneas prior to transplant in order to block vascularisation and to prevent graft rejection.

**OXB-302 (CAR-T 5T4): cancer**

OXB-302 aims to destroy cancerous cells expressing the 5T4 tumour antigen. It uses the Group’s LentiVector platform and 5T4 antigen to target cancer cells expressing 5T4 tumour antigen expressed on the surface of most solid tumours and some haematological malignancies.

Terminology not specific to Oxford Biomedica

AAV

Adeno-associated viruses (AAV) is a small virus which infects humans and some other primate species.

Biologics License Application (BLA)

The BLA is a request for permission to introduce or deliver for introduction, a biological product into the US market.

CAR-T therapy

Adoptive transfer of T cells expressing Chimeric Antigen Receptors (CAR) is an anti-cancer therapeutic as CAR-modified T cells can be engineered to target virtually any tumour associated antigen.

Cell therapy

Cell therapy is defined as the administration of live whole cells in a patient for the treatment of a disease often in an ex vivo setting.

Clinical trials (testing in humans)

Clinical trials involving new drugs are commonly classified into three phases. Each phase of the drug approval process is treated as a separate clinical trial. The drug-development process will normally proceed through the phases over many years. If the drug successfully passes through all phases it may be approved by the regulatory authorities:

- Phase I: screening for safety.
- Phase II: establishing the efficacy of the drug, usually against a placebo.
- Phase III: final confirmation of safety and efficacy.

CTL019

CTL019 is a CAR-T cell therapy for patients with B cell cancers such as acute lymphoblastic leukemia (ALL), B cell non-Hodgkin lymphoma (NHL), adult disease chronic lymphocytic leukemia (CLL) and diffuse large B cell lymphoma.

DLBCL

Diffuse large B-cell lymphoma (DLBCL) is a cancer of B cells, a type of white blood cell responsible for producing antibodies. It is the most common type of non-Hodgkin lymphoma among adults.

DNA

Deoxyribonucleic acid (DNA) is a molecule that carries genetic information.

Ex Vivo

Latin term used to describe biological events that take place outside the bodies of living organisms.

FDA

US Food and Drug Administration (FDA) is responsible for protecting the public health by assuring the safety, effectiveness, quality, and security of human and veterinary drugs, vaccines and other biological products, and medical devices.

Gene therapy

Gene therapy is the use of DNA to treat disease by delivering therapeutic DNA into a patient’s cells which can be in an ex vivo or in vivo setting. The most common form of gene therapy involves using DNA that encodes a functional, therapeutic gene to replace a mutated gene. Other forms involve directly correcting a mutation, or using DNA that encodes a therapeutic protein drug to provide treatment.

GxP, GMP, GCP, GLP

GxP is a general term for Good (Anything) Practice. GMP, GCP and GLP are the practices required to conform to guidelines laid down by relevant agencies for manufacturing, clinical and laboratory activities.

Innovate UK

Innovate UK is the UK’s innovation agency. Its role is to stimulate innovation, working with business and other partners, in order to accelerate economic growth.

In Vitro

Latin term (for within the glass) refers to the technique of performing a given procedure in a controlled environment outside of a living organism.

In Vivo

Latin term used to describe biological events that take place inside the bodies of living organisms.

IP

Intellectual Property (IP) refers to creative work which can be treated as an asset or physical property. Intellectual property rights fall principally into four main areas; copyright, trademarks, design rights and patents.

Lentiviral vectors

Gene delivery vector based on lentiviruses.

Pre-clinical studies

Pre-clinical studies (also known as non-clinical studies) is the stage of research that takes place before clinical trials can begin during which important feasibility, iterative testing and drug safety data is collected.

r/r paediatric ALL

Relapsed or refractory (r/r) acute lymphoblastic leukaemia (ALL) is a type of cancer in which the bone marrow in children and young adults make too many immature B lymphocytes (a type of white blood cell) that are resistant to treatment.

UK Corporate Governance Code (the Code)

The UK Corporate Governance Code is published by the UK Financial Reporting Council and sets out standards of good practice in relationship to board leadership and effectiveness, remuneration, accountability and relations with shareholders.

Viral vectors

Are tools commonly based on viruses used by molecular biologists to deliver genetic material into cells.

Definitions of non-GAAP measures

Operating EBITDA

Operating EBITDA (Earnings before Interest, Tax, Depreciation, Amortisation, revaluation of investments and share based payments) is a non-GAAP measure and is often used as a surrogate for operational Cash flow.

Operating EBIDA

Operating EBIDA is an internal measure used by the Group, defined as Operating EBITDA with the R&D tax credit included.

Gross income

Gross income is the aggregate of Revenue and Other operating income.

Adjusted Operating expenses

Being Operating espenses before Depreciation, Amortisation and Share based payments and the revaluation of investments.

Cash burn

Cash burn is net cash generated from operations plus net interest paid plus capital expenditure.

Other matters

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