

Focusing on gene therapy success. Annual report and accounts 2013

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## Introducing Oxford BioMedica

Oxford BioMedica (OXB) is one of the leading companies in Advanced Therapy Medicinal Products (ATMPs), a classification which covers gene and cell therapy medicinal products, and tissue engineered products. We have a platform of exclusive, pioneering technologies and capabilities on which we design, develop and manufacture unique gene-based medicines. Our product pipeline addresses diseases for which there is currently no treatment or that are inadequately treated today, including ocular diseases, neurodegenerative disorders and cancer. Our product candidates have the potential to transform treatment landscapes.

## Our mission

We have a unique contribution to make to healthcare. Our mission is to build a leading, profitable biopharmaceutical company founded on the successful development and commercialisation of breakthrough gene-based medicines.

Through our in-house development programmes and collaborations with leading industry partners, our goal is to improve the lives of patients with debilitating and life-threatening diseases while creating shareholder value.

**Our business is strongly positioned for success in the rapidly evolving gene and cell therapy sector**

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## A well-rounded investment proposition

### **Targeting unmet global healthcare needs**

We have seven gene therapy products in development, addressing ocular and central nervous system disorders.



Page 02

### **A rapidly emerging biotechnology business**

Our unique combination of capabilities and premium development and manufacturing services are creating new revenue streams.



Page 04

### **Confidence in gene and cell therapy is gathering momentum**

Using gene and cell therapy as mainstream treatments is now closer than ever. We are well-placed to benefit as rising interest boosts the value of companies in our sector.



Page 06

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## A unique, high-value business model

Building on a unique platform that combines our intellectual property, know-how and facilities, our business is now strongly positioned to succeed in the rapidly evolving gene and cell therapy sector.



See our business model in detail on page 14

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## A winning strategy

Our strategy over the next three years is to develop our product candidates to their next value inflection points whilst also continuing to build a valuable revenue-generating manufacturing and development services business.



See our strategy in action on page 20

# Targeting unmet global healthcare needs

**Our LentiVector® technology is one of the leading gene delivery systems available. We have moved our development focus decisively towards gene-based medicines with broad-based and high-growth market appeal.**

### **Changing healthcare landscape**

Oxford BioMedica's strategy is aligned with the shift from the blockbuster model to personalised healthcare, specialty medicines and innovative, targeted therapeutics to solve unmet medical needs. This shift will accelerate as payers and policy-makers look towards more effective treatments that will make a significant impact on reducing the increasing social burden resulting from ageing populations.

### **Our seven named product candidates in development target unmet and poorly treated disease areas**

Ranging from the pre-clinical phase to Phase I/IIa, two of our products are already licensed by Sanofi. One product, now approaching the end of Phase I, is under option with Sanofi. Two will soon enter Phase I while two are currently pre-clinical. Meanwhile, we also continue to explore other concepts currently at an earlier stage.







We have seven gene therapy products in development, addressing ocular and central nervous system disorders

# A rapidly emerging biotechnology business

**Our broad range of experience and expertise covers every phase of the product development cycle – from research and development to clinical trial management through to regulatory and manufacturing.**

As a critical part of our unique platform, our in-house know-how continues to drive our product candidate programmes. At the same time, it also makes us a valued partner to other companies working with Advanced Therapy Medicinal Products (ATMPs), a classification that covers gene and cell therapy medicinal products, and tissue engineered products.

### **Powerful platform**

The two other components of our platform are our intellectual property and our manufacturing facilities. The combined strengths of this platform and our capabilities continue to win recognition.

In 2013, for example we:

- signed a milestone collaboration agreement with Novartis;
- continued to work with Immune Design under our 2012 master services agreement;
- granted GlaxoSmithKline a non-exclusive licence option;
- continued to collaborate closely with Sanofi; and
- in addition, we also won a £71 million package of grant and loan funding from the UK Government.

### **Reducing cash burn**

The growing income from our development and manufacturing activities is helping to reduce our net cash burn, making us a more attractive investment proposition.

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Our unique combination of capabilities and premium development and manufacturing services are creating new revenue streams



# Confidence in gene and cell therapy is gathering momentum

**Experience and promising clinical trial results are building confidence, driving gene and cell therapy towards the medical mainstream. Interest from the industry and investors is also growing rapidly.**

### **Gene therapy is attracting growing attention**

Last year, the NASDAQ Biotechnology Index (NBI) rose by 60%. Merger and acquisition (M&A) activity is higher than ever before, funding is beginning to flow and collaborations are proliferating.

### **Moving towards mainstream medicine**

Since Glybera® won EU approval, Big Pharma players such as Sanofi, Novartis and GlaxoSmithKline are paying greater attention to our sector. Their interest is driven by the growing recognition that gene and cell therapy can offer a number of game-changing advantages over drug therapy. Among other benefits, it is capable of providing a cure rather than simply easing the symptoms. Currently, there are more than 1,200 open trials worldwide, of which 62 are in Phase III and 197 are in Phase II\*.

### **Winning worldwide recognition**

We are winning worldwide recognition for our expertise in lentiviral gene therapy delivery technology that targets unmet medical needs for chronic and inherited diseases.

\* Source: 'Gene therapy: the time is now', Lazard Capital Markets, March 2013



Using gene and cell therapy as mainstream treatments is now closer than ever. We are well placed to benefit as rising interest boosts the value of companies in our sector

# Product pipeline

Technology platform	Product
<b>LentiVector®</b> Ophthalmology	<b>RetinoStat®</b> Gene-based treatment for neovascular “wet” age-related macular degeneration (AMD) which aims to preserve and improve vision.
	<b>StarGen™</b> Gene-based treatment for Stargardt disease, which delivers a healthy version of the ABCR gene to address vision loss.
	<b>UshStat®</b> Gene-based treatment for the treatment of Usher syndrome type 1B. The disease leads to progressive retinitis pigmentosa combined with a congenital hearing defect.
	<b>EncorStat®</b> Gene-based treatment for the prevention of corneal graft rejection.
	<b>Glaucoma-GT</b> Gene-based treatment for chronic glaucoma which aims to provide long-term control of intraocular pressure to minimise the risk of vision loss.
<b>LentiVector®</b> Central Nervous System	<b>ProSavin®/OXB-102</b> Gene-based treatment for Parkinson’s disease which converts cells into a dopamine “factory”, thus replacing the patient’s own lost source of dopamine.
	<b>MoNuDin®</b> Gene-based treatment for motor neuron disease used to prevent further degeneration of the motor neurons and potentially restore motor function.
<b>LentiVector®</b>	<b>New opportunities</b>
<b>5T4 Antigen</b> Cancer	<b>TroVax®</b> A therapeutic vaccine that stimulates the immune system to destroy cancerous cells expressing the 5T4 tumour antigen which is present on most solid tumours.
	<b>Anti-5T4 antibody</b> A 5T4-targeted antibody-drug conjugate (ADC) which binds to 5T4 on the surface of cancerous cells. Once bound, the complex is internalised by the tumour cell, the anti-cancer agent is released from the antibody, and the free drug kills the cancerous cell.



More information on how our gene therapy products are progressing in our [progress against strategy report on page 22](#)



Find more information on our products at [www.oxfordbiomedica.com/products](http://www.oxfordbiomedica.com/products)

Indication	Stage of development
"Wet" age-related macular degeneration	Phase I trial ongoing Sanofi have option to license
Stargardt disease	Phase I/IIa trial ongoing Licensed to Sanofi
Usher syndrome type 1B	Phase I/IIa trial ongoing Licensed to Sanofi
Corneal graft rejection	Phase I/II trial preparation
Chronic glaucoma	Pre-clinical
Parkinson's disease	ProSavin® Phase I/II trial completed OXB-102 pre-clinical nearing completion
Motor neuron disease	Pre-clinical
Various	Research concept
Colorectal cancer, ovarian cancer, mesothelioma	Phase II trials ongoing
Cancer	Phase I trial ongoing Licensed to Pfizer

## Chairman's message

**In my previous Chairman's message, I said that we were seeing greater interest than ever in gene therapy and 2013 has seen a continuation of this trend with a step up in both financing and M&A activity involving gene therapy companies and projects. Much of the financing was driven from the USA and the NASDAQ Biotechnology Index (NBI) rose by 60% during 2013.**

2013 also saw the publication by the Food and Drug Administration (FDA) of its draft guidance on the Breakthrough Therapy Designation, which was created under s902 of the 2012 FDA Safety and Innovation Act (FDASIA). This is potentially very significant and positive for the development of drugs for conditions of unmet or poorly met medical needs. And recently in 2014, the UK Government has announced an Early Access to Medicines scheme. These developments are likely to be beneficial for the development of gene therapy and we will follow them closely.

### **Oxford BioMedica developments**

#### **Beside our long-term relationship with Sanofi, we signed deals with two other major pharmaceutical companies...**

In 2013, we turned some of this growing interest into reality. Beside our long-term relationship with Sanofi, we signed deals with two other major pharmaceutical companies: Novartis and GlaxoSmithKline. We are providing Novartis with process development services and manufacturing clinical grade material for its CTL019 programme using our LentiVector® gene delivery technology. We granted GSK an option to a non-exclusive licence under our LentiVector® platform technology patents for the development and commercialisation of up to six product candidates targeting rare orphan diseases.

We also received support for our manufacturing strategy from the UK Government's Advanced Manufacturing Supply Chain Initiative (AMSCI), which awarded us a £7.1 million package of grant and loan funding to expand our capacity; improve our manufacturing processes; and develop a centre of excellence in Oxford for the specialist manufacture of Advanced Therapy Medicinal Products (ATMPs).

We believe that these relationships are a clear validation of our platform technology and our expertise.

#### **We are steadily building a portfolio of gene therapy product candidates...**

We are steadily building a portfolio of gene therapy product candidates. We currently have seven named candidates ranging from StarGen™ and UshStat®, which are in Phase I/IIa studies and already licensed to Sanofi; through to MoNuDin®, which is still in early pre-clinical studies. We are also exploring a number of other concepts which could be brought through into pre-clinical development in future.

#### **I am immensely proud of our employees who investigated the impurity issue with great urgency...**

However, we did have a setback in June 2013 when we voluntarily paused recruitment into our clinical studies as a precautionary measure while we investigated a potential impurity. I am immensely proud of our employees who investigated this issue with great urgency. They were able to demonstrate that there were no safety concerns arising and gained agreement within five months from both the FDA and the French regulatory agency, ANSM, to resume recruitment into the clinical studies. Once again, this demonstrates the quality of our people.



**Nick Rodgers**  
Chairman



## We continue to work towards building a financially self-sustaining company...

We continue to work towards building a financially self-sustaining company, based on our proprietary LentiVector® platform, targeting high-value, fast-growing markets such as ophthalmology.

We see potential for several sources of revenue, as follows:

- partnering or licensing out our existing product portfolio;
- developing new product opportunities that can be partnered or licensed in the future;
- providing specialist development and/or manufacturing services to third parties; and
- our intellectual property.

In addition, the Board will continue to evaluate potential complementary acquisitions as a means to secure commercial success.

### Financing and going concern

Financing remains a challenge. We are pleased to have the continued support of Vulpes Life Sciences Fund (Vulpes), our largest shareholder, and we saw this in the form of the loan facility that we announced in November 2013.

### Going concern

The Group is continuing to develop its product pipeline and absorbs cash in doing so. Although it is starting to generate revenues from selling development and manufacturing services, these currently only cover a small portion of the Group's cost base. The Directors estimate that the cash held by the Group including known receivables and future funding available under the Vulpes loan facility will be sufficient to support the current level of activities into the third quarter of 2014. This estimate does not include the benefit of any upfront receipts from licence deals, including the potential option fee which would be payable by Sanofi should they exercise their option over RetinoStat®. The Directors also continue to explore other sources of finance available to the Group. Taking account of these together the Directors have confidence that they will be able to secure sufficient cash inflows for the Group to continue its activities for the foreseeable future, being not less than 12 months from the date of these financial statements, and have therefore prepared the financial statements on a going concern basis.

These circumstances nonetheless represent a material uncertainty which may cast significant doubt on the Group's ability to continue as a going concern. Should the Group be unable to obtain further funds, adjustments would be required to reduce balance sheet values of assets to their recoverable amounts, to provide for further liabilities that might arise and to reclassify fixed assets as current assets.

### Conclusion

Despite some significant challenges, last year saw great operational progress and the dedication of the staff at Oxford BioMedica has been exemplary. The Board is cautiously confident that the current year will bring further significant success and take us closer to achieving our goal of financial self-sufficiency.

**Nick Rodgers**  
Chairman

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**"2013 at Oxford BioMedica saw challenges as well as great operational progress and we will continue to strive towards achieving our goal of becoming a leading and financially self-sustaining gene therapy company."**

**"We are steadily building a portfolio of gene therapy product candidates. We currently have seven named candidates ranging from StarGen™ and UshStat®, which are in Phase I/IIa studies and are already licensed to Sanofi; through to MoNuDin®, which is still in early pre-clinical studies."**

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# £7.1m

£7.1 million in grant and loan funding from the Government's Advanced Manufacturing Supply Chain Initiative (AMSCI) is a vote of confidence in our manufacturing strategy

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# +60%

60% rise in the NASDAQ Biotechnology Index (NBI) during 2013 indicates a significant increase in interest among key investors

## Operational highlights

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# £1.8m

Won £1.8 million in grant funding from UK Government's Technology Strategy Board to support next development phase of EncorStat®

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# 6 products

Granted GSK an option to a non-exclusive licence under our LentiVector® platform technology patents, for the development and commercialisation of up to six product candidates targeting rare orphan diseases

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# US\$1m

US\$1 million milestone payment received from Pfizer, triggered by entry into human clinical trials of PF-06263507, a 5T4-targeted investigational antibody therapy

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# £7.1m

Government's Advanced Manufacturing Supply Chain Initiative awarded Oxford BioMedica a £7.1 million grant and loan funding package, further recognition of our potential to become a world-leader in Advanced Therapy Medicinal Products (ATMPs) manufacture and supply chain

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# £5m

£5 million loan facility from Vulpes Life Sciences Fund, our largest shareholder, will give us additional time to deliver our operational objectives

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# £2.5–£4m

Collaboration agreement with Novartis to provide development services and manufacture clinical grade material encoding CTL019 expected to be worth between £2.5 million and £4 million over 12 months

## Key financial performance indicators

# £5.4m

Total revenues £5.4 million (2012: £7.7 million). Although revenues dropped, the charts below show a significant change in their composition

# £2.6m

Total revenues include profit-generating revenues £2.6 million (2012: £0.1 million)

# £11.9m

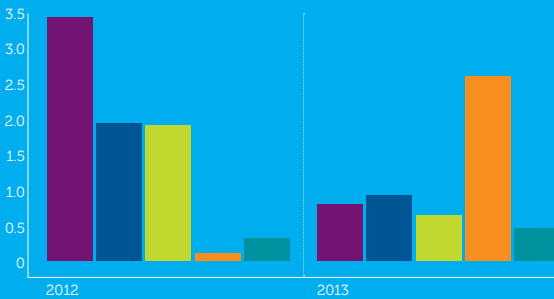
Cash burn (net cash used in/generated from operations plus sales and purchases of non-current assets and interest received) £11.9 million (2012: £10.5 million)

# £2.2m

Cash balance (total of cash, cash equivalents and current financial investments) £2.2 million (£14.1 million at the start of the year)

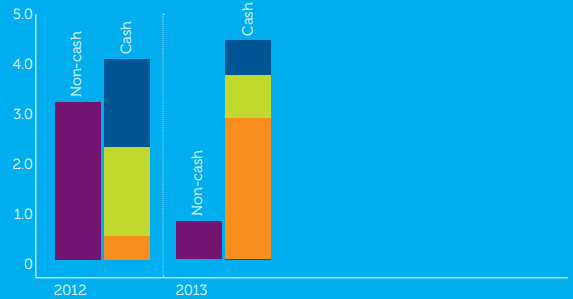
# 106 people

Headcount increased to 106 employees (81 at the start of the year) to support manufacturing revenue generation



Revenue analysis £m

- Deferred
- R&D reimbursement
- Milestones/options
- Development/manufacturing
- Licence/other



Non-cash versus cash revenue £m

- Deferred
- One-off items
- R&D reimbursement
- Recurring

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# €16bn

Ophthalmology is a high growth market estimated to be worth €13.4 billion in 2011, increasing to €16 billion worldwide by 2016

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# \$6.5bn

Glaucoma has an estimated market size of \$6.5 billion by 2017

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# 90%

Neovascular "wet" AMD accounts for 90% of all severe vision loss from the disease with up to 4.5 million patients worldwide

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# \$3.5bn

Parkinson's disease has an estimated market size of \$3.5 billion by 2018

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# 2.8m

Parkinson's disease affected approximately 2.3 million patients in 2011 in the seven major markets (US, Japan, UK, France, Germany, Italy and Spain), projected to rise to 2.8 million by 2021

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# 30,000

In the US, there are an estimated 30,000 patients with ALS and nearly 6,000 new cases are diagnosed annually

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# \$36.8bn

The cancer targeted therapies and immunotherapy market was \$19.5 billion in 2009, forecast to increase to \$36.8 billion in 2019



**We are a business at the forefront of gene and cell therapy, with a unique combination of skills, facilities and intellectual property.**

### **The therapies we are pioneering**

Gene and cell therapy is at the forefront of medical science and has the potential to transform treatment options for some of the most difficult diseases and disorders. For many genetic diseases, replacing the defective gene with a normal one may be the patient's only therapeutic option. With the possibility of a one-off treatment lasting many years or even a lifetime, gene therapy may be cost effective by eliminating expensive ongoing care, interventions and complications.

### **The foundations of our business**

We are building our business on our unique platform – a combination of our intellectual property, the range and skills of our workforce, and our facilities which include our GMP-approved manufacturing site.

### **Exploiting the platform**

We are using the platform for two main purposes. First and foremost, we are developing a pipeline of gene therapy products. And secondly we are starting to build a profitable business through providing development and manufacturing services to collaborators and partners working in gene and cell therapy. We call this business 'OXB Solutions' as we are able to provide solutions for our partners to their complex technical problems. The revenues and profits from OXB Solutions will be used to offset the costs of our platform and, over time, we aspire to reach the point where the overall business will start to make a profit.



Read more about our business model on the following pages...



We are developing a pipeline of gene therapy products, and starting to build a profitable business through providing development and manufacturing services called OXB solutions

## Our business model



The new medicines and treatments we are developing could improve life for millions of people

### Gene therapy explained

Gene and cell therapy requires the delivery of therapeutic DNA to patients' cells, either *in vivo* or *ex vivo*. This is achieved using viral vectors – viruses which have been modified so they are safe and can carry the required genetic payload. The most commonly used viruses are adeno-associated viruses (AAV) and lentiviruses. Lentivirus-based vectors have several advantages over AAV-based vectors – they can carry larger genetic payloads, they can modify both dividing and non-dividing cells, and can be used in cell therapy as well as gene therapy.

### A unique foundation/platform

Underpinned by a unique platform which combines our intellectual property (IP), know-how and facilities, we are recognised as a world leader in the development of Advanced Therapy Medicinal Products (ATMPs), particularly gene therapy products.

Our technology is protected by a more extensive patent portfolio covering lentiviral technology than any other commercial organisation or academic institution. Taken together, our patents, know-how and in-house capabilities give us an industry-leading platform on which we can develop ATMPs generally and gene therapy products in particular.

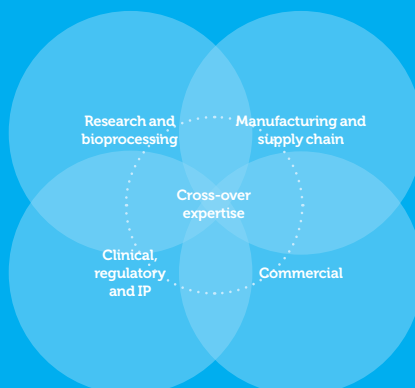
### Exploiting our platform...

Although the primary purpose of our in-house resources is to support the development of our own product pipeline, we are regularly approached by third parties who want to access our skill sets, know-how and capacity.

This is opening up new opportunities to generate revenues by using surplus capacity to provide development and manufacturing services to these third parties through OXB Solutions. This will allow us to reduce net cash burn and develop our product pipeline at a lower aggregate cost.

### LentiVector® technology

Oxford BioMedica's proprietary LentiVector® technology is a highly efficient system for the delivery of therapeutic genes to a wide range of tissues using lentiviruses. It is designed to overcome the safety and delivery problems associated with earlier generations of vector systems.



## Our exclusive technology

Although the primary purpose of our in-house resources is to support the development of our own product pipeline, we are regularly approached by third parties who want to access our skill sets, know-how and capacity.

This is opening up new opportunities to generate revenues by using surplus capacity to provide development and manufacturing services to these third parties. In this way, we can effectively reduce net cash burn across our cost base and develop our product pipeline at a lower aggregate cost. Gene therapy involves inserting one or more corrective gene(s) that have been designed in the laboratory into the genetic material of a patient's cells to cure a genetic disease. The most common form of gene therapy involves using DNA that encodes a functional, therapeutic gene to replace a mutated gene.

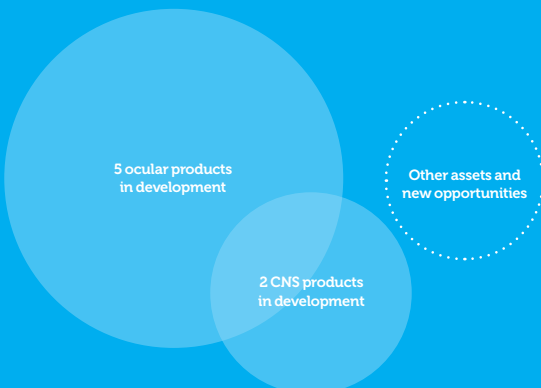
## LentiVector® is one of the best delivery systems available...

Our capabilities are underpinned by our proprietary LentiVector® technology, an advanced lentiviral vector-based gene delivery system designed to overcome the safety and delivery problems associated with earlier generations of vector systems.

This technology can reliably deliver genes into cells and can integrate genes into non-dividing cells, including neurons in the brain and retinal cells in the eye. In these cell types, studies suggest that gene expression could be maintained indefinitely. LentiVector® technology also has a larger capacity than most other vector systems and can accommodate multiple therapeutic genes.

## Seven named gene therapy products in development

LentiVector® is one of the most advanced gene delivery technology systems available. We are using it to develop treatment products that address diseases for which there is currently no treatment or that are inadequately treated today, including ocular diseases, neurodegenerative disorders and cancer. These product candidates have the potential to transform treatment landscapes.



## Our pioneering therapies

The majority of our gene therapy product candidates use our LentiVector® technology to treat eye disorders. The eye is widely thought to be a particularly suitable target area for gene therapy because it is relatively small and largely self-contained. Also the ophthalmology drug market is a large and growing market.

We are also currently working on two central nervous system (CNS) candidates in Parkinson's disease (PD) and motor neurone disease (MND). In addition we are exploring other research concepts, mainly but not exclusively in ophthalmology, with a view to identifying further candidates to bring into pre-clinical development over the next two to three years.

## Our other assets...

We also have product candidates in cancer based on our proprietary 5T4 tumour antigen, a potentially valuable target for anti-cancer interventions given its restricted expression in normal tissues and its high prevalence on the surface of both primary and metastatic cancerous cells.

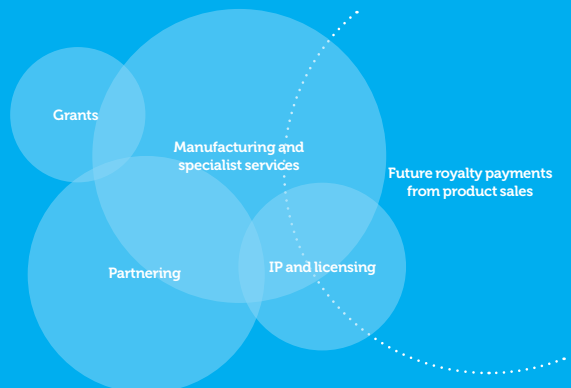
TroVax® is a therapeutic vaccine that stimulates the immune system to destroy cancerous cells expressing the 5T4 tumour antigen. We have out-licensed the technology to Pfizer, which is developing a 5T4-targeted antibody therapy.



See our product pipeline on page 08

## Building a profitable business

There are several potential revenue streams, they include: partnering or licensing out our existing product portfolio; developing new product opportunities that can be partnered or licensed in the future; providing specialist development and manufacturing services to third parties; and licensing revenues from our intellectual property.



## Chief Executive's review

**I believe that during 2013 and the first three months of 2014 the Company's position has strengthened considerably, despite the challenges presented by the temporary suspension of our clinical studies and the difficult funding environment.**

During 2013 we identified a potential impurity in our clinical study material through the use of highly sensitive analytical methods designed to enhance the characterisation of our products. I was delighted by the way our employees responded to this challenge by identifying the nature of the impurity and communicating very effectively with the relevant regulatory authorities and other stakeholders.

Although we faced and overcame the substantial challenge of having to suspend our clinical studies for five months, our ocular clinical studies have continued to progress. We are now working to move OXB-102 and EncorStat® into Phase I studies and we are following these up with two pre-clinical product opportunities.

Our collaboration with Novartis was a major milestone for the Company as it highlighted the potential we have to generate revenues by providing services to third parties and reduce our cash burn. In 2013 we were awarded grants and loans that will be a major support in advancing EncorStat® and strengthening our manufacturing and supply chain capabilities.

### **Gene therapy portfolio progress**

We are building an extensive portfolio of gene therapy products at various stages of development. StarGen™ and UshStat® are already in Phase I/IIa studies and are now licensed to Sanofi. Sanofi will take these products forward and we will be entitled to development milestones and, in due course, royalties on sales.

Following the resumption of the clinical studies, we have now completed the recruitment and dosing of the 21 patients required for the RetinoStat® Phase 1 study. Indicative results from the study are expected towards the end of 2014 and I look forward to reviewing these with Sanofi. As part of the StarGen™ and UshStat® licence negotiations with Sanofi, I was very pleased to be able to negotiate the return to us of full rights to EncorStat® in exchange for granting Sanofi wider indication rights to StarGen™ and UshStat®.

I believe that niche ocular indications have significant market value. Therefore, I am excited by the opportunity to execute our plans and to progress EncorStat® into Phase I. We have been awarded a £1.8 million grant for EncorStat®, which will fund a significant portion of this programme.

OXB-102, the follow-on to ProSavin®, has steadily progressed through pre-clinical studies in 2013 and these will be completed in 2014. We are already working on the best way to take this product into clinical studies. Glaucoma-GT and MoNuDin® are both also progressing satisfactorily through pre-clinical studies and I hope that these could be ready to enter Phase I studies in two to three years.

### **Manufacturing and development services**

***Our collaboration agreement with Novartis marks the start of a profitable business that will generate revenues from third parties to help reduce our net cash burn...***

In 2013 we were able to build on the GMP qualification in 2012 of our manufacturing facilities by starting to manufacture for our own product development needs as well as for third parties. We were delighted to enter a collaboration agreement with Novartis in which we are providing process development services and also manufacturing clinical-grade material for its exciting CTL019 project. I see this as the start of building a profitable business that will generate revenues from third parties and help us to reduce our net cash burn.

As well as the Novartis contract, we were also delighted to be awarded a £7.1 million package of grant and loan funding from the UK Government that will allow us to expand the capacity of our manufacturing facility and to develop better manufacturing processes to increase volume output and yield and so start to reduce the manufacturing cost per patient dose.



**John Dawson**  
Chief Executive Officer



## 5T4 antigen technology platform

### **In August, we received a US\$1 million development milestone from Pfizer, triggered by the start of a clinical study for its 5T4-targeted antibody therapy...**

There are now three investigator-led Phase II studies for TroVax® underway in the UK. All of these studies are using a biomarker to select patients for the studies. We are contributing clinical study material to these studies. Other expenditure on the studies is modest.

I was delighted that we were able to announce in August that we had received a US\$1 million development milestone from Pfizer, which was triggered by the initiation of a clinical study for its 5T4-targeted antibody therapy.

### **Partnering and licensing**

#### **We regularly attend meetings to identify potential partners for our unlicensed products...**

Our business model is based on the assumption that we will need to partner or out-license our products at some point in their development. Therefore, we regularly attend business development meetings where we identify potential partners for our unlicensed products. However, to maximise the return to shareholders, I believe it is in our interests to do this later rather than earlier.

We also meet companies working with lentiviral vectors to discuss their need for licences to use our IP. In December, we announced that we have granted GSK an option to license our technology for up to six product candidates targeting rare orphan diseases.

### **Share price and funding**

#### **The funding environment in the UK capital markets remained difficult for biotechnology companies...**

Despite the increasing interest in gene therapy internationally and particularly in the USA, where market valuations for biotechnology companies, including gene therapy companies, have risen strongly, our share price at the end of the year was only slightly above the opening price.

The funding environment in the UK capital markets remained difficult for biotechnology companies and we did not identify a suitable opportunity to strengthen our balance sheet in 2013. I am grateful to Vulpes Life Sciences Fund, our largest shareholder, for making a £5 million loan facility available to us, and to our shareholders for approving this related-party transaction, which will give us additional time to deliver our operational objectives.

### **Outlook**

#### **During 2014, the RetinoStat® Phase I study initial results should become available...**

In 2014, we will build on the substantial achievements of 2013. Our gene therapy products should all continue to make progress. In particular, the RetinoStat® Phase I initial study results will become available towards the end of the year. I remain confident that RetinoStat® is a highly attractive product candidate which will either be licensed by Sanofi, who have an option to do so, or another company should Sanofi choose not to.

We also plan to make significant strides towards developing our emerging revenue-generating business opportunity by providing high-margin development and manufacturing services that will, over time, allow us to reduce our cash burn significantly.

### **John Dawson**

Chief Executive Officer

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**"In 2014, we aim to make significant strides towards developing our emerging revenue generating business opportunity by providing high-margin development and manufacturing services that will, over time, allow us to reduce our cash burn significantly."**

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# £1.8m

£1.8 million of UK Government funding will finance a significant portion of our programme to progress EncorStat® into Phase I

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# £5m

£5 million loan facility from Vulpes Life Sciences Fund, our largest shareholder, will give us additional time to deliver our operational objectives

## Strategy in action

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### **Our strategy is to...**

Build and grow a financially self-sustaining company by using our proprietary LentiVector® technology platform to target high-value, rapidly expanding markets such as ophthalmology.

Our business has evolved from being a research-driven organisation into a more commercially-focused company.

Our strategic approach for the next two to three years is underpinned by three core objectives:

- Progress product candidates to the next critical decision point
- Assess the optimum point at which to enter into partnerships
- Build OXB Solutions into a profitable business and reduce the group's cash burn

### **Progress product candidates to the next key decision points**

Currently, we have seven named treatment candidates at different stages of development, from the pre-clinical phase to Phase I/IIa. StarGen™ and UshStat® are already licensed by Sanofi. RetinoStat®, now approaching the end of Phase I, is under option with Sanofi. EncorStat® and OXB-102 will soon enter Phase I while Glaucoma-GT and MoNuDin® are pre-clinical. We aim to progress each product through development as fast as possible.

### **Assess the optimal point at which to partner**

When it comes to securing successful partnerships, timing is of the essence.

The value of each product candidate rises incrementally as it passes through each successive phase in the development process. But, so do the development costs and risks.

To balance these factors, we progress our candidate products through the final stages of development and onto the market through partnerships or licensing agreements.

We select suitable partners on a product-by-product basis and we take rigorous measures to ensure we sign agreements at the optimum point in each product's development.

### **Build a profitable OXB Solutions business and reduce the Group's cash burn**

The value of our unique platform is winning widespread recognition among our peers and their demand for our IP, know-how and facilities is intensifying. We are now taking active steps to capitalise on this demand by offering our skills and expertise to third parties. The profitable revenues from these activities will help to reduce our cash burn.

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### Key achievements 2013...

- StarGen™'s Drug Safety Monitoring Board gives a positive review to first three patient cohorts (n=12)
- Won £1.8 million in grant funding from UK Government's Technology Strategy Board to support next development phase of EncorStat®
- Pre-clinical proof-of-concept studies for Glaucoma-GT with Mayo Clinic report positive outcome
- ProSavin® Phase I/II study results published in *The Lancet*
- Efficacy arm of OXB-102 non-clinical programme successfully completed, toxicology study continues
- Three investigator-led Phase II TroVax® studies now underway
- TroVax® Phase II prostate cancer data and pre-treatment biomarker analyses published in *Cancer, Immunology, Immunotherapy*

### Focus 2014...

- As RetinoStat®, StarGen™ and UshStat® start to demand less effort from us, allocate resources to the next wave of Phase I-ready projects, in particular EncorStat® and OXB-102
- Ensure that current pre-clinical projects, such as Glaucoma-GT and MoNuDin®, are progressed so they, in turn, become Phase I-ready over the next two to three years
- Identify new opportunities and conduct proof-of-concept work to assess which projects we can consider as candidates for pre-clinical programmes in the next two to three years
- Develop product candidates to next inflection points

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### Key achievements 2013...

- Completion of development and commercialisation licence with Sanofi for StarGen™/UshStat®
- We regain rights to EncorStat® in exchange for licensing broader indications to Sanofi for StarGen™ and UshStat®
- US\$1 million milestone payment received from Pfizer, triggered by entry into human clinical trials of PF-06263507, a 5T4-targeted investigational antibody therapy

### Focus 2014...

- Successfully complete our 2009 collaboration with Sanofi by:
  - completing the handover to Sanofi of the development activities for StarGen™ and UshStat®
  - completing the RetinoStat® Phase I clinical study so that Sanofi has all the information it needs to make its decision on whether or not to license RetinoStat®
- For each project assess whether to develop further in-house or partner/out-license

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### Key achievements 2013...

- Government's Advanced Manufacturing Supply Chain Initiative (AMSCI) awards Oxford BioMedica a £71 million grant and loan funding package, further recognition of our potential to become a world-leader in ATMP manufacture and supply chain
- Successful resolution of the impurity issue that caused us to voluntarily suspend our clinical trials
- Collaboration agreement with Novartis to provide development services and manufacture clinical grade material encoding CTL019
- Granted GSK an option to a non-exclusive licence under our LentiVector® platform technology patents, for the development and commercialisation of up to six product candidates targeting rare orphan diseases
- £5 million loan facility from Vulpes Life Sciences Fund, our largest shareholder, will give us additional time to deliver our operational objectives

### Focus 2014...

- Progress the AMSCI project to expand our manufacturing capability and improve the manufacturing processes
- Develop OXB Solutions business to reduce cash burn and build a valuable business

## Progress against strategy

### Gene therapy

#### Ophthalmology product candidates

In the first few months of the year, we made positive progress with patient recruitment into the three active clinical studies for RetinoStat<sup>®</sup>, StarGen<sup>™</sup> and UshStat<sup>®</sup>. In April 2013, the Drug Safety Monitoring Board (DSMB) for StarGen<sup>™</sup> gave the drug a positive safety review at the end of the third patient cohort. At this point, 12 patients had been treated.

Unfortunately, in June 2013 we had to voluntarily pause recruitment into these studies as a precautionary measure while we investigated a potential impurity that we had detected in the clinical trial material.

Over the next five months, we analysed the impurity, which we were able to identify as highly fragmented DNA derived from foetal bovine serum, which is the most widely-used growth supplement in the industry for cell culture media.

Following the submission of a comprehensive data package to the US Food and Drug Administration (FDA) and France's Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM), we received agreement in October from the US and French regulatory authorities to resume recruitment into the clinical trials using the existing clinical trial material. In all three studies, patient dosing has resumed.

#### **If Sanofi exercises its option on RetinoStat<sup>®</sup>, we will receive an undisclosed option fee...**

We have now completed the recruitment and dosing of the 21 patients required for the RetinoStat<sup>®</sup> Phase I study which will now move into patient follow-up. We hope that Sanofi will decide to exercise its option to enter into a development and commercialisation licence agreement in which case we will receive an undisclosed option fee. If Sanofi does not exercise its option, we are confident that there are other companies that would be interested in licensing a Phase II-ready product candidate for a major indication such as wet age-related macular degeneration (wet AMD).

In February 2014, we announced that we had completed and signed the development and commercialisation licence agreement covering StarGen<sup>™</sup> and UshStat<sup>®</sup> with Sanofi. Under this licence, we will be entitled to undisclosed future development milestone payments and royalties.

We also announced that, in return for broadening the indications to those products, we negotiated the return of EncorStat<sup>®</sup> which was originally included in our 2009 collaboration with Sanofi. We are excited about regaining control of EncorStat<sup>®</sup>. It is a gene-based, tissue-engineered product for preventing corneal graft rejection. EncorStat<sup>®</sup> uses our LentiVector<sup>®</sup> platform technology to deliver endostatin and angiostatin *ex vivo* to donor corneas before transplant to block vascularisation and prevent graft rejection.

#### **We estimate that the potential annual revenue from EncorStat<sup>®</sup> could reach US\$60 million...**

Although corneas are amongst the most successfully transplanted tissues, with over 100,000 grafts performed annually worldwide, a significant number of grafts are rejected due to vascularisation. The prognosis in these patients can be so poor that they are not offered a replacement transplant and are left blind. Given the obvious benefits to both patients and healthcare systems, we estimate that the potential annual revenue from EncorStat<sup>®</sup> could reach US\$60 million.

In November 2013, we confirmed that we had been awarded a grant of £1.8 million by the UK's innovation agency, the Technology Strategy Board (TSB), under the 2013 Supporting Regenerative Medicines and Cell Therapies competition. This grant will make a significant contribution to the costs of the EncorStat<sup>®</sup> Phase I/IIa clinical study which we are now actively planning.

#### **Five years after launch, Glaucoma-GT could generate annual sales approaching US\$200 million...**

Glaucoma-GT is a gene-based treatment for chronic glaucoma. Chronic glaucoma results from a partial blockage within the eye's trabecular meshwork, the tissue primarily responsible for draining the eye's internal fluid, aqueous humour. As the aqueous humour builds up, it causes increased intraocular pressure (IOP), which can damage the optic nerve and lead to premature patches of vision loss or, in some cases, blindness.



#### **OXB know-how**

"Oxford BioMedica's LentiVector<sup>®</sup> platform based products have now been administered to over 50 patients for three ocular indications and for Parkinson's disease; with over five years' experience in the earliest treated patients. The four products have been safe and well-tolerated to date and we were very encouraged by the reception of the Parkinson's clinical trial publication in *The Lancet*."

**Kyriacos Mitrophanous PhD**  
Head of Research



Current treatments are topically applied drugs. These suffer from disadvantages such as wash-out from the eye and poor compliance, which can lead to disease progression and the need for surgery in 10-20% of patients. Surgery is costly, only partially effective and has high failure rates, often requiring the need for repeat procedures.

Glaucoma-GT uses the LentiVector® platform technology in a one-off treatment that delivers two genes – a COX-2 gene and a PGF-2a receptor gene – to the front of the eye, leading to a constant, steady-state production of prostaglandins to reduce IOP leading to long-term therapy. We estimate that five years after its launch, Glaucoma-GT could be generating annual sales approaching US\$200 million.

In November 2013, we announced that the Glaucoma-GT pre-clinical programme conducted in collaboration with the Mayo Clinic in the USA had demonstrated gene expression maintained out to five months. We are now planning to continue the pre-clinical programme by generating the key manufacturing development, safety and efficacy data needed to progress this project to clinical evaluation.



#### **OXB know-how**

"In May 2013 Oxford BioMedica was selected to work with Novartis on their flagship chimeric antigen receptor (CAR) program which targets the CD19 B-cell-antigen for the treatment of leukaemia, a decision which was based on our expertise and competencies in lentiviral vector technology development, manufacturing and analytics. The relationship between the two has worked well and Oxford BioMedica is well-placed to facilitate the process of bringing this exciting treatment through clinical development to the marketplace."

**James Miskin PhD**

Head of Manufacturing Development

#### **Central Nervous System (CNS) product candidates**

##### **In January 2014, The Lancet published results from the ProSavin® Phase I/II study in patients with advanced PD...**

Parkinson's disease (PD) is a progressive, degenerative condition of the CNS with a rising incidence in an ageing population caused by the degeneration of dopamine-producing nerve cells in the brain. The early stages of the disease are effectively managed by oral dopaminergic treatments.

But after five years, around half of patients develop motor problems such as dyskinesias. Treatment options for mid-to-late stage PD patients include deep brain stimulation and apomorphine pumps that are costly and require regular calibration or replacement.

ProSavin®/OXB-102 uses our LentiVector® gene delivery technology to deliver the genes for three enzymes that are required for dopamine synthesis. The product is administered locally to the region of the brain called the striatum, converting cells into a replacement dopamine factory within the brain, replacing the patient's lost source of the neurotransmitter.

In January 2014, *The Lancet* published online results from the ProSavin® Phase I/II study in patients with advanced PD, previously reported in April 2012. According to the key findings published in *The Lancet*, ProSavin® has demonstrated a favourable safety profile and a statistically significant improvement in motor function relative to baseline at six and 12 months post-treatment. We are pleased that our research was recognised by such a highly regarded peer-reviewed journal as *The Lancet*, highlighting the significance of our findings.

##### **Behavioural and movement analysis indicated that OXB-102 is at least five times more potent than ProSavin®...**

Since April 2012, we have been evaluating a more potent product, which we are calling OXB-102, to ensure the greatest chance of success in future randomised Phase II studies by increasing the benefit for patients. We initiated a non-clinical programme in 2012 to evaluate the efficacious dose range of OXB-102 using the gold standard MPTP model of PD.

The efficacy arm of this programme successfully completed in Q3 2013, with Positron Emission Tomography (PET) data analysis demonstrating direct expression of transgenes and that expression following administration of OXB-102 increases relative to ProSavin®. Behavioural and movement analysis also indicated that OXB-102 is at least five times more potent than ProSavin®. These data are encouraging and we are currently completing a non-clinical toxicology and bio-distribution study which we anticipate will conclude during the first half of 2014.

Anticipating a successful outcome of the OXB-102 pre-clinical work, we are now evaluating the best way to take it forward into clinical studies. It is projected that there will be 2.8 million patients with PD in the USA, Japan and the five largest European markets by 2021 (source: *Datamonitor Epidemiology, April 2012*). We believe there is a substantial sales potential for OXB-102 as it represents a significant leap forward from existing treatment strategies.

## Progress against strategy

### In collaboration with VIB/University of Leuven we are exploring novel approaches to treating ALS...

Meanwhile, the pre-clinical development of MoNuDin® is supported by the UK Motor Neurone Disease Association (MNDA).

Although it is one of the most common adult onset neurodegenerative diseases, motor neuron disease has a high unmet need. Amyotrophic Lateral Sclerosis (ALS), often referred to as Lou Gehrig's disease, is the most prevalent type of motor neuron disease (MND). In the US, there are an estimated 30,000 patients with ALS and nearly 6,000 new cases are diagnosed annually (source: ALS Association).

In collaboration with VIB/University of Leuven we are exploring novel approaches to treating ALS. One of the major hurdles to treating motor neuron disease is ensuring that therapeutic agents are delivered to the relevant action site in the brain and spinal cord. An administration route directly into the cerebrospinal fluid bathing the spinal cord has been established. Two forms of vascular endothelial growth factor (VEGF) have since been evaluated using this method.

If MoNuDin® proves to be an effective neuroprotective treatment that can slow or arrest injury to patients' motor neurons, it would have compelling competitive advantages.

### Research concepts

#### We have added several ideas on lentiviral vector product candidates to those we were already exploring...

During the second half of 2013, we conducted an exercise to identify and screen potential concepts for lentiviral vector product candidates which might be suitable for bringing into pre-clinical development. As a result of this exercise, we have added several ideas to those we were already exploring. Many of these ideas, but not all, would be for ophthalmology indications.

### Other assets

#### 5T4 tumour antigen platform

#### Three Phase II TroVax® studies are underway using the biomarker...

Oxford BioMedica's proprietary 5T4 antigen is a unique protein found on most common types of solid cancer. Given its restricted expression in normal tissues and its high prevalence on the surface of both primary and metastatic cancerous cells, it is potentially a valuable target for novel anti-cancer interventions.

TroVax® is a therapeutic vaccine that stimulates the immune system to destroy cancerous cells expressing the 5T4 tumour antigen, which is present on most solid tumours. Using a simple blood test, we have identified a biomarker that predicts both the magnitude of the induced 5T4 antibody response and treatment benefit. This enables us to identify those patients who are most likely to benefit from treatment with TroVax®.

Led by academic collaborators, three sponsored Phase II TroVax® studies are currently underway in the UK in colorectal and ovarian cancers and mesothelioma. All three studies are using the biomarker to select patients for the studies. The studies are expected to conclude during 2015/2016. Our expenditure on these studies is modest and relates primarily to the supply of study material.

The 5T4-targeted antibody therapy, licensed to Pfizer, is an antibody-drug conjugate which binds to the 5T4 antigen on the surface of cancerous cells. Once bound, the complex is internalised by the tumour cell, the anti-cancer agent is released from the antibody, and the free drug kills the cancerous cell. In August 2013, we received a US\$1 million milestone payment from Pfizer, triggered by the entry of Pfizer's product into human clinical trials. The potential value of this licence is up to US\$28 million, comprising upfront payments, option fees and milestone payments.

In 2012 ImaginAb acquired an exclusive worldwide license for commercialisation of an *in vivo* 5T4-based imaging diagnostic. Oxford BioMedica could receive up to US\$4 million in future development milestone payments in addition to royalties on product sales.



#### OXB know-how

"Last September, we won £7.1 million of funding from the UK Government's Advanced Manufacturing Supply Chain Initiative which marks a defining point in recognising Oxford BioMedica as a world-class manufacturer and partner-of-choice for companies seeking manufacturing and process development solutions for gene-based ATMPs. Collaborating with lead specialists in our industry, the funds will be used to fast-track a third, state-of-the-art manufacturing suite and fill finish building at the existing manufacturing facility. This will allow full integration of the supply chain from raw material to clinical and commercial supply."

James Christie BSc MBA  
Head of Manufacturing

## Intellectual property and technology licensing

### We could potentially benefit from future milestone payments and royalties from licensing agreements...

The LentiVector® platform technology is protected by a comprehensive patent portfolio. These patents cover the use of minimal lentiviral vectors, which are essential for clinical applications, and also a number of important safety features. The lives of these patents range from 2017 to 2023. In December 2013, we signed an option agreement with GlaxoSmithKline (GSK) that grants GSK an option to a non-exclusive licence under Oxford BioMedica's LentiVector® platform technology patents for developing and commercialising up to six product candidates targeting rare orphan diseases. Financial terms were not disclosed. We have regular discussions with other companies working with lentiviruses.

Oxford BioMedica could also potentially benefit from future milestone payments and royalties from several other non-LentiVector® platform licensing agreements with partners who are developing mid-to-late stage products including:

#### MolMed, 2004

Licensed Oxford BioMedica's retroviral ex vivo gene delivery technology (TK008 is in Phase III for transplant rejection in patients with acute leukaemia)

#### Bavarian Nordic, 2010

Licensed Oxford BioMedica's heterologous PrimeBoost technology patents and poxvirus patents (PROSTVAC™ is in Phase III for advanced prostate cancer)

#### Emergent BioSolutions, 2010

Licensed Oxford BioMedica's heterologous PrimeBoost technology patents and poxvirus patents (tuberculosis vaccine is in Phase II)

## OXB Solutions

### Development and manufacturing services

#### We have broadened the range of capabilities we can offer to partners and collaborators...

2013 saw a significant development in our business model. In 2012, the UK Medicines and Healthcare products Regulatory Agency (MHRA) approved our manufacturing facility to manufacture bulk drug material for Investigational Medicinal Products (IMPs). This has broadened our range of capabilities for our in-house development projects – and which we can offer to partners and collaborators to help with their programmes.

We are increasingly recognised as having a unique array of skills and expertise in the ATMP arena. In September 2013, we were delighted to be awarded a combination of grant and loan funding worth £71 million as lead member of a consortium we have established to support us in becoming a world-leader in ATMP manufacture and supply chain expertise. The award was made under the UK Government's Advanced Manufacturing Supply Chain Initiative (AMSCI) and recognises the potential we can offer.

Oxford BioMedica, supported by the consortium, will expand its proprietary manufacturing facility in Oxford to incorporate a third production suite and a state-of-the-art fill and finish operation; and develop our capability in serum-free, non-adherent manufacturing techniques. The overall project cost is estimated at £9.2 million and is expected to take two years to complete. The project will bring significant benefits to our clinical programmes and further strengthens our position as a partner of choice for companies seeking manufacturing and process development solutions for gene-based ATMPs.

Further evidence of third-party recognition of our capabilities came in May 2013, when we announced a collaboration with Novartis to provide process development services and manufacture clinical grade material using our LentiVector® gene delivery technology. Oxford BioMedica will be responsible for manufacturing several batches of a lentiviral vector encoding CTL019 technology.

Novartis will use this vector to transduce patients' immune cells (T-cells) in an ex vivo process before they are re-infused into patients. CTL019 targets a protein called CD19 that is associated with a number of B-cell malignancies including chronic lymphocytic leukaemia, B-cell acute lymphocytic leukaemia and diffuse large B-cell lymphoma.

During 2013, we also continued to perform work for Immune Design under the master services agreement signed in 2012.



#### OXB know-how

"Oxford BioMedica has developed, and is continuing to develop, an extensive IP estate incorporating patents, know-how and trade marks. The Company's patent portfolio provides comprehensive and robust protection for its products and platform technologies."

#### Kati Hudson PhD

Head of Intellectual Property and Contracts



See more of our key people at:

[www.oxfordbiomedica.co.uk/other-senior-management](http://www.oxfordbiomedica.co.uk/other-senior-management)

## Chief Financial Officer's review

**2013 marked an important step in the evolution of Oxford BioMedica with the emergence of new and profitable revenues that could potentially develop over the next two to three years into a significant and sustainable cash contributor to offset our cash burn.**

In recent years, our revenues have been almost entirely derived from the ocular product collaboration with Sanofi. The accounting recognition of the US\$26 million received upfront in 2009 and the reimbursement of research and development (R&D) expenditure – primarily the out-licensed spend with third parties – provided most of these revenues. In 2013, these items were significantly lower than they were in previous years as the collaboration begins to reach its conclusion.

But they are now being replaced by new, profitable revenues derived from providing services to third parties. These new revenues have an important future role to play in reducing the net cash burn from our platform and infrastructure costs.

### Key financial performance indicators

- Profit-generating revenues £2.6 million (2012: £0.1 million)
- Cash burn (net cash used in/generated from operations plus sales and purchases of non-current assets and interest received) £11.9 million (2012: £10.5 million)
- Cash balance (total of cash, cash equivalents and current financial investments) £2.2 million (£14.1 million at the start of the year)
- Headcount 106 employees (81 at the start of the year)

### Revenues £5.4 million (2012: £7.7 million)...

Although revenues dropped, the charts opposite show a significant change in their composition. In 2012, 44% (£3.4 million) of revenue was the non-cash recognition of revenue deferred from the US\$26 million upfront payment received from Sanofi in 2009; 25% (£1.9 million) came from the reimbursement of R&D spent on the ocular products, mainly the pass-through of spend incurred with third parties; and a further 25% (£1.9 million) came from the one-off exercise by Sanofi of its option over StarGen™ and UshStat®; leaving only 6% (£0.5 million) of revenue of a recurring nature.

By contrast, in 2013, only 15% (£0.8 million) of revenue was represented by the non-cash recognition of deferred revenue; 17% (£0.9 million) from the reimbursement of R&D pass-through costs; and 12% (£0.6 million) from Pfizer's one-off milestone payment. This left 56% (£3.0 million) of 2013 revenues derived from recurring sources, mainly the provision of manufacturing and development services to Novartis and other third parties.

While the cash revenues in 2013 (£4.6 million) and 2012 (£4.3 million) are similar, the recurring element generated from services and licence receipts is much higher in 2013 (£3.0 million compared with £0.5 million).

### Cost of sales £1.1 million (2012: £0.7 million)...

As the composition of revenues has changed since 2012, so has the cost of sales composition. Previously, the cost of sales consisted entirely of royalties payable by us to third-party licensors. The £0.7 million in 2012 comprised the recognition of royalties which were paid in 2009 when we received the upfront payment from Sanofi; and those paid in 2012 on the option fees we received from Sanofi in respect of StarGen™ and UshStat®. In 2013, the royalties component of the cost of sales was £0.1 million while £1.0 million consisted of the cost of manufacturing the batches manufactured and sold to Novartis. The cost of manufacture includes raw materials, direct and indirect labour and overheads incurred in manufacture.



**Tim Watts**  
Chief Financial Officer

# £5.4m

Total revenues £5.4 million (2012: £7.7 million). Although revenues dropped, the charts below show a significant change in their composition

# £2.6m

Total revenues include profit-generating revenues £2.6 million (2012: £0.1 million)

# £11.9m

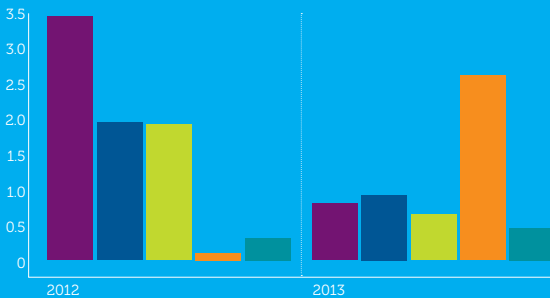
Cash burn (net cash used in/generated from operations plus sales and purchases of non-current assets and interest received) £11.9 million (2012: £10.5 million)

# £2.2m

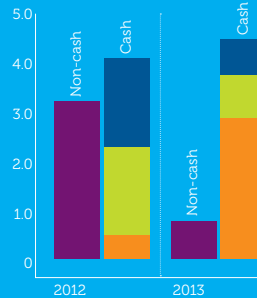
Cash balance (total of cash, cash equivalents and current financial investments) £2.2 million (£14.1 million at the start of the year)

# 106 people

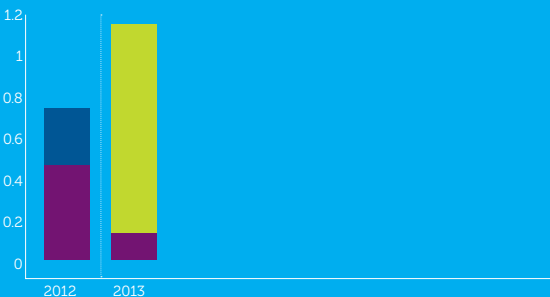
Headcount increased to 106 employees (81 at the start of the year) to support manufacturing revenue generation



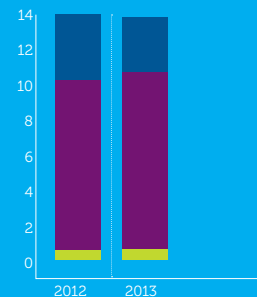
**Revenue analysis £m**  
 ■ Deferred  
 ■ R&D reimbursement  
 ■ Milestones/options  
 ■ Development/manufacturing  
 ■ Licence/other



**Non-cash versus cash revenue £m**  
 ■ Deferred  
 ■ One-off items  
 ■ R&D reimbursement  
 ■ Recurring



**Cost of sales £m**  
 ■ Royalties - regular  
 ■ Royalties on milestones  
 ■ Manufacturing COGS



**R&D costs £m**  
 ■ In-house costs  
 ■ External costs  
 ■ Intangibles and amortisation



## Chief Financial Officer's review

**"In recent years, our revenues have been almost entirely derived from the ocular product collaboration with Sanofi. But, they have been replaced by new, profitable revenues derived from providing services to third parties. These new revenues have an important future role to play in reducing our net cash burn"**

### Gross profit £4.2 million (2012: £7.1 million)...

The £2.9 million fall in gross profit is due to the reduction of £2.6 million in non-cash Sanofi deferred revenue; the £1.3 million lower one-off option and milestone receipts; and the £1.0 million lower R&D pass-through cost reimbursement, partially offset by £1.6 million gross profit from the fee-for-service activities.

### R&D costs £13.8million (2012: £14.0 million)...

R&D costs overall were slightly lower in 2013 than in 2012. This is mainly due to lower external spend on R&D projects of £2.8 million in 2013 compared with £3.8 million in 2012, partially offset by higher in-house costs of £10.6 million, compared with £9.8 million in 2012. Amortisation of intangible assets was unchanged at £0.4 million.

The reduction in external project spend came mainly from the Sanofi collaboration products on which £1.3 million was spent, compared with £1.9 million in 2012. £0.7 million in aggregate was incurred in 2013 on ProSavin®/OXB-102, Glaucoma-GT, MoNuDin® and other new product opportunities, and the TroVax® Phase II studies. The remaining £0.8 million was incurred on a number of activities, including the resolution of the impurity issue (see page 22).

In-house R&D costs include all the relevant staff and facility costs, R&D consumables, IP costs and depreciation of R&D physical assets. However, they exclude that portion of costs which are allocated to cost of sales because they relate directly to the manufacturing of product for sale.

### Administration costs £3.4 million (2012: £3.6 million)...

Administration costs of £3.4 million were £0.2 million lower than in 2012 which included a one-off amount of £0.4 million professional fees on a confidential corporate project.

### Loss for the year £12.8 million (2012: £10.5 million)...

The operating loss for the year of £12.8 million was £2.3 million higher than in 2012. This is explained by the £2.9 million fall on gross profit offset by £0.5 million lower costs. Finance income was £0.1 million lower in 2013 due to lower average cash balances, but the tax credit at £1.7 million was £0.1 million higher than in 2012. This means that the after-tax loss for the year of £11.1 million was £2.4 million greater than the £8.7 million loss in 2012.

### Cash flow

The cash burn in 2013 was £11.9 million, £1.4 million higher than the £10.5 million in 2012. Although the loss before tax in 2013 was £2.3 million higher than in 2012, this is almost entirely explained by the reduction in non-cash revenue. The increased cash burn is largely explained by an increase of £1.6 million in working capital outflows, notably including £0.7 million in inventory, both raw materials and work-in-progress, arising for the first time because of our manufacturing contract with Novartis.

The operating loss for the year, as described above, was £12.8 million. After adjusting for non-cash items such as depreciation and amortisation, the charge for share-based payments and working capital, the cash used in operations was £13.0 million. We incurred £0.8 million expenditure on tangible fixed assets, mainly on manufacturing equipment, and a further £0.1 million on intangible assets.

During the year we received £2.0 million in tax credits, which included the UK R&D Tax Credit tax credit for 2012; the residual element of the tax credit for 2011; and also a small credit arising from BioMedica Inc, our US subsidiary, which ceased trading in 2012. The net result was a cash burn of £11.9 million in 2013. As we started 2013 with £14.1 million cash and cash equivalents, we finished the year with £2.2 million.



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# £3m

The recurring cash revenues generated from services and licence receipts is much higher in 2013 (2012: £0.5 million)

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# 56%

More than half of our revenues in 2013 were derived from recurring sources, mainly the provision of manufacturing and other development services

## Headcount

The increase in headcount during 2013 is explained by the need to fully staff the manufacturing operations to support the Novartis contract including manufacturing, quality control and analytical staff.

## Financial outlook

In 2013, we made a promising start towards developing a more commercial focus by bringing in £2.6 million of profitable revenues from providing manufacturing and development services to third parties. We intend to develop this activity further in 2014 and to create a growing revenue stream to offset partially the cost of our operations. We also have opportunities to bring in license revenues, in particular the significant option fee should Sanofi exercise its option over RetinoStat®.

On 6 January 2014, shareholders approved a loan facility arranged with our largest shareholder, Vulpes Life Sciences Fund, which has provided some operational flexibility in the first half of 2014 while we develop these opportunities.

## Going concern

The Group is continuing to develop its product pipeline and absorbs cash in doing so. Although it is starting to generate revenues from selling development and manufacturing services, these currently only cover a small portion of the Group's cost base. The Directors estimate that the cash held by the Group including known receivables and future funding available under the Vulpes loan facility will be sufficient to support the current level of activities into the third quarter of 2014. This estimate does not include the benefit of any upfront receipts from licence deals, including the potential option fee which would be payable by Sanofi should they exercise their option over RetinoStat®. The Directors also continue to explore other sources of finance available to the Group. Taking account of these together the Directors have confidence that they will be able to secure sufficient cash inflows for the Group to continue its activities for the foreseeable future, being not less than 12 months from the date of these financial statements, and have therefore prepared the financial statements on a going concern basis.

These circumstances nonetheless represent a material uncertainty which may cast significant doubt on the Group's ability to continue as a going concern. Should the Group be unable to obtain further funds, adjustments would be required to reduce balance sheet values of assets to their recoverable amounts, to provide for further liabilities that might arise and to reclassify fixed assets as current assets.

## Tim Watts

Chief Financial Officer

# Corporate social responsibility

At Oxford BioMedica we recognise our obligation to behave as a responsible corporate citizen and believe that by doing so we will minimise business risk and enhance our reputation. The Board recognises the potential benefits of corporate social responsibility (CSR) for the competitiveness of Oxford BioMedica and encourages a culture of continuous improvement in CSR-related issues. We have set specific policies that cover key aspects of CSR and strive to operate at the highest level of integrity.

## Our relationships

### **Internal relationships**

Attracting, motivating and retaining a highly skilled workforce is critical to Oxford BioMedica's success and sustainability. The Company's employment policies are based on guidelines for best practice. They recognise the rights and ensure equal opportunities for all employees without discrimination. The Board as a whole takes considerable interest in employment matters which are represented at board level by the Chief Executive Officer.

### Company values

Our mission, vision and values aim to encourage innovation amongst our people. The values are designed to engage and inspire our staff to work to the best of their ability, to work together to achieve timely delivery and to cultivate enthusiasm in the work place.

### Diversity

The table below shows the gender split at different levels in the organisation as at 31 December 2013.

	Male	Female	Total	% Male	% Female
PLC Board including non-Executive Directors	7	–	7	100%	–
Senior managers excluding directors	6	1	7	86%	14%
All other employees	34	62	96	35%	65%
Total	47	63	110	43%	57%



Our values are designed to engage and inspire our staff to work to the best of their ability, to work together to achieve timely delivery and to cultivate enthusiasm in the work place

### Training and development

We aim to develop and maintain a motivated and professional workforce through career development, performance management, training and promotion. Our managers are responsible for developing employees and identifying talent within the workforce. Training is given in a wide variety of ways including on-the-job coaching, in-house and external courses. Our annual employee appraisal process continues to function well, providing a formal process for setting objectives and reviewing performance.

### Sharing information

We acknowledge the importance of communication between colleagues. Company briefings, R&D seminars and informal all-staff meetings are held to keep employees informed of general business issues and any other matters of interest. The circulation of press announcements and internal newsletters keeps employees informed of business and employee activities.

### **External relationships**

Our external stakeholders include shareholders, patients, healthcare professionals, patient advocacy organisations, charitable institutions, partners, collaborators, licensors, licensees, customers, suppliers and advisers. These relationships are a fundamental aspect of our business activities. We are committed to interacting with all stakeholders in an ethical manner, and to ensuring that the relationships are maintained at a professional and appropriate level. Our interactions with external stakeholders are regularly reviewed by the Senior Management Group.

### Clinical trials

We have a policy for the management of clinical trials to ensure compliance with appropriate guidelines and legislation. Our website ([www.oxfordbiomedica.co.uk](http://www.oxfordbiomedica.co.uk)) provides information on ongoing clinical trials, and we also disclose our trials on a US government-sponsored website ([www.clinicaltrials.gov](http://www.clinicaltrials.gov)).

### Communication

The Chief Executive Officer and Executive Directors have primary responsibility for communication with shareholders and related stakeholders. We also use the services of external financial and corporate communications agencies. We seek to disseminate information in a timely, reliable and comprehensive fashion, and we comply with the rules and guidelines of the UK Listing Authority for a company on the Official List. Further information is given in the governance report on page 41.

### Product development

#### Animal testing

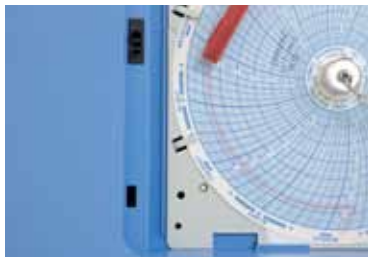
It is legally mandated by regulatory authorities worldwide that all new therapeutic products must be extensively tested for safety before they are administered to patients, and there is currently no alternative to using animal models as part of this process. We are committed to following the principles of the three "Rs": replacement, refinement and reduction of animal testing. These principles ensure that animals are only used when necessary and where there are no alternatives. Oxford BioMedica minimises the use of animal models by cross-referring LentiVector® platform data packages for the regulatory authorities.

#### Quality assurance

We are committed to operating all of our activities at a high level of scientific quality and regulatory compliance. Our policies reinforce senior management's commitment to high standards of quality being maintained at all times. A set of regulations and procedures provide guidance and instruction pertaining to the development, manufacturing, testing, clinical evaluation, storage and distribution of investigational medicinal products (IMP) performed by or authorised by the Company.

We place the highest priority on the safety and well-being of our clinical trial patients who are treated with our products. It is a regulatory and company requirement that employees are aware of the implications and importance of maintaining drug safety, quality and efficacy throughout its clinical trial programmes. Oxford BioMedica regularly holds company-wide Good Manufacturing Practice (GMP), Good Clinical Practice (GCP), Good Laboratory Practice (GLP) and Pharmacovigilance training to ensure that employees are aware of and compliant with current best practice. The Company continues to support ongoing and periodic training as an essential part of its continuous improvement philosophy.

Strong emphasis is also placed on maintaining the integrity of the Company's products including their safe manufacture, controlled distribution and compliance with all relevant regulations. Oxford BioMedica is responsible for ensuring that each batch of product is fit-for-purpose in terms of safety, quality, identity, strength, purity and expected efficacy. Oxford BioMedica continues to operate under GCP, GMP and GLP accreditations on an ongoing basis and has remained within compliance throughout 2013.



We are committed to operating all of our activities at a high level of scientific quality and regulatory compliance

# Corporate social responsibility

**“We are committed to protecting the health, safety and welfare of our employees and strive to maintain an effective health and safety culture within the organisation”**

# 2,297t

Total CO<sub>2</sub> emissions in 2013 were 2,297 tonnes

## Our environment

### Health and safety

We are committed to protecting the health, safety and welfare of our employees and strive to maintain an effective health and safety culture within the organisation. Our Health and Safety Management System covers all work activities such as the usage of biological, chemical and radioactive materials, and the operation of laboratory equipment.

The Health and Safety Management System is reviewed and updated in order to improve current systems and procedures, 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 represented at board level by Peter Nolan and are a standing item on the Board's agenda.

### Environmental policies

We fully recognise our responsibility to protect the environment and we review our environmental policy, objectives and guidelines regularly. The Company complies with all regulations that cover the processing and disposal of laboratory waste, using qualified licensed contractors for the collection and disposal of chemical and radioactive waste and decontaminated biological materials. No laboratory waste goes to landfill sites. As part of our commitment to the environment, our policies are designed to motivate our staff to be energy conscious and environmentally friendly. The Company's recycling programme continues to function effectively and the majority of our cardboard and office paper is recycled. A summary of our greenhouse gas emissions is set out below. Environmental issues are represented at board level by the Chief Executive Officer.

### Greenhouse Gas Emissions report

The table below shows the usage in 2013 of energy and water at our two sites in Oxford, UK. We have also estimated our total CO<sub>2</sub> emissions. This is the first year for which this information has been collected and reported; comparative data for 2012 is not available. We have also indicated the usage "intensity" by dividing the usage by the average number of employees which is a relevant indicator of the amount of activity undertaken in the business.

The Group's activities have significantly increased during 2013, particularly in manufacturing. The Board will be monitoring environmental measures and performance indicators to ensure that we utilise natural resources as efficiently as possible.

	Unit	Usage	Usage per employee	CO <sub>2</sub> emission (tonnes)
Electricity	MW hours	3,238	34.1	1,443
Gas	MW hours	1,897	20.0	411
Water supply	Cubic metres	9,355	98.5	3
Other activities (estimated) including waste disposal and travel				440
<b>Total</b>				<b>2,297</b>

### Charitable giving

The company did not make any charitable donations in 2013. In June 2012 Oxford BioMedica donated £1,200 to the Sue Kingsman Memorial Scholarship Fund which, via the Carriacou Children's Education Fund (CCEF), will fund a student's two year college course.

### Human Rights

The Group does not have a specific human rights policy since the Board does not consider this necessary in the context of the Group's activities.

## Principal risks and uncertainties

**“Many of the Group’s risks and uncertainties are common to all development-stage biopharmaceutical companies. Where possible, the Group’s strategy and processes are designed to manage and mitigate these risks”**

Risk assessment and evaluation is an integral part of Oxford BioMedica’s planning. Many of the Group’s risks and uncertainties are common to all development-stage biopharmaceutical companies. Where possible, the Group’s strategy and processes are designed to manage and mitigate these risks. The Board has overall responsibility for the Group’s systems of risk management and internal control. The management structure of the Group allows the Executive Directors to be closely involved in all material aspects of risk assessment, management and mitigation. Some risks are difficult to mitigate, in particular those related to gene therapy and its efficacy. For other risks, management’s experience, planning and vigilance can mitigate the risks to a greater extent, for example those associated with intellectual property and financial risk. The Board members have relevant qualifications and experience, and they have access to external resources where required. The Board meets regularly and frequently enough to ensure that it is fully informed to oversee this activity in a timely manner. The following are the principal risks and uncertainties facing the business.

### **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 Oxford BioMedica’s products 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 have 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 products or technology, there can be no assurance that a competitor or potential competitor will not independently develop the same or similar products 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.

### **Gene therapy risk**

The commercial success of Oxford BioMedica’s gene therapy products will depend, in part, on their acceptance by the medical community and the public for the prevention and/or treatment of diseases. To date only one gene therapy product has been approved in Europe, and none in the USA. Furthermore, specific regulatory requirements, over and above those imposed on other products, apply to gene therapy 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 the Group’s products.

### **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 manufacture product before they can apply for authorisation to market the product. 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 manufacturing processes

## Principal risks and uncertainties

- Failure to find a development partner or alternative funding
- Failure to obtain regulatory approvals to conduct clinical studies or, ultimately, to market the product
- 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 Company'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.

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**"The Group's LentiVector® platform product candidates use specialised manufacturing processes for which there are only a few suitable manufacturers including the Group's own facility"**

### Safety risks

Safety issues may arise at any stage of the drug development process. An independent data safety monitoring board, 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 an independent data safety monitoring board or review body does not necessarily indicate that all clinical trials will ultimately be successfully completed.

### 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.

### Technical risks

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

### Manufacturing 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 manufacturing processes for which there are only a few suitable manufacturers including the Group's own facility. There can be no assurance that the Group will be able to manufacture the Group's product candidates at economic cost or that contractors who are currently able to manufacture the Group's product candidates will continue to make capacity available at economic prices, or that suitable new contractors will enter the market. Manufacturing 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 manufacturers will be able to provide sufficient manufacturing capacity when required.

### Collaboration and funding risk

Collaborations and licensing are an important component of the Group's strategy to realise value and manage risk. The Group is dependent on collaborative relationships with third parties to facilitate and fund the research, development, manufacture, commercialisation and marketing of products. There is no guarantee that such collaborations and funding will continue to be found. There can also be no assurance that the Group's existing relationships will not be terminated or require re-negotiation for reasons that may be unrelated to the potential of the programme.



Circumstances may also arise where the failure by collaborators and third parties, such as contract manufacturers, to perform their obligations in accordance with our agreements could delay, or halt entirely, development, production or commercialisation of our products, or adversely impact our cash flows.

#### Regulatory risk

The clinical development and marketing approval of Oxford BioMedica's product candidates, and the Group's manufacturing 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's use or may require additional data before granting approval. If regulatory approval is obtained, the product and manufacturer 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, manufacturing facility and conduct of clinical studies are also subject to regular audits by the MHRA to ensure that they comply with Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP) and Good Clinical Practice (GCP) standards. Failure to meet such standards could result in the laboratories or the manufacturing site being closed or the clinical studies suspended until corrective actions have been implemented and accepted by the regulator.



The success of the Group's products will depend on the regulatory and commercial environment several years into the future

#### Failure to recruit sufficient patients into clinical studies

Clinical trials are established under specific 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. 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.

#### **Longer-term commercialisation risks**

In the longer term, the success of the Group's products 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/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.

#### **Manufacturing operations risk**

The Group manufactures clinical study material for its own product development and for third parties. The manufacturing processes for gene and cell therapy products are still relatively immature. There is a risk of contamination or other process failure during the manufacturing process which results in material which has been produced having to be destroyed and re-manufactured at additional cost.

## Principal risks and uncertainties

### Attraction and retention of key employees

Whilst the Group has entered into employment arrangements with each of its key personnel with the aim of securing their services, the retention of their services cannot be guaranteed. Oxford BioMedica is significantly dependent on certain scientific and management personnel. Incentivisation of key employees to remain with the Group remains critical to the Group's success. The loss of those employees could weaken the Group's scientific and management capabilities, resulting in delays in the development of its drugs and impacting negatively on the Group's business. The biotechnology industry has a highly competitive market for qualified scientific and managerial employees. Competitors may try to recruit some of the Group's important employees. Recruiting and retaining management and scientific personnel as the Group develops will be critical to the Group's success.

### Financial risks

The Group is exposed to several financial risks:

- Product liability and insurance risk
- Foreign currency exposure
- Continuing losses

#### 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, manufacturing, 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.

#### Foreign currency exposure

The Group records its transactions and prepares its financial statements in pounds sterling. 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 other currencies, especially the Euro, relating primarily to pre-clinical and clinical development that it conducts in the US and other countries outside the UK. The Group's cash balances are predominantly held in pounds sterling. In the short to medium term, covering a period that is at least 12 months from the date of this document, expenditure denominated in foreign currency is matched to a significant degree by income denominated in US dollars such that the risk of material losses or gains on one is hedged by the other. To the extent that the Group's foreign currency assets and liabilities in the longer term are not so well 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. This may increase or decrease the Group's results of operations and may adversely affect the Group's financial condition. 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.

#### Continuing losses

The Group expects to incur significant further costs as it continues to develop its portfolio of candidate products, manufacturing capability and related technology. The Directors estimate that the current cash held by the Group, together with known receivables and future funding available under the Vulpes loan facility, will be sufficient to support the current level of activities into the third quarter of 2014. This estimate does not include the benefit of any upfront receipts from licence deals, including the potential option fee which would be payable by Sanofi should they exercise this option over RetinoStat®. The Directors continue to explore other sources of finance available to the Group. However, there is no certainty that adequate resources will be available on a timely basis, and in the event that further funding is not achieved, then the Group would have to curtail or suspend the existing programme development in order to conserve cash and extend the cash runway.



Incentivisation of key employees to remain with the Group remains critical to the Group's success

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# The Board of Directors



## 01. Nick Rodgers (55)

### Non-Executive Chairman

#### Appointment:

– appointed a Director in March 2004 and became Chairman in May 2011

#### Committee membership:

– Chairman of Nomination and Audit Committees

Mr Rodgers is a former investment banker with considerable experience in the life sciences sector. He is currently chairman of SEHTA Enterprises Limited, the commercial arm of South East Health Technologies Alliance and a director of Productiv Limited, an automotive technology enabler. Until January 2013 he was Chief Executive of Ipso Ventures plc having been Head of Life Sciences and joint-Head of Corporate Finance at Evolution Beeson Gregory until December 2003. Mr Rodgers qualified as an accountant with Ernst & Young.

## 02. John Dawson (54)

### Chief Executive Officer

#### Appointment:

– appointed a Director in August 2008 and became Chief Executive Officer in October 2008

#### Committee membership:

– none

From 1996 to 2007, Mr Dawson held senior management positions in the European operations of Cephalon Inc. including, from 2005, a management board position as Chief Financial Officer and Head of Business Development, Europe. In his time at Cephalon he led many of the deals that built the European business to over 1,000 people, taking the business from having no sales in 1998 to revenue of several hundred million US dollars. In 2005, Mr Dawson led the US\$360 million acquisition of Zeneus by Cephalon. Between 1991 and 1996 he was Director of Finance and Administration of Sero Laboratories (UK) Limited.

### 03. Tim Watts (56)

#### Chief Financial Officer

##### Appointment:

- appointed a Director and Chief Financial Officer in February 2012

##### Committee membership:

- none

Mr Watts has over 20 years experience in the Pharmaceutical and Biotech sectors. From 1 January 2014 he has become a Director of the UK BioIndustry Association. In 1985 he joined ICI, initially in the corporate headquarters and from 1990 in the pharmaceuticals division, eventually becoming Finance Director of the Zeneca Pharmaceuticals business. Following the merger of Astra and Zeneca, Mr Watts became Group Financial Controller of AstraZeneca PLC in 2001. In 2007 he left AstraZeneca to become Chief Financial Officer at Archimedes Pharma. Mr Watts is a member of the Institute of Chartered Accountants in England and Wales.

### 04. Peter Nolan (61)

#### Senior Vice President, Commercial Development

##### Appointment:

- appointed a Director in May 2002

##### Committee membership:

- none

Peter Nolan was appointed to the Board in May 2002 having been a senior member of the Company since its foundation. Until the end of 2013 he was a Director of the UK BioIndustry Association and he is a past Chairman of the Oxfordshire Bioscience Network. Prior to joining Oxford BioMedica, Mr Nolan served as Head of the Biotechnology Unit at the UK Department of Trade and Industry for eight years. In that role he was responsible for establishing and managing complex collaborative research programmes involving industry, research councils and other government departments.

### 05. Dr Andrew Heath (65)

#### Deputy Chairman and Senior Independent Director

##### 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

Dr Heath is a biopharmaceutical executive with in-depth knowledge of US and UK capital markets and international experience in marketing and sales, R & D and business development. He was Chief Executive Officer of Protherics plc from 1997 to 2008, taking the Company from 30 to 350 staff and managing its eventual acquisition by BTG for £220 million. Prior to this, Dr Heath held senior positions at Astra AB and Astra USA, including Vice President Marketing & Sales, and at Glaxo Sweden as Associate Medical Director.

### 06. Dr Paul Blake (65)

#### Non-executive Director

##### Appointment:

- appointed a Director in January 2010

##### Committee membership:

- Chairman of Remuneration Committee, Nomination Committee

Dr. Blake has over 30 years international pharmaceutical/biotech experience. From 2006 to 2014 he was Senior Vice President and Chief Medical Officer of Eterna Zentaris Inc., a global biopharmaceutical company focused on oncology and endocrine therapy. From 2001 to 2006, he held senior management positions at Cephalon Inc, including executive vice president, Worldwide Medical & Regulatory Operations from 2005. Dr Blake's previous positions include senior vice president and medical director, Clinical Research and Development at SmithKline Beecham Pharmaceuticals. He gained his medical degree from the London University, Royal Free Hospital.

### 07. Martin Diggle (51)

#### Non-executive Director

##### Appointment:

- appointed a Director in October 2012

##### Committee membership:

- Remuneration Committee

Mr Diggle is a founder of Vulpes Investment Management, a Cayman Fund Manager which currently manages five funds including the Vulpes Life Sciences Fund which is the Group's largest shareholder. An investment professional with over 29 years' experience in investment banking and fund management, Mr Diggle has extensive, first-hand knowledge of the global financial markets and is an expert in emerging markets and Russia, in particular, where he was a partner and director of UBS Brunswick between 1994 and 2003. He has been an investor in life sciences and biotechnology since 1999 and has developed a passionate interest in the sector having worked closely with several companies as a stakeholder over the past decade. Mr Diggle holds a master's degree in Philosophy, Politics and Economics from University of Oxford.

# Corporate governance

## 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 there are robust corporate governance and risk management processes in place.

The Board considers that it has complied throughout the year with the UK Corporate Governance Code (the "Code") except where indicated below in this report.

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

Each director is provided with an appropriate induction on appointment, and is supplied on a timely basis with financial and operational information sufficient for the Board to discharge its duties. 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 44 to 55 incorporating the Remuneration Committee report.

The current Board members are set out on pages 38 to 39. On 6 June 2013 Stuart Naylor stepped down from the Board. There are now three Executive Directors and four non-Executive Directors. The Chairman met the independence criteria recommended by the Code when he was appointed in May 2011. Andrew Heath, the Senior Independent Director, and Paul Blake are 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 Code. The Group therefore complies with provision B.1.2 of the Code which recommends that a small company should have at least two independent non-Executive Directors.

There is a clear division of responsibilities between the Chairman and Chief Executive Officer. 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. The Chairman's other commitments do not adversely impact the time he can devote to the Group.

## Board meetings

The Board meets regularly with meeting dates agreed for each year in advance. During 2013 there were 10 regular Board meetings and one specifically to approve the 2012 annual report. The attendance of individual directors at Board and Committee meetings was as follows:

	Board		Audit Committee		Remuneration Committee		Nominations Committee	
	Possible	Attended	Possible	Attended	Possible	Attended	Possible	Attended
Paul Blake	11	10			8	8		
John Dawson	11	11						
Martin Diggle <sup>1</sup>	11	9			5	5		
Andrew Heath	11	9	3	3	8	8		
Stuart Naylor <sup>2</sup>	5	3						
Peter Nolan	11	10						
Nick Rodgers	11	11	3	3				
Tim Watts	11	11						

1. Martin Diggle was appointed to the Remuneration Committee on 2 May 2013

2. Stuart Naylor resigned from the Board on 6 June 2013



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

### **Retirement of Directors**

In accordance with the articles of association, at each annual meeting any Director who was appointed after the last annual general meeting 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 the 2014 annual general meeting John Dawson will retire from the Board and stand for re-election in accordance with article 38 of the Company's articles of association. Nick Rodgers, who has served for more than 9 years, will also submit himself for re-election in compliance with the UK Corporate Governance Code.

### **Review of performance**

Following on from the comprehensive review of board performance in 2012 the Chairman and Deputy Chairman carried out an informal review in January 2014. The Company Secretary prepared an analysis of Company's governance performance as compared with the requirements of the Code with input from the auditors. The Board collectively reviewed and discussed these inputs in March 2014 and concluded that the Board's composition, modus operandi and dynamics are appropriate for the Company at its stage of development and have worked well during 2013.

### **Communication with shareholders**

The Board recognises the importance of effective communication with shareholders and endeavours to achieve this using a variety of channels. These include:

- Vulpes Life Sciences Fund, the Company's largest investor, is represented on the Board by Martin Diggle
- Chief Executive Officer and Chief Financial Officer meetings with major shareholders – the Company maintains contact with other major shareholders and meets with them as required
- Chairman and Senior Independent Director meetings with shareholders – the Chairman and Senior Independent Director have meetings, as required, with major shareholders and the Senior Independent Director is available to shareholders if concerns cannot be resolved through normal channels
- Announcement of preliminary results (27 February 2013), interim results (29 August 2013) and interim management statements (16 May 2013 and 19 November 2013) – The preliminary and interim results announcements are followed with an analyst briefing and simultaneous conference call which can be accessed by all shareholders
- Annual report – the 2012 annual report was published on 17 April 2013
- Annual General Meeting – this was held in London on 6 June 2013. A number of shareholders attended the meeting, the results of which were announced on the same day
- Announcements of material developments through the London Stock Exchange and other news services
- The Company works closely with the Company's brokers and PR agency and regularly discusses Company matters with current and potential investors
- Group website – the website contains details of the Group's activities as well as copies of regulatory announcements and press releases, and copies of the Group's financial statements

### **Management**

Management is conducted by the Executive Directors who, together with other senior managers, form the senior management team. Recognising the increasing breadth and complexity of the Group's operations, during 2013 the Chief Executive Officer established three new management committees which now meet monthly. These committees are:

- the Product Development Committee – covering the development of new gene therapy products from initial concept through to clinical development
- the Technical Development Committee – covering the development of new and improved assays and production and other processes, including cell and vector engineering
- Manufacturing Operations Committee – covering the manufacture of clinical batches

# Corporate governance

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.

All senior managers come together monthly in the Senior Management Group to cover those aspects of the Group's activities which are not covered in the above committees. These include, for example, organisational and HR matters, health and safety monitoring, and internal and external communication.

The Executive Directors meet as needed but also monthly after the cycle of committee meetings to agree what matters should be reported up to the Board.

## 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. The Executive Directors and other senior managers are accountable for identifying the risks and formulating risk mitigation plans. The active involvement of the Executive Directors in the management committees allows them to monitor and assess significant business, operational, financial, compliance and other risks. The Executive Directors provide reports to each board meeting covering, inter alia, financing, investor relations, research and development, clinical development, financial performance, commercial interactions and intellectual property management.

## Board committee reports:

### Audit Committee report

The Audit Committee comprises two non-Executive Directors: Nick Rodgers (Chairman) and Andrew Heath. The Board considers that both members of the Audit Committee possess recent and relevant financial experience. Provision C.3.1 of the Code states that a company Chairman should not chair the Audit Committee. When the composition of Board and its committees was re-organised in May 2011, Nick Rodgers became Company Chairman and retained the chair of the Audit Committee. The Board recognises that this arrangement is not in compliance with the Code and the intention is to appoint an appropriately qualified independent non-Executive Director who could chair the Audit Committee.

The primary duties of the Audit Committee, as set out in its written terms of reference which is available on the Group's website, 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 Code states that the Audit Committee should review the effectiveness of the Company's internal audit function. The Audit Committee considers that, given the size of the Company, it is unnecessary for it to have an internal audit function.

The Audit Committee met three times in 2013 – shortly before the announcements of the 2012 preliminary results in February 2013, before the 2013 interim results in August 2013 and finally in October to review the 2013 Audit Strategy. The Chief Executive Officer, Chief Financial Officer and the external auditors attended all three meetings at the Committee's invitation. The main issues which concerned the Committee during 2013 were the accounting for and reporting of the activities being carried out under the contract with Novartis since this created new and therefore unfamiliar activities in 2013 and the question of going concern.

At the February 2013 meeting, the auditors presented their Audit Clearance Memorandum for the year ended 31 December 2012. The key issues highlighted for discussion at this meeting by the auditors were the recognition of revenue arising from the 2009 collaboration agreement with Sanofi and the disclosures and assessment of the Group's going concern status. On both of these issues the auditors had satisfied themselves that the estimates and judgements made by management and the directors were reasonable. Regarding the going concern issue, the auditors concluded that they need not make an emphasis of matter statement in their audit opinion provided that adequate disclosures were made in the 2012 annual report.

The primary issue for discussion at the August 2013 meeting ahead of the interim results for 2013, which were not audited, was that of going concern. The Directors reviewed the potential sources of revenue and funding at that time and concluded that the Group had good prospects of securing additional resources sufficient to allow the Group to continue in operational existence for the foreseeable future and accordingly they adopted the going concern basis in preparing the 2013 interim financial statements.

The 2013 Audit Strategy presented by the auditors in October identified the following key areas of audit risk – contract accounting and revenue recognition, completeness of clinical trial accruals, management override of controls, and going concern. It should be noted that auditing standards specify that there is a non-rebuttable significant risk on all audit engagements that management could override controls to manipulate results or releases to the market. The Committee met in March 2014 to discuss PwC's report following the 2013 audit and the annual report and financial statements for the year. The main issues highlighted by PwC arising from their work were that of going concern, the accounting requirements arising from the new manufacturing activities and the changes required by the new narrative reporting regulations issued by the UK Department of Business, Innovation and Skills. The conclusions regarding going concern are set out in several places in this report including the Director's report on page 58 and note 1 to the consolidated financial statements on page 69. The Committee reviewed management's papers and the conclusions reached and satisfied itself that the activities carried out under the contract with Novartis had been properly accounted for and reported on in the annual report and financial statements. PwC's report concluded that the manufacturing accounting and narrative reporting regulations had been implemented effectively and appropriately.

PricewaterhouseCoopers LLP (PwC) have been auditors to the Company and the Group since 1997. The Audit Committee has reviewed the relationship with the auditors and is satisfied with their effectiveness and that they remain independent. The review of audit effectiveness included discussions with the Group's Chief Executive Officer and Chief Financial Officer, an assessment of subsequent events which might have exposed shortcomings in the audit process, and the direct experience of the Audit Committee members with the audit team. At the end of the 2012 audit Miles Saunders stepped down as the Company's Senior Statutory Auditor in accordance with PwC's rotation policy. He has been replaced as Senior Statutory Auditor for the 2013 audit by Stuart Newman. The review also included the terms of engagement and audit fees. There are no contractual obligations restricting the Company's choice of external auditor.

The Audit Committee is aware of the developments within the EU regarding auditor rotation and the UK Competition Commission proposals and FRC guidance on the matter. The matter was also raised at the 2013 AGM. The Committee has given specific and careful consideration to audit re-tendering, and has had a number of discussions on the matter including with PwC. Given the significant ongoing evolution of the Group's business to include manufacturing and the significant time commitment on senior management that an audit tender process would require, and also recognising that there have been significant changes in PwC's audit team - a new Senior Statutory Audit partner and a new audit manager – and that the Group has a new financial controller, the committee has concluded that it would defer an audit tender process for at least 12 months.

Following this assessment, the Audit Committee has recommended to the Board that PwC should be reappointed for the 2014 audit and this will be recommended to shareholders at the 2014 Annual General Meeting.

Under the Company's policy on non-audit services, the Audit Committee is advised of and approves all non-audit services provided by the Company's auditors. As part of this approval process, the Audit Committee ensures that the provision of non-audit services will not impact the auditors' objectivity and independence. During 2013, non-audit services provided by PwC included corporate finance services connected with the related party circular, and tax compliance and advisory services. The fees payable to PwC in respect of services provided during 2013 are set out in note 7 to the consolidated financial statements.

#### 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. In addition the Board annually reviews the effectiveness of all significant aspects of internal control, including financial, operational and compliance controls and risk management. The review for 2013 was prepared by the Chief Financial Officer and the Financial Controller and discussed with the chairman of the Audit Committee. The Audit Committee reported its conclusions to the Board and considers that there are no matters that require reporting to shareholders.

#### Nomination Committee report

The Nomination Committee leads the process for making appointments to the Board, and comprises the non-Executive Directors and the Company Chairman, who is Chairman of the Nomination Committee. As there were no new appointments to the Board, the Nominations Committee did not meet during 2013.

#### **Share capital**

The information about the share capital required by the takeover directive is in the Directors' report on page 56.

# Directors' remuneration report

for the year ended 31 December 2013

## Introduction

This report is on the activities of the Remuneration Committee. It sets out the remuneration policy and remuneration details for the directors of the company. This is the first time the Company has prepared the report in accordance with Schedule 8 of the Large and Medium-sized Companies and Groups (Accounts and Reports) (Amendment) Regulations 2013. The report contains:

- The Annual Statement from the Remuneration Committee Chair
- The Directors' remuneration policy, setting out the Company's proposed policy for the next three years
- The annual report on remuneration showing payments and awards made to the Directors and explaining the link between company performance and remuneration for the 2013 financial year

The annual statement and the report on remuneration are subject to an advisory vote at the Company's 2014 AGM. The remuneration policy is subject to a binding shareholder vote at the 2014 AGM and after that at least every third year.

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 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

(not subject to audit)

Dear Shareholder

As explained above in the Introduction, this is the first of the new style Directors' remuneration reports to be prepared under the amended regulations.

The responsibilities of the Committee are set out in its terms of reference and include:

- Recommending to the Board the policy and framework for the remuneration of the Executive Directors and senior management. The remuneration of the non-Executive Directors are a matter for the chairman
- Approval of individual remuneration packages for Executive Directors
- Approval of annual performance incentive plans and bonuses payable
- Approval of the Company's Long Term Incentive Plan (LTIP) for Executive Directors and senior management, and awards granted under the plan
- Approval of options granted to all employees under the Company's share option plan

The Remuneration Committee members are Paul Blake (chairman), Andrew Heath and Martin Diggles, who joined the Committee in May 2013. At the invitation of the Committee chairman and on an agenda-driven basis, other Directors have been invited to attend meetings. During 2013 the Committee met seven times.

During 2013 the main activities of the Committee have been to:

- In January, approve the 2012 Executive Director bonuses, the total amount of bonuses payable to other employees, and the overall % salary increases awarded to employees other than Executive Directors, who received no salary increases in 2013
- In June, approve the 2013 LTIP awards to Executive Directors and other senior managers
- In April and November, to approve share option awards to employees who are not eligible for the LTIP

Also during 2013 the Committee commissioned the Compensation and Benefits Practice of Deloitte LLP to conduct a review of incentives for the Executive Directors, including benchmarking against comparable companies, and to make proposals for an incentive structure which will support the evolving strategy of the Group. The Committee's objectives were that the incentive policy and package should align the Executive Directors' interests with those of shareholders by promoting ownership of shares in the Company, and share price growth, and rewarding the delivery of annual performance targets which will deliver the Group's strategy.

The outcome of this review was that the Committee concluded that the Executive Directors' salary and benefits packages are appropriate for a Group with the level of complexity and ambition of Oxford BioMedica, but that some alterations should be made to the annual bonus and Long Term Incentive Plan (LTIP). Previously Executive Directors have been contractually entitled to an annual bonus payable in cash, with a payment at the Remuneration Committee's discretion of up to 60% of base salary. The LTIP is not a contractual entitlement but, under the plan adopted by shareholders, the Remuneration Committee may award up to 150% of base salary in nominal cost share options to eligible employees. As a result of the review, the Committee decided that in future the maximum LTIP award would normally not exceed 30% of base salary and that the maximum annual bonus would be increased to 100% but that one half of any future bonus payment would be given in the form of deferred shares.

The deferred shares element of the new bonus arrangements is not subject to any further performance conditions and vest in one-third tranches on the first three anniversaries of the bonus award.

The Remuneration Committee and Board are clear that long-term shareholder value will be delivered by the Group successfully developing multiple early stage product opportunities, controlling its costs appropriately and by generating sustainable revenues which will at least partially offset the cost base. Annual performance targets designed to deliver on this strategy are set and the Committee believes this amended incentive structure is better aligned with these goals.

The performance of the business in 2013 is set out in detail in the strategic report from pages 13 to 29. In summary, there has been substantial progress during the year including:

- StarGen™ – positive review of 1st three cohorts by Drug Safety Monitoring Board
- EncorStat® – the Company has successfully negotiated the return of this product from Sanofi and secured a grant of £1.8 million from the UK Technology Strategy Board which will partially fund the next stage of development
- ProSavin®/OXB-102 – ProSavin Phase I/II study results were published in *The Lancet* and the efficacy arm of OXB-102 indicates that OXB-102 is at least five-fold more potent than ProSavin®
- Glaucoma-GT – successful outcomes to pre-clinical proof-of-concept studies
- Novartis collaboration to provide process development services and manufacture clinical grade material
- Manufacturing – the Company has won a grant and loan funding package of £7.1 million from the UK's Advanced Manufacturing Supply Chain Initiative to support our goal of becoming a global leader in ATMP manufacture and supply chain management
- GlaxoSmithKline granted an option to a non-exclusive licence under the Company's LentiVector platform patents
- Pfizer paid the Company a \$1 million milestone triggered by the entry of its 5T4-targeted investigational antibody therapy into human clinical trials
- TroVax® – all three Phase II investigator-led studies are now recruiting patients

There was a significant set-back during the year when the Company voluntarily paused its clinical studies following the identification of very low concentrations of potential impurities, introduced by a commonly-used raw material. However, the manner in which the Company responded to and resolved this issue was exemplary and demonstrated the quality, commitment and innovativeness of the employees.

Taking all of these factors into account, in February 2014 the Remuneration Committee decided to award the Executive Directors bonuses of 30% of target and increases in base salary for Mr Nolan and Mr Watts of £10,000 each

### **Paul Blake**

Chair, Remuneration Committee

### **Directors' remuneration policy**

(not subject to audit)

As described in the Annual Statement above, during 2013 the Remuneration Committee reviewed the Executive Directors' incentive structure. The policy underlying the incentive structure is to:

- Recruit and retain the best candidates possible
- Provide Executive Directors with a competitive incentive package which is broadly in line with comparable companies taking into account size, complexity and level of risk
- Ensure that a significant proportion of the Executive Directors' total potential remuneration is performance related

# Directors' remuneration report

for the year ended 31 December 2013

## Future policy table

(to take effect from the 2014 AGM)

Component and purpose	Operation	Maximum potential and payment at threshold	Performance targets and metrics
<b>Executive Directors</b>			
<b>Base salary</b>			
To provide a base salary which is sufficient to attract and retain	Base salaries are initially set by reference to market information at the time of appointment and taking into account the previous package of the new Director. Base salaries are normally reviewed annually and any changes are effective from 1 January. Salaries are paid in 12 equal monthly instalments	The current salaries for Executive Directors are set out in the annual report on remuneration. Increases above these levels require Remuneration Committee approval, taking into account the Director's performance, any changes in responsibility and market conditions. There is no pre-defined maximum base salary	Not applicable
<b>Benefits</b>			
To provide benefits consistent with the role and which are similar to comparable roles in other companies	Benefits currently cover only medical insurance. Premia are paid monthly	Insurance premia are determined by the policy provider. There is no pre-determined maximum but the totals are reviewed annually by the Remuneration Committee	Not applicable
<b>Annual bonus</b>			
To ensure a market competitive package and to incentivise delivery of the Group's objectives	Annual bonuses are determined by the Remuneration Committee. 50% of the bonus is delivered as cash	The maximum payment is 100% of base salary (50% in cash, 50% in deferred shares)	The objectives and performance metrics are decided annually by the Remuneration Committee taking into account the strategic needs of the business
Delivery of 50% of any bonus payment via deferred shares is intended to align the incentive package with shareholders interests	50% of the bonus is delivered through deferred shares structured as nil cost options which 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 although malus provisions apply which gives the Remuneration Committee the right to cancel or reduce unvested awards  Dividend equivalents may be attached to the nil cost options over the deferral period  The awards are discretionary and can be removed or adjusted at the Committee's discretion  Awards may vest early on a change of control (or other relevant events) and also in "good leaver" circumstances  Awards are made under an HMRC EMI plan where appropriate	There is no minimum bonus required if threshold performance is not met so payments can range from 0% to 100% of base salary	Given the nature of the business, these objectives and metrics may change significantly each year  Deferred shares will only vest if the participant is still employed at the 1 <sup>st</sup> anniversary of the award
<b>Pension</b>			
To provide funding for retirement	The Company operates a Defined Contribution scheme for all employees including the Executive Directors  A cash allowance is available to be added to base salary for those not participating in the scheme	10% of base salary annually.  If the cash allowance is taken as an addition to base salary, the allowance including Employer's National Insurance must not exceed 10% of base salary	Not applicable



Component and purpose	Operation	Maximum potential and payment at threshold	Performance targets and metrics
<b>Executive Directors</b>			
<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	<p>At the discretion of the Remuneration Committee, annual grants of conditional nominal cost share options which vest after three years on the achievement of specified performance targets. There are no provisions for dividend equivalents to be attached to the LTIP grants. If a participant ceases to be employed prior to vesting, the grant will lapse unless the Remuneration Committee decides otherwise</p> <p>Awards may vest early on a change of control (or other relevant events) and also in "good leaver" circumstances</p> <p>Awards are made under an HMRC EMI plan where appropriate</p>	<p>Maximum grant will normally not exceed 30% of base salary in respect of any financial year. In exceptional circumstances the Remuneration Committee may award up to 100% of base salary in respect of any financial year</p>	<p>For 2012 and 2013 awards, the performance condition has been share price growth performance. At the time of grant a threshold share price target is set for the 3rd anniversary. No options vest if this share price target is not achieved. This has been chosen as the most direct way of aligning the Executive Directors' interests with those of shareholders.</p> <p>For the achievement of threshold growth performance, no more than 25% of the award will vest and 100% of the award will vest for maximum share price growth performance. Below threshold performance, none of the award will vest</p> <p>The 2011 awards had performance conditions linked to a) Total Shareholder Return over a three year period compared with a peer group of comparable companies and b) delivery of specific objectives. These performance conditions will be assessed in April 2014 and the level of vesting determined at that point</p> <p>The Remuneration Committee will consider the most appropriate performance conditions when awarding any future LTIP grants</p>
<b>Non-Executive Directors</b>			
<b>Non-Executive Directors' fees</b>			
To compensate non-Executive Directors for their services to the Group	<p>Non-Executive Directors' fees are determined by the Company's Chairman at time of appointment of a Director. The Chairman's fees are set by the other non-Executive Directors</p> <p>Non-Executive Directors fees are paid in cash in 12 equal monthly instalments through the Company's payroll system</p>	<p>Fees would normally be reviewed at the start of each 3 year period of appointment. However increases in non-Executive Directors' fees may be made at other times and would normally be dependent on the director taking on additional responsibility, such as chairing a board committee. Any changes to non-Executive Directors' fees require approval from the Company's Chairman. Changes to the Chairman's fees require approval by the other non-Executive Directors</p>	Not applicable

# Directors' remuneration report

for the year ended 31 December 2013

## Notes to the policy table

### Performance targets and metrics

Performance targets for the annual bonus are set by the Remuneration Committee after taking into account the strategic needs of the business. A key component of the Group's strategy is to develop gene 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 to the stage of development of each opportunity. The annual objectives are also likely to include targets related to recurring revenue generating activities such as manufacturing or development services to third parties. The Committee considers that the performance targets for the annual bonus are commercially sensitive and that it would be detrimental to disclose them in detail before the start of the financial year.

For 2012 and 2013, the performance metric for the LTIP is shareholder return over the three year vesting period. Since Oxford BioMedica is not yet profitable and does not pay dividends, the simplest measure for shareholder return is share price growth. When making a LTIP grant, the Remuneration Committee takes into account the share price at the date of grant and specifies a target range for the share price. If, on the third anniversary, the share price is below the lower end of the range, all LTIP awards will lapse without vesting. At the lower end of the range a specified percentage, currently 25%, of the awards will vest and at the top end of the range 100% of the awards will vest. The target share price range is disclosed when the awards are granted at the time of announcement. The Remuneration Committee at its discretion may change the LTIP performance metrics for future grants to ensure that the most appropriate targets are set for the Company's situation at the time.

### Changes to remuneration policy from that operating in 2012 and 2013

As described in the annual statement from the Remuneration Committee Chair, during 2013 the Remuneration Committee carried out a review of the Executive Directors' remuneration and incentive structure. This resulted in the changes described in the annual statement.

### Differences in remuneration policy for all employees

All employees receive a base salary and are entitled to participate in benefits including the Group's defined contribution pension scheme to which the Group contributes.

Executive Directors, senior managers and certain other staff receive annual bonuses. The maximum bonus potentially receivable varies between the participating employees. 50% of the Executive Directors' bonuses are delivered by deferred shares whereas all other staff receive 100% of their bonuses in cash.

Executive Directors and certain senior managers participate in the LTIP but not the Share Option Scheme. All other staff are eligible to participate in the Group's Share Option Scheme.

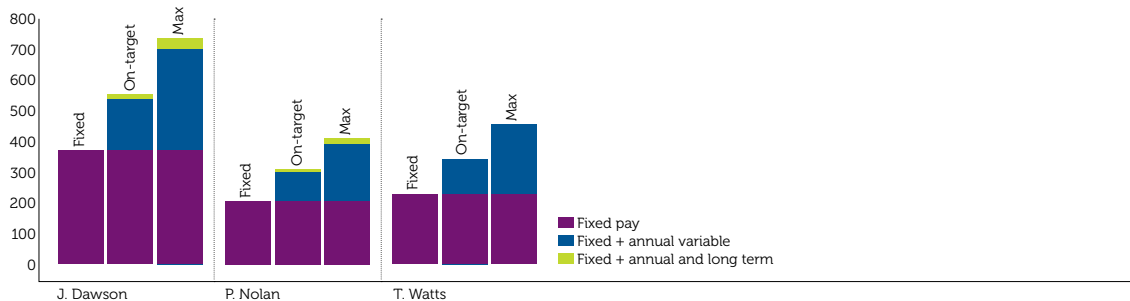
### Statement of consideration of employment conditions elsewhere in the Group

The Chief Executive Officer determines any salary increases and bonuses for all employees other than the Executive Directors. The Group participates in an annual benchmarking exercise across the UK Biotech sector which covers the majority of staff and which informs the decision making process. The Chief Executive Officer discusses the overall increase in payroll cost and the total amount to be paid in bonuses with the Chair of the Remuneration Committee before implementing the salary increases and bonuses.

The Remuneration Committee considers the pay and employment conditions of all other employees when setting the policy for Directors' remuneration. The Remuneration Committee has not consulted with other employees when preparing the policy for Directors' remuneration.

### Total Remuneration Opportunity

The total remuneration for each of the Executive Directors that could result from the proposed remuneration policy in 2014 under three different performance levels is shown below.



Remuneration of Executive Directors £'000

### Approach to recruitment remuneration

Should it become necessary to recruit a new Executive Director, the Committee would negotiate the remuneration package of the new Director from the same elements described above in the policy table as are applied to existing Directors. The Committee would determine the individual components and overall package in the light of prevailing market conditions, remuneration of other Executive Directors, and the previous package of the new Director. The maximum level of variable remuneration would be consistent with the remuneration policy table set out above.

Compensation for the forfeit of any award under arrangements with a previous employer would be considered on a case-by-case basis but would only be paid in exceptional circumstances. Relocation expenses may be offered if appropriate.

Fees for new non-Executive Directors will be determined by reference to market rates for non-executive director fees for similar companies.

### Service contracts and policy on payment for loss of office

Executive Directors' service contracts are subject to 12 months' notice from both the Company and from the Director. Directors may be required to work during the notice period or paid in lieu of notice if not required to work for the full notice period. Contractual termination payments may not exceed the Director's current salary and benefits for the notice period. Annual bonuses on termination are only paid if the director is still employed at the date of the bonus payment other than good leavers and otherwise at the Committee's discretion. Unvested LTIP and deferred bonus share awards lapse on termination except for good leavers and otherwise at the Committee's discretion. Non-Executive Directors' appointments are for an initial term of three years and their letters of appointment are available for inspection at the Company's registered office during normal business hours and at the AGM.

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 2013	Notice period
John Dawson	10 October 2008	NA	12 months
Stuart Naylor	1 July 2008	Nil <sup>1</sup>	N/A
Peter Nolan	1 May 2002	NA	12 months
Tim Watts	9 February 2012	NA	12 months

Letters of appointment	Date of appointment	Unexpired term at 31 December 2013	Notice period
Nick Rodgers	5 May 2011	4 months	3 months
Paul Blake	1 January 2013	24 months	3 months
Martin Diggle	4 October 2012	21 months	3 months
Andrew Heath	1 January 2013	24 months	3 months

1. Stuart Naylor resigned from the Board on 6 June 2013

All Directors are subject to election by shareholders at the first opportunity after their appointment and thereafter to re-election at intervals of not more than three years. At the 2014 Annual General Meeting John Dawson will retire from the Board and stand for re-election in accordance with Article 38 of the Company's articles of association. Nick Rodgers, who has served for more than nine years, will also submit himself for re-election in compliance with the UK Corporate Governance Code.

### Statement of consideration of shareholder views

The Committee takes into account views of shareholders with regard to Directors' remuneration. Martin Diggle, a founder of Vulpes Life Sciences Fund ("Vulpes"), the Company's largest investor, is a member of the Committee and is able to communicate the views of Vulpes on this matter.

# Directors' remuneration report

for the year ended 31 December 2013

## Annual report on remuneration

(subject to audit except where indicated)

### Single total figure of remuneration

The following tables show a single total figure of remuneration for 2013 for each Director and comparative figures for 2012.

2013	Salary £'000	Benefits <sup>1</sup> £'000	Bonus £'000	LTIP <sup>2</sup> £'000	Pension <sup>4</sup> £'000	Total £'000
John Dawson	330	6	99	–	33	468
Stuart Naylor <sup>3</sup>	87	1	–	–	8	96
Peter Nolan	173	4	52	–	17	246
Tim Watts	200	–	60	–	20	280
<b>Total</b>	<b>790</b>	<b>11</b>	<b>211</b>	<b>–</b>	<b>78</b>	<b>1,090</b>

2012	Salary £'000	Benefits <sup>1</sup> £'000	Bonus £'000	LTIP <sup>2</sup> £'000	Pension <sup>4</sup> £'000	Total £'000
John Dawson	330	5	33	–	33	401
Stuart Naylor <sup>3</sup>	187	2	9	–	19	218
Peter Nolan	173	3	9	–	17	203
Tim Watts	184	–	20	–	18	223
Andrew Wood <sup>5</sup>	68	2	–	–	26	96
<b>Total</b>	<b>943</b>	<b>13</b>	<b>71</b>	<b>–</b>	<b>114</b>	<b>1,141</b>

1. Benefits comprise medical insurance

2. LTIP awards granted in 2009 and 2010 lapsed without vesting in 2012 and 2013 respectively because threshold performance conditions were not met

3. Stuart Naylor resigned from the Board on 6 June 2013. In addition to the figures shown above he also received £208,000 in compensation for loss of office

4. Pension contributions are made into the Group's defined contribution scheme

5. Andrew Wood resigned from the Board on 9 February 2012. In addition to the figures shown above he also received £214,000 in compensation for loss of office

The Remuneration Committee determined that bonuses of 30% of salary should be paid to the three Executive Directors in respect of performance against 2013 targets. This compares with a possible maximum bonus of 100%. The 30% was built up as follows:

- Progressing the gene therapy product portfolio – 15%
- Securing external funding including grants – 9%
- Developing manufacturing capability and revenue generation – 3%
- Improving organisational capabilities – 3%

The 2013 bonuses will be paid 50% in cash and 50% in deferred share awards. The deferred share awards are not subject to further performance conditions 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 1st anniversary of the award.

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

Fees	2013 £'000	2012 £'000
Nick Rodgers	75	75
Andrew Heath	46	46
Paul Blake	38	38
<b>Total</b>	<b>159</b>	<b>159</b>

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

Aggregate Directors' emoluments	2013 £'000	2012 £'000
Salaries	790	943
Benefits	11	13
Pension	78	114
Bonuses	211	71
Non-Executive Directors fees	159	159
<b>Total</b>	<b>1,249</b>	<b>1,300</b>

### LTIPs awarded during 2013

On 12 June 2013, the Executive Directors were awarded the following options under the Company's LTIP scheme:

	Number of options granted
John Dawson	5,577,465
Peter Nolan	2,933,493
Tim Watts	3,380,282

The performance metric for this award is Absolute Total Shareholder Return (TSR) but as the Company is unlikely to pay a dividend in the foreseeable future, TSR growth is essentially represented by the share price. The awards will only vest if share price growth is achieved over the 3 year vesting period of each award. The vesting schedule is as follows:

Share price target	% of award vesting
Below 5.0p	0%
At 5.0p*	25%
At 7.5p*	100%

\* Straight line vesting between these points

The closing share price on the day preceding the award was 1.73p, so the threshold target of 5p requires growth of 189% over the three year vesting period. The number of options awarded was calculated by reference to 30% of salary divided by the average share price in the five business days preceding the award.

The awards are nominal cost options exercisable at par 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 above performance condition. Although no award can be exercised until the end of the three year vesting period, Directors are able to "bank" a fraction of the appropriate vesting percentage on each anniversary of the date of grant, should the target have been met at those dates. This will be limited to 25% of the potential vesting amount after one year, 50% after two years and 100% after three years. Banked awards will not actually vest until the third anniversary of award.

#### Payments for loss of office

Stuart Naylor resigned from the Board on 6 June 2013. In addition to the figures shown above he also received £208,000 in compensation for loss of office. This amount comprised an ex gratia payment of £40,000 and pay in lieu of notice of £168,000. The Company agreed that the LTIP awards held by Dr Naylor at 6 June 2013 should not lapse as a result of the termination of his employment but should continue as if he had remained an Eligible Employee and Participant (both terms as defined in the LTIP rules) until the expiry date of the last of such LTIP awards.

Andrew Wood resigned from the Board on 9 February 2012. In addition to the figures shown above he also received £214,000 in compensation for loss of office. This amount comprised an ex gratia payment of £25,000 and pay in lieu of notice of £189,000. The Company agreed that the LTIP awards held by Mr Wood at 9 February 2012 should not lapse as a result of the termination of his employment but should continue as if he had remained an Eligible Employee and Participant (both terms as defined in the LTIP rules) until the expiry date of the last of such LTIP awards.

#### Payments to past Directors

Dr Alan Kingsman (former Group Chairman) was paid a consulting fee of £37,500 in 2013 (2012: £75,000).

# Directors' remuneration report

for the year ended 31 December 2013

## Statement of Directors' shareholding and share interests

The Executive Directors are encouraged to build up a shareholding but there is no specific required target level. The interests in shares of the Directors are as follows:

	Shares held outright		Vested but unexercised share options		Unvested LTIP awards subject to performance conditions	
	2013	2012	2013	2012	2013	2012
<b>Executive Directors</b>						
John Dawson	2,282,829	2,000,000	1,000,000	1,000,000	13,881,465	9,996,000
Peter Nolan	733,313	563,638	–	–	7,309,493	5,266,000
Tim Watts	3,682,829	3,000,000	–	–	9,380,282	6,000,000
<b>Non-executive Directors</b>						
Paul Blake	533,097	420,000	–	–	–	–
Martin Diggle <sup>1</sup>	401,000,100	361,841,956	–	–	–	–
Andrew Heath	600,000	320,000	–	–	–	–
Nick Rodgers	842,829	352,000	–	–	–	–

1. Includes interest of Vulpes Life Science Fund, Vulpes Testudo Fund and other parties connected to Martin Diggle

2. There were no changes in the Directors' shareholdings between 31 December 2013 and the date of this report

On 15 June 2013 the LTIP award made on 15 June 2010 was tested against its performance condition which was to achieve at least median Total Shareholder Return (TSR) performance as measured on the third anniversary against a peer group of 20 companies. Since the Company's TSR performance fell below the median level in the peer group, all of the awards granted to Directors on that date have lapsed.

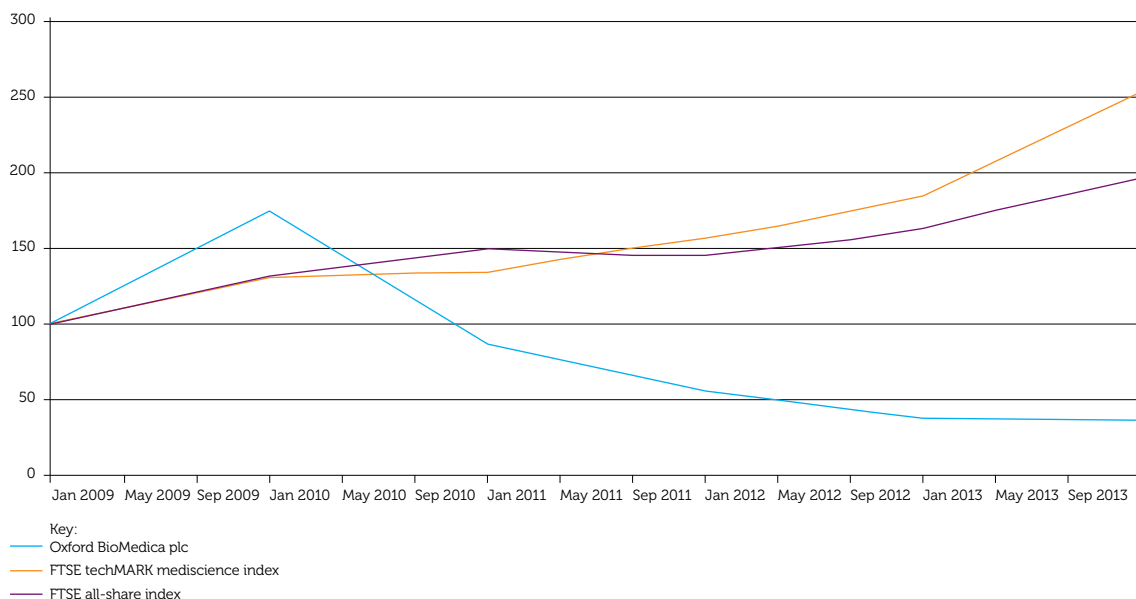
Based on the share price on 31 December 2013, it is also unlikely that the LTIP awards granted in April 2011 will vest when the performance criteria are tested in April 2014.

## Performance graph and comparison with CEO's remuneration

(not subject to audit)

The chart below illustrates the Company's TSR performance over the last five years 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.

The decline at the end of 2010 was prompted by the announcement of a fundraising, and in December 2011 there was a further decline following the announcement of an interim update on the ProSavin® Phase I/II study in Parkinson's disease.



## CEO's remuneration in last five years

(not subject to audit)

Year	2009	2010	2011	2012	2013
CEO's total single figure of remuneration £'000	817*	450	413	401	468
LTIP vesting % of maximum	0%	0%	40%	0%	0%

\* On 1 September 2009 1,500,000 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

(not subject to audit)

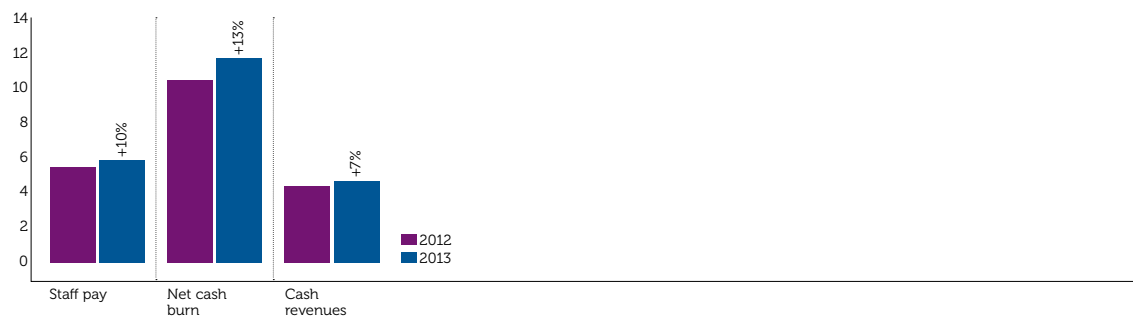
The table below shows how the percentage change in the CEO's salary, benefits and bonus between 2012 and 2013 compares with the equivalent changes in those components for a group of employees. As 2012 and 2013 has seen significant changes in headcount numbers, the Committee has chosen as the comparator group all those employees other than the CEO who were employed throughout the whole of both 2012 and 2013.

	Salary			Benefits			Bonus		
	2013	2012	% increase	2013	2012	% increase	2013	2012	% increase
John Dawson	330	330	0%	6	5	0%	99	33	200%
Comparator employee group	2,899	2,818	2.9%	19	17	14.7%	187	89	110%

## Relative importance of spend on pay

(not subject to audit)

The chart below illustrates the spend on employee remuneration compared with the Company's total net cash burn and its cash revenues (i.e. excluding non-cash revenue recognition). Since the Company does not make dividend or other distributions, these have not been included in the table.



Spend on employee remuneration compared with the Company's total net cash burn and its cash revenues £m



# Directors' remuneration report

for the year ended 31 December 2013

## Statement of implementation of remuneration policy in 2014

(not subject to audit)

As this is the first year in which the remuneration report has been prepared in accordance with the amended regulations, the proposed remuneration policy will not be approved until the Company's 2014 AGM and the Board intends that the policy will take effect from the date of the AGM.

However during 2014 the policy will be implemented, as if it had been approved, as follows:

<b>Salary</b>	<b>2013 £'000</b>	<b>2014 £'000</b>
John Dawson	330	330
Peter Nolan	173	183 <sup>1</sup>
Tim Watts	200	228 <sup>1,2</sup>

(1) Mr Nolan and Mr Watts have each been awarded a £10,000 salary increase with effect from 1 January 2014. This is the first increase Mr Nolan has received since January 2011 and the first for Mr Watts since he joined the Company in February 2012

(2) From the start of 2014 Mr Watts has elected to receive his entitlement to a 10% pension contribution by the Company paid instead as a cash allowance added to his base salary. So that there is no additional cost to the Company after payment of Employer's National Insurance, the actual allowance paid as salary has been netted down by the amount of National Insurance payable by the Company

## Annual bonus

The precise definition of the bonus targets for 2014 are commercially sensitive but in broad terms they include:

<b>Target area</b>	<b>Weighting</b>
Financial performance targets	25%
Progression of Sanofi collaboration products	20%
Secure IP licenses and manufacturing contracts	20%
Develop other product candidates and improve manufacturing capabilities	20%
Continuous improvement of organisational effectiveness	15%

## Non-Executive Directors' fees

<b>Fees</b>	<b>2013 £'000</b>	<b>2014 £'000</b>
Nick Rodgers	75	75
Andrew Heath	46	46
Paul Blake	38	38
<b>Total</b>	<b>159</b>	<b>159</b>

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

## **Consideration by Directors of matters relating to Directors' remuneration**

(not subject to audit)

During 2013 the Committee commissioned the Compensation and Benefits Practice of Deloitte LLP to conduct a review of incentives for the Executive Directors, including benchmarking against comparable companies, and to make proposals for an incentive structure which will support the evolving strategy of the Group. Deloitte were selected on the basis of Committee members' previous experience using Deloitte for similar work at other companies. The Committee's objectives were that the incentive policy and package should align the Executive Directors' interests with those of shareholders by promoting ownership of shares in the company, and share price growth, and rewarding the delivery of annual performance targets which will deliver the Group's strategy. The Remuneration Committee incurred fees of £14,000 payable to Deloitte LLP for these services. The fees were based on hourly charge out rates. All three members of the Committee participated fully in this review and they were satisfied that Deloitte's advice was objective as there was no incentive for it to be otherwise and Deloitte have a professional reputation for objectivity.

The outcome of this review was that the Committee concluded that the Executive Directors' salary and benefits packages are appropriate for a Group with the level of complexity and ambition of Oxford BioMedica but that some alterations should be made to the annual bonus and Long Term Incentive Plan (LTIP). Previously Executive Directors have been contractually entitled to an annual bonus payable in cash, with a payment at the Remuneration Committee's discretion of up to 60% of base salary. The LTIP is not a contractual entitlement but, under the plan adopted by shareholders, the Remuneration Committee may award up to 150% of base salary in nominal cost share options to eligible employees. As a result of the review, the Committee decided that in future the maximum LTIP award would normally not exceed 30% of base salary and that the maximum annual bonus would be increased to 100% but that one half of any future bonus payment would be given in the form of deferred shares. The deferred shares element of the new bonus arrangements are not subject to any further performance conditions and vest in one-third tranches on the first three anniversaries of the bonus award.

The Remuneration Committee and Board are clear that long-term shareholder value will be delivered by the Group successfully developing multiple early stage product opportunities, controlling its costs appropriately and by generating sustainable revenues which will at least partially offset the cost base. Annual performance targets designed to deliver on this strategy are set and the Committee believes this amended incentive structure is better aligned with these goals.

## **Statement of voting at AGM**

(not subject to audit)

At the 2013 AGM, the resolution recommending the 2012 Directors' remuneration report was passed with a majority of 99.2%. 0.07% of the votes were cast against the resolution and 891,828 votes were withheld.

# Directors' report

for the year ended 31 December 2013

The Directors present their annual report and audited consolidated financial statements for the year ended 31 December 2013 as set out on pages 65 to 93. This report should be read in conjunction with the corporate governance report on pages 40 to 43.

## Strategic report

The strategic report is on pages 13 to 37. 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 2013 audit, and the full Board reviewed the contents of the report at its February 2014 and March 2014 meetings. Since the Board meets routinely 10 times in the year the Directors consider that they are sufficiently well informed to be able to make this judgement.

## Key performance indicators (KPIs)

Key performance indicators are outlined in the Chief Financial Officer's review on pages 26 to 29.

## Corporate governance

The Company's statement on corporate governance is included in the corporate governance statement on pages 40 to 43 of these financial statements.

## Risk management

The Group's exposure to risks is set out on pages 33 to 37 (principal risks and uncertainties) and on page 75 (note 3: financial risk management).

## Dividends

The Directors do not recommend payment of a dividend (2012: £nil).

## Directors

The current Directors of the Company and their biographical details are given on pages 38 to 39. The contracts of employment of the Executive Directors are subject to twelve months' notice. The Directors' remuneration and their interests in the share capital of the Company at 31 December 2013 are disclosed in the Directors' remuneration report on pages 44 to 55.

### 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 following annual general meeting (AGM) and may offer himself for re-election. At each AGM any director who has served for three years, and one third of the other directors must retire, 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 is prohibited by law from being a director; in the event of bankruptcy; if he is suffering from specified mental disorders; if he 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 Company maintains a qualifying third party indemnity insurance policy to provide cover for legal action against its Directors. This was in force throughout 2013 and at 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. At 31 December 2013 the Company had 1,416,149,005 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 6 June 2013, authority was given to allot up to 472,049,700 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 472,049,700 shares, solely in a rights issue. Authority was also given, subject to certain conditions, to waive pre-emption rights over up to 70,807,500 shares, being 5% of the shares then in issue. No rights have been granted to the Directors to buy back shares.

### Substantial shareholdings

At 15 March 2014, 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	401,000,100	28.3%
M&G Investment Management Limited	237,994,371	16.8%
TD Direct Investing	90,515,583	6.4%
Barclays Wealth Management (UK)	87,661,222	6.2%
Hargreaves Lansdown Asset Management	75,237,831	5.3%
Halifax Share Dealing	49,165,203	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.

### Group research and development activities

During 2013 the Group incurred research and development expenditure of £13,750,000 (2012: £14,015,000). Further information is given in the progress against strategy (pages 22 to 25) and Chief Financial Officer's review (pages 26 to 29).

### Employees

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 social responsibility statement on pages 30 to 32.

### Employee share schemes

The Company has a share incentive plan under which shares may be held in trust for employees. The trustees may only exercise the voting rights in respect of such shares in accordance with the employees' instructions. Currently there are no such shares held in trust.

### 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.

# Directors' report

for the year ended 31 December 2013

## Going concern

The Group is continuing to develop its product pipeline and absorbs cash in doing so. Although it is starting to generate revenues from selling development and manufacturing services, these currently only cover a small portion of the Group's cost base. The Directors estimate that the cash held by the Group including known receivables and future funding available under the Vulpes loan facility will be sufficient to support the current level of activities into the third quarter of 2014. This estimate does not include the benefit of any upfront receipts from licence deals, including the potential option fee which would be payable by Sanofi should they exercise their option over RetinoStat®. The Directors also continue to explore other sources of finance available to the Group. Taking account of these together the Directors have confidence that they will be able to secure sufficient cash inflows for the Group to continue its activities for the foreseeable future, being not less than 12 months from the date of these financial statements, and have therefore prepared the financial statements on a going concern basis.

These circumstances nonetheless represent a material uncertainty which may cast significant doubt on the Group's ability to continue as a going concern. Should the Group be unable to obtain further funds, adjustments would be required to reduce balance sheet values of assets to their recoverable amounts, to provide for further liabilities that might arise and to reclassify fixed assets as current assets.

## 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.

## Statement of Directors' responsibilities

The Directors are responsible for preparing the annual report and financial statements and they consider that, taken as a whole, they are fair, balanced and understandable, and provide shareholders with the information necessary to assess the Group's performance, business model and strategy.

Company law requires the Directors to prepare financial statements for each financial year. Under that law the Directors have prepared the Group and parent company financial statements in accordance with International Financial Reporting Standards (IFRSs) as adopted by the European Union. 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 the Company and of the profit or loss of the Group for that period. In preparing these financial statements, the Directors are required to:

- select suitable accounting policies and then apply them consistently;
- make judgements and accounting estimates that are reasonable and prudent; and
- state whether applicable IFRSs as adopted by the European Union have been followed, subject to any material departures disclosed and explained in the financial statements.

The Directors are responsible for keeping adequate accounting records that are sufficient to show and explain the Company's transactions and disclose with reasonable accuracy at any time the financial position of the Company and the Group and enable them to ensure that the financial statements and the Directors' remuneration report comply with the Companies Act 2006 and, as regards the Group financial statements, Article 4 of the IAS Regulation. They are also responsible for safeguarding the assets of the Company and the Group and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

The Directors are responsible for the maintenance and integrity of the Company's website.

Legislation in the United Kingdom governing the preparation and dissemination of financial statements may differ from legislation in other jurisdictions.

Each of the Directors, whose names and functions are listed in this section confirm that, to the best of their knowledge:

- the Group financial statements, which have been prepared in accordance with IFRSs as adopted by the EU, give a true and fair view of the assets, liabilities, financial position and loss of the Group; and
- the Directors' report contained in this section includes a fair review of the development and performance of the business and the position of the Group, together with a description of the principal risks and uncertainties that it faces.

**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 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 Company's auditors are aware of that information.

**Independent auditors**

The auditors, PricewaterhouseCoopers LLP, have indicated their willingness to continue in office and a resolution concerning their reappointment will be proposed at the AGM.

**Greenhouse gas emissions report**

Details on greenhouse gas emissions are set out in the corporate social responsibility section on pages 30 to 32.

By order of the Board

**Tim Watts**

Company secretary

9 April 2014

# Independent auditors' report

to the members of Oxford BioMedica plc

## Report on the financial statements

### **Our opinion**

In our opinion:

- The financial statements, defined below, give a true and fair view of the state of the Group's and of the Company's affairs as at 31 December 2013 and of the Group's loss and of the Group's and Company's cash flows for the year then ended;
- The Group financial statements have been properly prepared in accordance with International Financial Reporting Standards (IFRSs) as adopted by the European Union;
- The Company financial statements have been properly prepared in accordance with IFRSs as adopted by the European Union 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.

This opinion is to be read in the context of what we say in the remainder of this report.

### **Emphasis of matter – going concern**

In forming our opinion on the financial statements, which is not modified, we have considered the adequacy of the disclosure made in note 1 to the financial statements concerning the Group's and the Company's ability to continue as a going concern and the existence of a material uncertainty as of the date of approval of the financial statements. At the balance sheet date, the Group held cash, including known receivables and future funding available under the Vulpes loan facility, that the Directors believe is sufficient to support the current level of activities into the third quarter of 2014. This estimate does not include the benefit of any upfront receipts from licence deals, including the potential option fee which would be payable by Sanofi should that company exercise their option under the ocular collaboration. The Directors also continue to explore other sources of finance available to the Group and Company (see note 1 for further details).

Whilst the Directors have concluded that they will be able to secure sufficient cash inflows for the Group and Company to continue their activities for the foreseeable future, being not less than 12 months from the date of approval of these financial statements, and have therefore prepared the financial statements on a going concern basis, these circumstances represent a material uncertainty which may cast significant doubt about the Group's and the Company's ability to continue as a going concern. The financial statements do not include the adjustments that would result if the company was unable to continue as a going concern.

### **What we have audited**

The Group financial statements and Company financial statements (the "financial statements"), which are prepared by Oxford BioMedica plc, comprise:

- the Group and Company balance sheets as at 31 December 2013;
- the Consolidated statement of comprehensive income for the year then ended;
- the Group and Company statements of changes in equity attributable to owners of the parent and statements of cash flows for the year then ended; and
- the notes to the financial statements, which include a summary of significant accounting policies and other explanatory information.

The financial reporting framework that has been applied in their preparation comprises applicable law and IFRSs as adopted by the European Union and, as regards the Company, as applied in accordance with the provisions of the Companies Act 2006.

Certain disclosures required by the financial reporting framework have been presented elsewhere in the Annual report and accounts (the "annual report"), rather than in the notes to the financial statements.

These are cross-referenced from the financial statements and are identified as audited.



## What an audit of financial statements involves

We conducted our audit in accordance with International Standards on Auditing (UK and Ireland) ("ISAs (UK & Ireland)"). An audit involves obtaining evidence about the amounts and disclosures in the financial statements sufficient to give reasonable assurance that the financial statements are free from material misstatement, whether caused by fraud or error. This includes an assessment of:

- whether the accounting policies are appropriate to the Group's and Company's circumstances and have been consistently applied and adequately disclosed;
- the reasonableness of significant accounting estimates made by the Directors; and
- the overall presentation of the financial statements.

In addition, we read all the financial and non-financial information in the annual report to identify material inconsistencies with the audited financial statements and to identify any information that is apparently materially incorrect based on, or materially inconsistent with, the knowledge acquired by us in the course of performing the audit. If we become aware of any apparent material misstatements or inconsistencies we consider the implications for our report.

## Overview of our audit approach

### Materiality

We set certain thresholds for materiality. These helped us to determine the nature, timing and extent of our audit procedures and to evaluate the effect of misstatements, both individually and on the financial statements as a whole.

Based on our professional judgement, we determined materiality for the Group financial statements as a whole to be £0.5 million. In arriving at this judgement we have had regard to the average annual loss before taxation incurred by the group over the previous four years, excluding non-recurring exceptional items, which in 2011 and 2010 related to the impairment of intangible assets. We consider 5% of this value to be an appropriate benchmark that reflects the underlying recurring business performance.

We agreed with the Audit Committee that we would report to them misstatements identified during our audit above £27,000 as well as misstatements below that amount that, in our view, warranted reporting for qualitative reasons.

### Overview of the scope of our audit

The Group consists of one material trading subsidiary, Oxford BioMedica (UK) Limited, and the Company, Oxford BioMedica plc.

Our overall approach to the Group audit included an audit of the complete financial information of the trading subsidiary, as this accounted for all of the Group's revenue and 96% of its assets.

This work, together with additional procedures performed at the Company level, including testing the carrying value of the investment in the trading subsidiary and cash balances, gave us the evidence we needed for our opinion on the Group financial statements as a whole.

### Areas of particular audit focus

In preparing the financial statements, the Directors made a number of subjective judgements, for example in respect of significant accounting estimates that involved making assumptions and considering future events that are inherently uncertain. We primarily focussed our work in these areas by assessing the Directors' judgements against available evidence, forming our own judgements, and evaluating the disclosures in the financial statements.

In our audit, we tested and examined information, using sampling and other auditing techniques, to the extent we considered necessary to provide a reasonable basis for us to draw conclusions. We obtained audit evidence through testing the effectiveness of controls, substantive procedures or a combination of both.

We considered the following areas to be those that required particular focus in the current year. This is not a complete list of all risks or areas of focus identified by our audit. We discussed these areas of focus with the Audit Committee. Their report on those matters that they considered to be significant issues in relation to the financial statements is set out on page 42.

# Independent auditors' report

to the members of Oxford BioMedica plc

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## Area of focus

## How the scope of our audit addressed the area of focus

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### Going concern

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We considered the Directors' decision to adopt the going concern basis in preparing the financial statements in the light of the Group's forecast cash resources for a period of 12 months from the date of approval of the financial statements. The Group's going concern status is dependent on the availability of sufficient cash resources

We obtained the Directors' forecast of the Group's funding requirements for a period of 12 months from the date of approval of these financial statements, together with details of the identified available sources of finance and additional revenue streams

We considered the risk that such revenue streams will not occur or will be of lower value than forecast and challenged management over the completeness and valuation of forecast cash outflows

We also considered the probability that the Directors could take actions to alter the timing and/or amount of cash flows and the sensitivity of changes in assumptions on the forecasts

We obtained an understanding of the status of the Directors' commercial negotiations and whether assumptions around future resources were appropriately reflected in forecasts

Our conclusion on going concern is below

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### Fraud in revenue recognition

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ISAs (UK & Ireland) presume there is a risk of fraud in revenue recognition. We focussed on the recognition of revenue derived from the Ocular studies and its presentation in the income statement because this involves the exercise of management judgement owing to the effect of the uncertainty in the trials' end point on the measurement of the stage of completion. (Refer to note 2 to the financial statements)

We tested the timing of revenue recognition, which is dependent on contractual obligations as the trials progress. This involved consideration of the timing and amount of revenue recognised in the light of the contract terms. We also challenged management's estimates of cost to come on long-term contracts, which is a key driver of the timing of revenue recognition. We evaluated the relevant internal controls over the completeness, accuracy and timing of revenue recognised in the financial statements. We also tested journal entries posted to revenue accounts to identify unusual or irregular items, understanding the rationale for any such adjustment and obtaining supporting evidence

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### Completeness of clinical accruals

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We focussed on this area as the completeness of the liabilities arising from the principal clinical and non-clinical programmes, which are material to the balance sheet, is judgemental in nature

We obtained an understanding of the nature of the costs recognised on contracts and the related year-end balances. We also interviewed senior operational staff and recalculated the value of significant accruals using third-party records of the progress of clinical trials as the basis for our recalculations

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### Risk of management override of internal controls

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ISAs (UK & Ireland) require that we consider this

We tested key reconciliations and manual journal entries. We examined the significant accounting estimates and judgements relevant to the financial statements for evidence of bias by the Directors that may represent a risk of material misstatement due to fraud. We also assessed the overall control environment of the Group, including consideration of the risk of the miscommunication of findings from clinical and non-clinical trials or the progress of the Group's manufacturing collaboration, either through fraud or error, which may misrepresent the financial results or future prospects of the Group

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### **Going Concern**

Under the Listing Rules we are required to review the Directors' statement, set out on page 58, in relation to going concern. We have nothing to report having performed our review.

As noted in the Directors' statement, set out on page 58, the Directors have concluded that it is appropriate to prepare the Group's and Company's financial statements using the going concern basis of accounting but with additional disclosure in note 1 to bring the readers' attention to the material uncertainty relating to whether the Group and Company will have sufficient funds for one year from the date of approval of the financial statements. The going concern basis presumes that the Group and Company have adequate resources to remain in operation, and that the Directors intend them to do so, for at least one year from the date the financial statements were signed.

As part of our audit we have concluded that the Directors' use of the going concern basis is appropriate, although because securing additional cash inflows is a prerequisite for the Group's and the Company's ability to continue as a going concern, a material uncertainty exists which may cast significant doubt about this ability.

As not all future events or conditions can be predicted, even if additional cash inflows are secured these statements are not a guarantee as to the Group's and the Company's ability to continue as a going concern.

### **Opinions on other matters prescribed by the Companies Act 2006**

In our opinion:

- the information given in the Strategic Report and the Directors' Report for the financial year for which the financial statements are prepared is consistent with the financial statements;
- the part of the Directors' Remuneration Report to be audited has been properly prepared in accordance with the Companies Act 2006; and
- the information given in the Corporate Governance Statement set out on page 43 in the annual report with respect to internal control and risk management systems and about share capital structures is consistent with the financial statements.

### **Other matters on which we are required to report by exception**

#### **Adequacy of accounting records and information and explanations received**

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

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

We have no exceptions to report arising from this responsibility.

#### **Directors' remuneration**

Under the Companies Act 2006 we are required to report to you if, in our opinion, certain disclosures of Directors' remuneration specified by law have not been made, and under the Listing Rules we are required to review certain elements of the report to shareholders by the Board on Directors' remuneration. We have no exceptions to report arising from these responsibilities.

# Independent auditors' report

to the members of Oxford BioMedica plc

## Corporate governance statement

Under the Companies Act 2006, we are required to report to you if, in our opinion a corporate governance statement has not been prepared by the Company. We have no exceptions to report arising from this responsibility.

Under the Listing Rules we are required to review the part of the Corporate Governance Statement relating to the Company's compliance with nine provisions of the UK Corporate Governance Code ("the Code"). We have nothing to report having performed our review.

On page 56 of the annual report, as required by the Code Provision C.1.1, the Directors state that they consider the annual report taken as a whole to be fair, balanced and understandable and provides the information necessary for members to assess the Group's performance, business model and strategy. On page 42, as required by C.3.8 of the Code, the Audit Committee has set out the significant issues that it considered in relation to the financial statements, and how they were addressed. Under ISAs (UK & Ireland) we are required to report to you if, in our opinion:

- the statement given by the Directors is materially inconsistent with our knowledge of the Group acquired in the course of performing our audit; 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 have no exceptions to report arising from this responsibility.

## Other information in the annual report

Under ISAs (UK and Ireland), we are required to report to you if, in our opinion, information in the annual report is:

- materially inconsistent with the information in the audited financial statements; or
- apparently materially incorrect based on, or materially inconsistent with, our knowledge of the Group and Company acquired in the course of performing our audit; or
- is otherwise misleading.

We have no exceptions to report arising from this responsibility.

## Responsibilities for the financial statements and the audit

### Our responsibilities and those of the Directors

As explained more fully in the Statement of Directors' Responsibilities set out on page 58, the Directors are responsible for the preparation of the Group and Company financial statements and for being satisfied that they give a true and fair view.

Our responsibility is to audit and express an opinion on the Group and Company financial statements in accordance with applicable law and ISAs (UK and Ireland). Those standards require us to comply with the Auditing Practices Board's Ethical Standards for Auditors.

This report, including the opinions, has been prepared for and only for the Company's members as a body in accordance with Chapter 3 of Part 16 of the Companies Act 2006 and for no other purpose. We do not, in giving these opinions, accept or assume responsibility for any other purpose or to any other person to whom this report is shown or into whose hands it may come save where expressly agreed by our prior consent in writing.

### Stuart Newman (Senior Statutory Auditor)

for and on behalf of PricewaterhouseCoopers LLP

Chartered Accountants and Statutory Auditors

Reading

9 April 2014

- (a) The maintenance and integrity of the Oxford BioMedica plc website is the responsibility of the Directors; the work carried out by the auditors does not involve consideration of these matters and, accordingly, the auditors accept no responsibility for any changes that may have occurred to the financial statements since they were initially presented on the website
- (b) Legislation in the United Kingdom governing the preparation and dissemination of financial statements may differ from legislation in other jurisdictions

# Consolidated statement of comprehensive income

for the year ended 31 December 2013

<b>Continuing operations</b>	Notes	2013 £'000	2012 £'000
Revenue	4	<b>5,375</b>	7,756
Cost of sales		<b>(1,140)</b>	(667)
<b>Gross profit</b>		<b>4,235</b>	7,089
Research and development costs	7	<b>(13,750)</b>	(14,015)
Administrative expenses	7	<b>(3,422)</b>	(3,619)
Other operating income: grants receivable		<b>114</b>	58
<b>Operating loss</b>		<b>(12,823)</b>	(10,487)
Finance income	6	<b>64</b>	141
Finance costs	6	<b>(4)</b>	(3)
<b>Loss before tax</b>		<b>(12,763)</b>	(10,349)
Taxation	8	<b>1,667</b>	1,619
<b>Loss for the year</b>	26	<b>(11,096)</b>	(8,730)
<b>Basic loss and diluted loss per ordinary share</b>	9	<b>(0.79p)</b>	(0.76p)

There were no other gains or losses.

# Balance sheets

as at 31 December 2013

	Notes	Group		Company	
		2013 £'000	2012 £'000	2013 £'000	2012 £'000
<b>Assets</b>					
<b>Non-current assets</b>					
Intangible assets	11	2,633	2,931	–	–
Property, plant and equipment	12	4,070	3,902	–	–
Investments in subsidiaries	13	–	–	32,400	31,841
		<b>6,703</b>	6,833	<b>32,400</b>	31,841
<b>Current assets</b>					
Inventories	14	680	–	–	–
Trade and other receivables	15	2,592	1,705	3	11
Current tax assets		1,500	1,824	–	–
Available for sale investments	16	–	5,105	–	–
Cash and cash equivalents	16	2,169	8,956	43	743
		<b>6,941</b>	17,590	<b>46</b>	754
<b>Current liabilities</b>					
Trade and other payables	17	2,934	2,702	36	23
Deferred income	18	1,280	1,568	–	–
		<b>4,214</b>	4,270	<b>36</b>	23
<b>Net current assets</b>		<b>2,727</b>	13,320	<b>10</b>	731
<b>Non-current liabilities</b>					
Provisions	19	532	510	–	–
		<b>532</b>	510	–	–
<b>Net assets</b>		<b>8,898</b>	19,643	<b>32,410</b>	32,572
<b>Equity attributable to owners of the parent</b>					
Ordinary shares	22	14,162	14,162	14,162	14,162
Share premium account	23	130,304	130,304	130,304	130,304
Merger reserve	27	14,310	14,310	13,599	13,599
Other reserves	27	(682)	(682)	4,993	4,642
Accumulated losses	26	(149,196)	(138,451)	(130,648)	(130,135)
<b>Total equity</b>		<b>8,898</b>	19,643	<b>32,410</b>	32,572

The Company's registered number is 03252665.

The financial statements on pages 65 to 93 were approved by the Board of Directors on 9 April 2014 and were signed on its behalf by:

**John Dawson**  
Chief Executive Officer

# Statements of cash flows

for the year ended 31 December 2013

	Notes	Group		Company	
		2013 £'000	2012 £'000	2013 £'000	2012 £'000
<b>Cash flows from operating activities</b>					
Cash used in operations	28	(13,005)	(11,470)	(492)	(293)
Interest paid		(4)	(3)	–	–
Tax credit received		1,990	1,500	–	–
Overseas tax paid		–	(64)	–	–
Net cash used in operating activities		(11,019)	(10,037)	(492)	(293)
<b>Cash flows from investing activities</b>					
Loan to subsidiary		–	–	(208)	(9,226)
Purchases of property, plant and equipment		(839)	(476)	–	–
Purchases of intangible assets		(98)	(195)	–	–
Net maturity of available for sale investments		5,105	2,395	–	–
Interest received		64	172	–	–
Net cash generated from/(used in) investing activities		4,232	1,896	(208)	(9,226)
<b>Cash flows from financing activities</b>					
Proceeds from issue of ordinary share capital		–	11,779	–	11,779
Costs of share issues		–	(1,517)	–	(1,517)
Net cash generated from financing activities		–	10,262	–	10,262
<b>Net (decrease)/increase in cash and cash equivalents</b>		<b>(6,787)</b>	2,121	<b>(700)</b>	743
Cash and cash equivalents at 1 January		8,956	6,835	743	–
<b>Cash and cash equivalents at 31 December</b>	16	<b>2,169</b>	8,956	<b>43</b>	743



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

for the year ended 31 December 2013

Group	Notes	Ordinary shares £'000	Share premium account £'000	Merger reserve £'000	Other reserves £'000	Accumulated losses £'000	Total equity £'000
At 1 January 2012		9,449	124,755	14,310	(682)	(130,061)	17,771
Year ended 31 December 2012:							
Loss for the year		–	–	–	–	(8,730)	(8,730)
Total comprehensive expense for the year		–	–	–	–	(8,730)	(8,730)
Transactions with owners:							
Share options							
Value of employee services	25	–	–	–	–	340	340
Issue of shares excluding options	22, 23	4,713	7,066	–	–	–	11,779
Costs of share issues	23	–	(1,517)	–	–	–	(1,517)
<b>At 31 December 2012</b>		<b>14,162</b>	<b>130,304</b>	<b>14,310</b>	<b>(682)</b>	<b>(138,451)</b>	<b>19,643</b>
Year ended 31 December 2013:							
Loss for the year		–	–	–	–	(11,096)	(11,096)
Total comprehensive expense for the year		–	–	–	–	(11,096)	(11,096)
Transactions with owners:							
Share options							
Value of employee services	25	–	–	–	–	351	351
<b>At 31 December 2013</b>		<b>14,162</b>	<b>130,304</b>	<b>14,310</b>	<b>(682)</b>	<b>(149,196)</b>	<b>8,898</b>

Company	Notes	Ordinary shares £'000	Share premium account £'000	Merger reserve £'000	Other reserves £'000	Accumulated losses £'000	Total equity £'000
At 1 January 2012		9,449	124,755	13,599	4,302	(119,035)	33,070
Year ended 31 December 2012:							
Loss for the year		–	–	–	–	(11,100)	(11,100)
Total comprehensive expense for the year	10	–	–	–	–	(11,100)	(11,100)
Transactions with owners:							
Share options							
Credit in relation to employee share schemes	25	–	–	–	340	–	340
Issue of shares excluding options	22, 23	4,713	7,066	–	–	–	11,779
Costs of share issues	23	–	(1,517)	–	–	–	(1,517)
<b>At 31 December 2012</b>		<b>14,162</b>	<b>130,304</b>	<b>13,599</b>	<b>4,642</b>	<b>(130,135)</b>	<b>32,572</b>
Year ended 31 December 2013:							
Loss for the year		–	–	–	–	(513)	(513)
Total comprehensive expense for the year	10	–	–	–	–	(513)	(513)
Transactions with owners:							
Share options							
Credit in relation to employee share schemes	25	–	–	–	351	–	351
<b>At 31 December 2013</b>		<b>14,162</b>	<b>130,304</b>	<b>13,599</b>	<b>4,993</b>	<b>(130,648)</b>	<b>32,410</b>

# Notes to the consolidated financial statements

for the year ended 31 December 2013

## 1. Accounting policies

Oxford BioMedica plc (the Company) is a company incorporated and domiciled in the United Kingdom and listed on the London Stock Exchange. The consolidated financial statements for the year ended 31 December 2013 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 therapy research and development business with no currently-marketed 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 IFRIC interpretations, as applicable to companies using International Financial Reporting Standards ('IFRS') as adopted by the European Union and with the Companies Act 2006 under the historic cost convention.

As more fully explained in the Directors' report on pages 56 to 59 the going concern basis has been adopted in preparing the financial statements.

A summary of the more important Group accounting policies are set out in Note 1 below.

The preparation of 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 is continuing to develop its product pipeline and absorbs cash in doing so. Although it is starting to generate revenues from selling development and manufacturing services, these currently only cover a small portion of the Group's cost base. The Directors estimate that the cash held by the Group including known receivables and future funding available under the Vulpes loan facility will be sufficient to support the current level of activities into the third quarter of 2014. This estimate does not include the benefit of any upfront receipts from licence deals, including the potential option fee which would be payable by Sanofi should they exercise their option over RetinoStat®. The Directors also continue to explore other sources of finance available to the Group. Taking account of these together the Directors have confidence that they will be able to secure sufficient cash inflows for the Group to continue its activities for the foreseeable future, being not less than 12 months from the date of these financial statements, and have therefore prepared the financial statements on a going concern basis.

These circumstances nonetheless represent a material uncertainty which may cast significant doubt on the Group's ability to continue as a going concern. Should the Group be unable to obtain further funds, adjustments would be required to reduce balance sheet values of assets to their recoverable amounts, to provide for further liabilities that might arise and to reclassify fixed assets as current assets.

### Accounting developments

The following new standards, amendments to standards and interpretations are mandatory for the first time for the financial year beginning 1 January 2013, but are not currently relevant for the Group.

- IFRS 13, 'Fair value measurement'
- IAS 19 (revised 2011) 'Employee benefits'
- Amendment to IAS 12, 'Income taxes' on deferred tax
- Amendment to IAS 1, 'Presentation of financial statements' on OCI
- Amendment to IFRS 1, 'First time adoption' on hyperinflation and fixed dates
- Amendment to IFRS 1, 'First time adoption' on government grants
- Amendments to IFRS 7 on Financial instruments asset and liability offsetting
- Annual improvements 2011
- IFRIC 20, 'Stripping costs in the production phase of a surface mine'

The new standards, new interpretations and amendments to standards and interpretations listed below have been issued but are not effective for the financial year beginning 1 January 2013 and have not been adopted early.

# Notes to the consolidated financial statements

for the year ended 31 December 2013

The following standards are not expected to have a significant impact on the Group:

- IFRS 10, 'Consolidated financial statements'
- IFRS 11, 'Joint arrangements'
- IFRS 12, 'Disclosures of interests in other entities'
- IAS 27 (revised 2011) 'Separate financial statements'
- IAS 28 (revised 2011) 'Associates and joint ventures'
- Amendments to IFRS 10,11 and 12 on transition guidance
- Amendments to IFRS 10, 12 and IAS 27 on consolidation for investment entities (not yet endorsed by the EU)
- Amendments to IAS 32 on Financial instruments asset and liability offsetting
- Amendment to IAS 36, 'Impairment of assets' on recoverable amount disclosures (not yet endorsed by the EU)
- IFRIC 21, 'Levies' (not yet endorsed by the EU)

The Group is assessing whether the following standard will have any impact on the accounting for financial instruments:

- IFRS 9, 'Financial instruments', issued in December 2009. This addresses the classification and measurement of financial assets. The standard is not applicable until 1 January 2015 and has not yet been endorsed by the EU.

## 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 product and technology licence transactions, funded research and development programmes, fees charged for providing development services to third parties, and manufacturing of clinical product for third parties.

Product and technology licence transactions typically have an initial upfront non-refundable payment on execution of the licence, and the potential for further payments conditional on achieving specific milestones, plus royalties on product sales. Where the initial amount received is non-refundable and there are no ongoing commitments from the Group and the licence has no fixed end date, the Group recognises the amount received up front as a payment in consideration of the granting of the licence on execution of the contract. Amounts receivable in respect of milestone payments are 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, achievement of specified sales volumes, are recognised in full when the relevant event has occurred. Maintenance fees within the contracts are spread over the period to which they relate. Otherwise, amounts receivable are recognised 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.

Research and development funding is recognised as revenue over a period that corresponds with the performance of the funded research and development services.

Fees charged for providing development services to third parties are recognised during the period in which the service is rendered on a percentage of completion basis.

Manufacturing of clinical product for third parties is recognised under IAS11, construction contracts, with revenues recognised on a percentage of completion basis dependent on the stage of completion of the contract.

The gross amount due from customers on all contracts in progress for which costs incurred plus recognised profits exceed progress billings is presented as an 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.

#### **Cost of sales**

Cost of sales comprises royalties arising on third party licenses and the cost of manufacturing clinical product for third parties.

The Group's products and technologies include technology elements that are licensed from third parties. Royalties arising from such third party licenses 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.

The cost of manufacturing clinical product for third parties 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.

#### **Research and development**

Research and development 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 benefit, 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. Other development expenditures are recognised as an expense as incurred.

#### **Employee benefit costs**

Employee benefit costs, notably holiday pay and contributions to the Group's defined contribution pension plan, are charged to the income statement 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 share option scheme and Long Term Incentive Plan 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 income statement 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 scheme is measured using the Black-Scholes model. The fair value of options granted under the LTIP scheme, which includes performance criteria, is measured using a Monte Carlo model taking into account the conditions under which the options were granted. 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.

# Notes to the consolidated financial statements

for the year ended 31 December 2013

## 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 and development costs and administrative expenses. The difference between grant income receivable and income recognised is included in deferred 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, and fair value adjustments.

## Taxation

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 recognised 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 with indefinite lives 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 Company sales value less cost to sell 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:

- 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 5 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 and development 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 so as 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%
Short leasehold improvements	20%
	(or the remaining lease term if shorter)
Office equipment and computers	20–33%
Manufacturing and laboratory equipment	10–20%

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

The manufacturing plant is reviewed annually for impairment triggers and, where necessary, a full impairment review is performed.

### Financial assets: investments

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 UITF44, 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 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 Group for this purpose.

### Inventories

Inventories are stated at the lower of cost and net realisable value. Cost is determined using the first-in, first-out (FIFO) 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 fair value and subsequently measured at amortised cost using the effective interest method, less provision for impairment. A provision for impairment of trade receivables is established when there is evidence that the Group will not be able to collect all amounts due according to the original terms of the receivables.

### Financial assets: available for sale investments

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.

### 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.

### 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.

# Notes to the consolidated financial statements

for the year ended 31 December 2013

## Deferred income

Deferred income is the excess of cash received under license transactions, grants, funded research and development, fees for services provided to third parties, and commercial manufacturing of clinical product for third parties, over the amounts recognised as revenue.

## Provisions

Provisions for dilapidation costs and other potential liabilities 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 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 interest expense.

## 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.

## Translation reserve

The translation reserve comprises all foreign exchange differences arising from the translation of the financial statements of foreign operations that are not integral to the operations of the Group.

## 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. The key sources of estimation uncertainty and critical accounting judgements that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year are discussed below.

### Revenue recognition

In 2009 the Group received an up-front non-refundable payment of US\$26.0 million (£16.6 million) from Sanofi under the ocular product collaboration. This has been recognised as revenue over the expected duration of the collaboration for each of the products. During 2013, the remaining £787,000 (2012: £3,414,000) of this receipt was recognised such that the full amount of £16,641,000 has now been recognised and there is no further deferred revenue.

Over the term of the ocular product collaboration with Sanofi, Oxford BioMedica may recover up to US\$24.0 million in research and development funding and recognise this as revenue. Project costs in excess of US\$24.0 million will be borne by Oxford BioMedica. The amount of research and development funding that is recognised as revenue is based on an estimate of the amount of project costs expected to be borne by the Group by the end of the collaboration. Up to 31 December 2013 £14.2 million (2012: £13.3 million) had been recognised as revenue and £0.7 million (2012: £0.6 million) had been classified as current deferred income. If the estimated total project expenditure had been 5% higher, the amount of revenue recognised to 31 December 2013 would have been £0.6 million (2012: £0.6 million) lower and the amount of deferred income higher by the same amounts.

### Intangible asset impairment

The Group has significant intangible assets arising from purchases of intellectual property rights and in-process R&D. Amortisation is charged over the assets' patent life on a straight line basis from the date that the asset becomes available for use. When there is an indicator of a significant and permanent reduction in the value of intangible assets, an impairment review is carried out. The impairment analysis is principally based on estimated discounted future cash flows. Actual outcomes could vary significantly from such estimates of discounted future cash flows, due to the sensitivity of the assessment to the assumptions used. The determination of the assumptions is subjective and requires the exercise of considerable judgement. Any changes in key assumptions about the Group's business and prospects or changes in market conditions affecting the Group or its development partners could materially affect whether an impairment exists. This risk is now concentrated on purchased patent rights which have been sublicensed to collaborative partners. At 31 December 2013 the book value of intangible assets was £2.6 million of which £1.7 million related to PrimeBoost technology.



### **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 58) and Note 1 to the financial statements (page 69).

## **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 and, until the end of 2013, the Group has been financed entirely by equity (note 33). Revenues from Sanofi under the 2009 collaboration agreement are received in US dollars but in 2013 these have predominantly covered costs which were incurred in the USA. Revenues from Novartis are in Sterling and cover costs predominantly incurred in the UK. 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 2013 the Group's revenues were mostly receivable in Sterling and United States Dollars, and certain of its expenditures are payable in Euros and United States Dollars. The majority of operating costs are denominated in Sterling. The US Dollar-denominated receipts from Sanofi were largely matched by US-Dollar denominated payments, such that a 10% difference in the £/\$ exchange rate would have had an impact of approximately £17,000 over the year. In the future, if this degree of matching was not present, it could present a possible source of foreign exchange risk. The Company had a slightly greater 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 2013 would have been approximately £145,000. The Group's policy is to hold the majority of its funds in Sterling. No other hedging of foreign currency cash flows is undertaken.

#### **(b) Interest rate risk**

During 2013 the Group did not have any borrowing facilities. Current operations are financed from its own cash resources. 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 2013 was just £64,000 (2012: £141,000).

If interest rates had been 100 basis points higher/lower in 2013 the impact on net loss would have been a increase/decrease of £42,000 (2012: £73,000) due to changes in the amount of interest receivable.

On 6 January 2014 shareholders approved a £5 million loan facility made available by Vulpes Life Sciences, the Company's largest shareholder. This facility is available until 31 December 2014 and interest is payable at 10% on amounts outstanding.

#### **(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.

### **Derivative financial instruments and hedging**

There were no derivatives at 31 December 2013 or 31 December 2012, 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.

## **4, Segmental analysis**

### **Segmental reporting**

The chief operating decision-maker has been identified as the Executive Committee, comprising the Executive Directors. The Committee considers that the business comprises a single activity, which is biotechnology research and development, and the related manufacturing. The Committee reviews the Group's financial performance on a whole-company, consolidated basis in order to assess performance and allocate resources. Therefore the segment financial information is the same as that set out in the consolidated statement of comprehensive income, the consolidated balance sheet, the consolidated statement of cash flows and the consolidated statement of changes in equity.

# Notes to the consolidated financial statements

for the year ended 31 December 2013

The Group's revenue derives wholly from assets located in the United Kingdom. Analysed by location of customers, revenue derives predominantly from the European Union.

Revenue by customer location	2013 £'000	2012 £'000
Europe	4,316	7,376
Rest of world	1,059	380
<b>Total revenue</b>	<b>5,375</b>	<b>7,756</b>

Revenue attributable to Novartis was £2,355,000 (2012: nil), all of which related to manufacturing and development services. Revenue attributable to the ocular collaboration with Sanofi was £1,659,000 (2012: £7,259,000) of which £787,000 related to recognition of deferred licence fees.

## 5, Employees and Directors

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

By activity	2013 Number	2012 Number
Office and management	14	10
Research, development and manufacturing	81	73
<b>Total</b>	<b>95</b>	<b>83</b>

Employee benefit costs	2013 £'000	2012 £'000
Wages and salaries	4,934	4,446
Social security costs	610	561
Other pension costs (note 29)	346	342
Termination benefits	208	398
Share based payments (note 25)	351	340
<b>Total employee benefit costs</b>	<b>6,449</b>	<b>6,087</b>

Key management compensation	2013 £'000	2012 £'000
Wages and salaries	1,908	1,812
Social security costs	278	208
Other pension costs	147	152
Termination benefits	208	266
Share based payments	204	230
<b>Total</b>	<b>2,745</b>	<b>2,668</b>

The key management figures above include Executive and non-Executive Directors and other senior managers. Further information about the remuneration of individual Directors is provided in the audited part of the Directors' remuneration report on pages 44 to 55, which forms part of these financial statements.

The Company had no employees during the year (2012: none).

## 6, Finance income and costs

Group	2013 £'000	2012 £'000
Finance income:		
Bank interest receivable	64	141
<b>Total finance income</b>	<b>64</b>	<b>141</b>
Finance costs:		
Unwinding of discount in provisions (note 19)	(4)	(3)
<b>Total finance costs</b>	<b>(4)</b>	<b>(3)</b>
<b>Net finance income</b>	<b>60</b>	<b>138</b>

## 7, Expenses by nature

	Notes	Group		Company	
		2013 £'000	2012 £'000	2013 £'000	2012 £'000
Employee benefit costs	5	6,449	6,087	172	–
Depreciation of property, plant and equipment	12	671	601	–	–
Amortisation	11	396	370	–	–
Impairment of investment	13	–	–	–	10,840
Research and development		13,750	14,015	–	–
Operating lease payments		558	523	–	–
Net (gain)/loss on foreign exchange		(116)	74	–	–

Company employee benefit costs of £172,000 relates to non-Executive Directors costs paid by Oxford BioMedica UK Ltd and recharged to the Company. Since April 2013 non-Executive Directors' fees have been paid through Oxford BioMedica UK Ltd's payroll system and recharged to Oxford BioMedica Plc. Previously the fees had not been recharged.

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

	Group	
	2013 £'000	2012 £'000
<b>Services provided by the Group's auditors</b>		
Fees payable for the audit of the parent company and consolidated financial statements	25	23
Fees payable for other services:		
The audit of the Company's subsidiaries	66	68
Additional fees related to the prior year audit	–	10
Other services	4	–
Tax advisory services	46	85
Tax compliance services	14	15
Corporate finance relating to the shareholder circular in December 2013	13	229
<b>Total</b>	<b>168</b>	<b>430</b>

# Notes to the consolidated financial statements

for the year ended 31 December 2013

## 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 2013 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 2013 have not yet been agreed with the relevant tax authorities.

	Group	
	2013 £'000	2012 £'000
<b>Current tax</b>		
United Kingdom corporation tax research and development credit	(1,500)	(1,497)
Overseas taxation	(3)	1
	<b>(1,503)</b>	<b>(1,496)</b>
<b>Adjustments in respect of prior periods</b>		
United Kingdom corporation tax research and development credit	(142)	(120)
Overseas taxation	(22)	(3)
<b>Taxation credit</b>	<b>(1,667)</b>	<b>(1,619)</b>

The Company has no tax liability, nor is it entitled to tax credits (2012: £nil).

The tax credit for the year is lower (2012: lower) than the standard rate of corporation tax in the UK. The differences are explained below:

	Group		Company	
	2013 £'000	2012 £'000	2013 £'000	2012 £'000
Loss on ordinary activities before tax	(12,763)	(10,349)	(513)	(11,100)
Loss on ordinary activities before tax multiplied by the standard rate of corporation tax in the UK of 23.25% (2012: 24.5%)	(2,967)	(2,536)	(119)	(2,720)
Effects of:				
Tax depreciation and other timing differences	220	66	–	–
Expenses not deductible for tax purposes (includes impairment of investments in subsidiaries)	98	93	–	2,656
R&D relief mark-up on expenses	(1,817)	(1,977)	–	–
Difference in rate relating to R&D tax credits	1,676	1,743	–	–
Tax deduction for share options less than share option accounting charge	46	101	–	–
Overseas tax	–	–	–	–
Tax losses carried forward to future periods	1,241	1,026	–	64
Overseas tax difference in rate	–	(12)	–	–
Adjustments in respect of prior periods	(164)	(123)	–	–
<b>Current tax credit for the year</b>	<b>(1,667)</b>	<b>(1,619)</b>	<b>(119)</b>	<b>–</b>

At 31 December 2013, the Group had tax losses to be carried forward of approximately £94.8 million (2012: £90.9 million). Of the Group tax losses, £94.8 million (2012: £90.9 million) arose in the United Kingdom.

There is no deferred tax recognised (see note 21).

## 9. Basic loss and diluted loss per ordinary share

The basic loss per share has been calculated by dividing the loss for the year by the weighted average number of shares in issue during the year ended 31 December 2013 (1,416,149,005; 2012: 1,146,473,109).

As the Group is loss-making, there were no potentially dilutive options in either year. There is therefore no difference between the basic loss per ordinary share and the diluted loss per ordinary share.

## 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 £513,000 (2012: £11,100,000). The loss includes a charge of Enil (2012: £10,840,000) for impairment of investments in subsidiaries.

## 11. Intangible assets

Group	Intellectual property rights £'000
<b>Cost</b>	
At 1 January 2013	5,493
Additions	98
<b>At 31 December 2013</b>	<b>5,591</b>
<b>Accumulated amortisation and impairment</b>	
At 1 January 2013	2,562
Amortisation charge for the year	396
<b>At 31 December 2013</b>	<b>2,958</b>
<b>Net book amount at 31 December 2013</b>	<b>2,633</b>
<b>Cost</b>	
At 1 January 2012	5,298
Additions	195
<b>At 31 December 2012</b>	<b>5,493</b>
<b>Accumulated amortisation and impairment</b>	
At 1 January 2012	2,192
Amortisation charge for the year	370
<b>At 31 December 2012</b>	<b>2,562</b>
<b>Net book amount at 31 December 2012</b>	<b>2,931</b>

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 £396,000 (2012: £370,000) is included in 'Research and development 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 intangibles at 31 December 2013 or 31 December 2012.

# Notes to the consolidated financial statements

for the year ended 31 December 2013

## 12, Property, plant and equipment

	Freehold property £'000	Short leasehold improve- ments £'000	Office equipment and computers £'000	Manufac- turing and Laboratory equipment £'000	Total £'000
<b>Cost</b>					
At 1 January 2013	3,130	2,604	591	3,570	9,895
Additions at cost	95	19	30	695	839
<b>At 31 December 2013</b>	<b>3,225</b>	<b>2,623</b>	<b>621</b>	<b>4,265</b>	<b>10,734</b>

### Accumulated depreciation

At 1 January 2013	258	2,449	467	2,819	5,993
Charge for the year	218	66	76	311	671
<b>At 31 December 2013</b>	<b>476</b>	<b>2,515</b>	<b>543</b>	<b>3,130</b>	<b>6,664</b>

<b>Net book amount at 31 December 2013</b>	<b>2,749</b>	<b>108</b>	<b>78</b>	<b>1,135</b>	<b>4,070</b>
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	Freehold property £'000	Short leasehold improve- ments £'000	Office equipment and computers £'000	Manufac- turing and Laboratory equipment £'000	Total £'000
<b>Cost</b>					
At 1 January 2012	3,115	3,011	606	3,316	10,048
Additions at cost	15	17	30	254	316
Disposals	–	(424)	(45)	–	(469)
<b>At 31 December 2012</b>	<b>3,130</b>	<b>2,604</b>	<b>591</b>	<b>3,570</b>	<b>9,895</b>

### Accumulated depreciation

At 1 January 2012	45	2,810	388	2,592	5,835
Charge for the year	213	63	98	227	601
Disposals	–	(424)	(19)	–	(443)
<b>At 31 December 2012</b>	<b>258</b>	<b>2,449</b>	<b>467</b>	<b>2,819</b>	<b>5,993</b>

<b>Net book amount at 31 December 2012</b>	<b>2,872</b>	<b>155</b>	<b>124</b>	<b>751</b>	<b>3,902</b>
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The Company had no property, plant and equipment at 31 December 2013 or 31 December 2012.

### 13, Investment in subsidiaries

	2013	2012
	£'000	£'000
<b>Fixed asset investments: Company</b>		
<b>Shares in group undertakings</b>		
<b>At 1 January and 31 December</b>	<b>17,158</b>	17,158
<b>Loans to group undertakings</b>		
At 1 January	138,082	128,856
Loan advanced in the year	208	9,031
Subsidiary debt settled by issue of parent shares	–	195
<b>At 31 December</b>	<b>138,290</b>	138,082
<b>Total investments in shares and loans to group undertakings</b>	<b>155,448</b>	155,240
<b>Impairment</b>		
At 1 January	128,041	117,201
Impairment charge in the year	–	10,840
<b>At 31 December</b>	<b>128,041</b>	128,041
<b>Net book amount at 31 December</b>	<b>27,407</b>	27,199
<b>Capital contribution in respect of employee share schemes (see note 25)</b>		
At 1 January	4,642	4,302
Additions in the year	351	340
<b>At 31 December</b>	<b>4,993</b>	4,642
<b>Total investments</b>	<b>32,400</b>	31,841

The Group had no investments at 31 December 2013 (2012: nil).

### Interests in subsidiary undertakings

Name of undertaking	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
BioMedica Inc	United States of America	\$0.001	100%	Not active
Oxxon Therapeutics Limited	Great Britain	1p ordinary shares	100%	Dormant

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, 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 Group for this purpose. Following an impairment review at 31 December 2013 no impairment charge was assessed to be required. Cumulative impairment of £128.0m has been recognised up to 31 December 2013.

# Notes to the consolidated financial statements

for the year ended 31 December 2013

## 14, Inventories

	2013 £'000	2012 £'000
Raw Materials	<b>558</b>	–
Work-in-progress	<b>122</b>	–
<b>Total inventory</b>	<b>680</b>	–

Inventories constitute raw materials held for commercial manufacturing purposes, and work-in-progress inventory related to contractual manufacturing obligations.

The Company holds no inventories.

## 15, Trade and other receivables

	Group		Company	
	2013 £'000	2012 £'000	2013 £'000	2012 £'000
<b>Current</b>				
Trade receivables	<b>1,040</b>	315	–	–
Accrued income	<b>637</b>	400	–	–
Other receivables	<b>28</b>	184	–	–
Other tax receivable	<b>285</b>	140	–	–
Prepayments	<b>602</b>	666	<b>3</b>	11
<b>Total trade and other receivables</b>	<b>2,592</b>	1,705	<b>3</b>	11

The fair value of trade and other receivables are the current book values.

Included in the Group's trade receivable balance are debtors with a carrying amount of £142,000 (2012: £204,000) which are past due at the reporting date. The Group does not hold any collateral over these balances. No provision for impairment of receivables has been recognised as the Directors do not believe there has been a significant change in credit quality and consider the remaining amounts to be recoverable in full.

Ageing of past due but not impaired trade receivables:

	2013 £'000	2012 £'000
0 – 30 days	<b>95</b>	40
30 – 60 days	–	–
60+ days	<b>47</b>	164
	<b>142</b>	204

Accrued income of £637,000 (2012: £400,000) relates to amounts receivable from Sanofi and Novartis (2012: Sanofi).

The carrying amounts of the Group's trade and other receivables are denominated in the following currencies:

	2013 £'000	2012 £'000
Sterling	<b>1,993</b>	968
US Dollar	<b>599</b>	737
	<b>2,592</b>	1,705

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

	Group		Company	
	2013	2012	2013	2012
	£'000	£'000	£'000	£'000
Cash at bank and in hand	<b>2,169</b>	8,956	<b>43</b>	743

In addition to the cash and cash equivalents described above, the Group held Sterling bank deposits of £nil (2012: £5,105,000) with a maturity of between three and twelve months classified as available for sale investments. None of these deposits were past due or impaired.

The Company held no available for sale investments in 2013 or 2012.

## 17, Trade and other payables

	Group		Company	
	2013	2012	2013	2012
	£'000	£'000	£'000	£'000
Trade payables	1,218	881	–	–
Other taxation and social security	201	157	–	–
Accruals	1,515	1,664	36	23
<b>Total trade and other payables</b>	<b>2,934</b>	2,702	<b>36</b>	23

## 18, Deferred income

Group	2013	2012
	£'000	£'000
Current	1,280	1,568
<b>Total deferred income</b>	<b>1,280</b>	1,568

On 28 April 2009 the Company entered into a collaborative programme with Sanofi to develop gene therapy products to treat ocular diseases. An initial non-refundable sum of US\$26 million (£16,641,000) was received. This has been recognised as revenue over the expected duration of the collaboration for each of the products. During 2013, the remaining £787,000 (2012: £3,414,000) of this receipt was recognised such that the full amount of £16,641,000 has now been recognised and there is no further deferred revenue.

Over the term of the collaboration with Sanofi, Oxford BioMedica may recover from Sanofi up to US\$24 million in research and development funding. Project costs in excess of US\$24 million will be borne by Oxford BioMedica. To date, £14,191,000 (\$22,428,000) has been recognised as revenue, of which £872,000 was recognised in 2013. £673,000 (2012: £621,000) has been classified as current deferred income.

£413,000 (2012: £nil) deferred income arises from the collaboration with Novartis.

The balance of £194,000 deferred income relates to other small contractual agreements.

The Company had no deferred income in 2013 or 2012.

# Notes to the consolidated financial statements

for the year ended 31 December 2013

## 19, Provisions

Group	Dilapidations £'000	Onerous lease £'000	Total £'000
At 1 January 2013	510	–	510
Unwinding of discount	4	–	4
Change of discount rate – adjustment to recognised property, plant and equipment	18	–	18
<b>At 31 December 2013</b>	<b>532</b>	<b>–</b>	<b>532</b>
At 1 January 2012	501	41	542
Utilised in the year	–	(41)	(41)
Unwinding of discount	3	–	3
Change of discount rate – adjustment to recognised property, plant and equipment	6	–	6
<b>At 31 December 2012</b>	<b>510</b>	<b>–</b>	<b>510</b>

The dilapidations provision relates to anticipated costs of restoring the leasehold property in Oxford, UK to its original condition at the end of the present leases in 2016, discounted using the rate per the Bank of England nominal yield curve. The equivalent rate was used in 2012. The provision will be utilised at the end of the leases if they are not renewed.

The Company had no provisions at 31 December 2013 or 31 December 2012.

## 20, Financial instruments

The Group's and Company's financial instruments comprise cash and cash equivalents, together with available for sale investments, trade and other receivables, 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:

	Assets		Liabilities	
	2013 £'000	2012 £'000	2013 £'000	2012 £'000
Cash and cash equivalents (note 16)	2,169	8,956	–	–
Available for sale investments (note 16)	–	5,105	–	–
Trade receivables and other receivables (note 15)	1,068	499	–	–
Trade and other payables excluding tax (note 17)	–	–	2,733	2,545
	<b>3,237</b>	<b>14,560</b>	<b>2,733</b>	<b>2,545</b>

The available for sale investments held at 31 December 2012 were denominated in Sterling.

The Company had the following financial instruments at 31 December each year:

	Assets		Liabilities	
	2013 £'000	2012 £'000	2013 £'000	2012 £'000
Cash and cash equivalents (note 16)	43	743	–	–
Trade receivables and other receivables (note 15)	3	11	–	–
Trade and other payables excluding tax (note 17)	–	–	36	23
	<b>46</b>	<b>754</b>	<b>36</b>	<b>23</b>

The weighted average interest rates and average deposit terms for fixed rate deposits are shown below. Floating rate instant access deposits earned interest at prevailing bank rates.

	2013			2012		
	Year end deposits		Yr. average	Year end deposits		Yr. average
	Weighted average rate	Weighted average term	Weighted average rate	Weighted average rate	Weighted average term	Weighted average rate
Sterling	<b>1.22%</b>	<b>205 days</b>	<b>1.27%</b>	1.64%	93 days	1.70%
Euro	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	0.65%	262 days	1.15%
US Dollars	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	0.65%	262 days	0.65%

In accordance with IAS 39 'Financial instruments: Recognition and measurement' 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 2013 or 31 December 2012.

### 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:

	2013 £'000	2012 £'000
Sterling	<b>1,982</b>	6,133
US Dollar	<b>187</b>	2,823
	<b>2,169</b>	8,956

### 21. Deferred taxation

Neither the Company nor the Group had any recognised deferred tax assets or liabilities at 31 December 2013 (2012: £nil). In light of the Group's continuing losses, recovery of the deferred tax asset is not sufficiently certain, and therefore no asset has been recognised.

During the year, as a result of the change in the UK corporation tax rate from 23% to 21% that was substantively enacted on 2 July 2013 and that will be effective from 1 April 2014, the relevant unrecognised deferred tax balances have been re-measured.

Further changes to the UK Corporation tax system were announced in the Autumn Statement 2012. This includes a further reduction to the main rate to reduce the rate to 20% from 1 April 2015. This change has been substantively enacted at the balance sheet date and, is therefore included in these financial statements.

Deferred tax expected to reverse in the year to 31 December 2014 has been measured using the effective rate that will apply in the UK for the period (21%).

Group	Tax depreciation £'000	Provisions £'000	Tax losses £'000	Share options £'000	Total £'000
<b>Deferred tax (assets)/liabilities – not recognised</b>					
At 1 January 2013	(741)	(124)	(20,912)	(38)	(21,815)
Origination and reversal of temporary differences	(66)	8	1,957	(26)	1,873
<b>At 31 December 2013</b>	<b>(807)</b>	<b>(116)</b>	<b>(18,955)</b>	<b>(64)</b>	<b>(19,942)</b>
At 1 January 2012	(696)	(343)	(21,828)	(60)	(22,927)
Origination and reversal of temporary differences	(45)	219	916	22	1,112
<b>At 31 December 2012</b>	<b>(741)</b>	<b>(124)</b>	<b>(20,912)</b>	<b>(38)</b>	<b>(21,815)</b>

# Notes to the consolidated financial statements

for the year ended 31 December 2013

## 22, Ordinary shares

<b>Group and Company</b>	<b>2013</b>	<b>2012</b>
<b>Issued and fully paid</b>	<b>£'000</b>	<b>£'000</b>
Ordinary shares of 1p each		
At 1 January – 1,416,149,005 (2012: 944,875,557) shares	<b>14,162</b>	9,449
Allotted for cash in placing and open offer – nil (2012: 463,362,652) shares	–	4,634
Allotted for cash to licensors of patent rights – nil (2012: 7,910,796) shares	–	79
<b>At 31 December – 1,416,149,005 (2012:1,416,149,005) shares</b>	<b>14,162</b>	14,162

## 23, Share premium account

<b>Group and Company</b>	<b>2013</b>	<b>2012</b>
	<b>£'000</b>	<b>£'000</b>
At 1 January	<b>130,304</b>	124,755
Premium on shares issued for cash in placing and open offer	–	6,950
Premium on shares issued to licensors of patent rights	–	116
Costs associated with the issue of shares	–	(1,517)
<b>At 31 December</b>	<b>130,304</b>	130,304

## 24, Options over shares of Oxford BioMedica plc

The Company has outstanding share options that were issued under the following schemes:

- the Oxford BioMedica 2007 Share Option Scheme (approved February 2007)
- the Long Term Incentive Plan (LTIP) for Executive Directors and senior executives (approved February 2007)

Share options are granted to Executive Directors and selected senior managers under the Company's Long Term Incentive Plan (LTIP) and to other employees under the Share Option Scheme. All option grants are at the discretion of the Remuneration Committee.

Options granted under the LTIP 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 par 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 and 2013, with one exception, vest in tranches of 25% from the first to fourth anniversaries of the grant dates.

Share options outstanding at 31 December 2013 have the following expiry date and exercise prices:

### Options granted to employees under the Oxford BioMedica 1996 (No. 1) Share Option Scheme

2013 Number of shares	2012 Number of shares	Exercise price per share	Date from which exercisable	Expiry date
–	623,693	28.25p to 31.0p	21/03/09 to 06/09/09	21/03/13 to 06/09/13

All outstanding options expired during 2013.

### Options granted to employees under the Oxford BioMedica 2007 Share Option Scheme

2013 Number of shares	2012 Number of shares	Exercise price per share	Date from which exercisable	Expiry date
–	722,017	22.0p to 49.25p	08/03/10 to 14/12/10	08/03/17 to 14/12/17
<b>550,000</b>	1,025,221	5.75p to 22.5p	13/03/11 to 13/10/11	13/03/18 to 13/10/18
<b>244,883</b>	1,587,554	6.10p to 11.25p	25/03/12 to 08/10/12	25/03/19 to 08/10/19
–	1,693,408	9.50p to 9.69p	01/04/13 to 13/09/13	01/04/20 to 13/09/20
<b>2,270,248</b>	2,625,381	5.40p to 5.82p	15/03/14 to 04/10/14	15/03/21 to 04/10/21
<b>4,812,752</b>	5,322,945	2.28p to 3.10p*	08/05/13 to 21/12/13	08/05/22 to 21/12/22
<b>8,309,593</b>	–	1.56p to 2.83p*	22/05/14 to 19/11/14	22/05/23 to 19/11/23
<b>16,187,476</b>	12,976,526			

\* Options granted in 2012 and 2013 are vesting in 25% tranches on the first to fourth anniversaries of the grant date. The date from which exercisable shows the date on which the first 25% becomes exercisable.

### Options granted under the Oxford BioMedica Long Term Incentive Plan

2013 Number of shares	2012 Number of shares	Exercise price per share	Date from which exercisable	Expiry date
<b>1,150,000</b>	1,150,000	1p	13/10/11	13/10/18
–	5,568,000	1p	15/06/13	15/06/20
<b>6,537,000</b>	6,537,000	1p	13/04/14 to 07/09/14	13/04/21 to 07/09/21
<b>25,590,000</b>	25,590,000	1p	30/06/15	30/06/22
<b>19,501,808</b>	–	1p	12/06/16	12/06/23
<b>52,778,808</b>	38,845,000			
<b>68,966,284</b>	52,445,219			

Options granted to UK employees could give rise to a national insurance (NI) liability on exercise. A provision of £2,000 (2012: £2,000) 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 2.3p (2012: 2.3p) per share.

# Notes to the consolidated financial statements

for the year ended 31 December 2013

## 25, Share based payments

The fair values of options granted during the year were calculated using the following assumptions:

<b>Share options</b>	<b>Share options granted 02.05.13 to 19.11.13</b>
Share price at grant date	1.56p to 2.83p
Exercise price	1.56p to 2.83p
Vesting period (years)	25% annual tranches
Total number of shares under option	8,819,344
Expected volatility	55% to 60%
Expected life (years)	4 to 7 depending on tranche
Risk free rate	0.8% to 3.5% depending on life
Expected rate of forfeit before vesting	5% to 25%
Fair value per option	1.04p to 1.47p
Model used: Black-Scholes	

<b>LTIP awards</b>	<b>LTIP award 12.06.13</b>
Share price at grant date	1.7p
Exercise price	1.00p
Vesting period (years)	3.00
Total number of shares under option	19,501,808
Expected volatility (weighted average)	55%
Expected life (years)	3.00
Risk free rate (weighted average)	0.66%
Expected rate of forfeit before vesting (weighted average)	0.0%
Expectation of meeting performance criteria (weighted average)	6%
Fair value per option	0.32p
Model used: Monte Carlo	

The tables below show the movements in both the Share Option Scheme and the LTIP during the year together with the related weighted average exercise prices. Excluding the LTIP awards which are exercisable at par, the weighted average exercise price for options granted during the year was 2.1p (2012: 3.1p). All 623,693 options outstanding under the 1996 scheme at the start of 2013 expired during the year. In September 2013 the Remuneration Committee decided to cancel 4,097,585 vested share options for which the exercise prices were 9.5p and above. Recognising that these options were providing little if any incentive to the holders of the options, the Remuneration Committee replaced the cancelled options with 2,137,915 new options which will vest in September 2014, with an exercise price of 2.83p, the average market price for the 5 days preceding the grant. The new options and the cancelled options were each valued using the Black-Scholes valuation model to establish an exchange ratio for each cancelled option. Both the cancellation and re-issue of the share options was at a nil gain, nil loss, with no incremental fair value granted to the employee. None of the directors held any of the cancelled options, nor were they granted any of the replacement options. No options were exercised in 2013 or 2012.

The total charge for the year relating to employee share based payment plans was £351,000 (2012: £340,000), all of which related to equity-settled share based payment transactions.

	2013		2012	
	Number	Weighted average exercise price	Number	Weighted average exercise price
<b>Share options excluding LTIP</b>				
Outstanding at 1 January	13,600,219	9.1p	13,701,557	15.1p
Granted	8,819,344	2.1p	5,826,902	3.07p
Expired	(4,721,278)	18.4p	(1,853,999)	29.2p
Forfeited	(1,510,809)	4.3p	(4,074,241)	40.3p
Exercised	–	–	–	–
Outstanding at 31 December	16,187,476	3.0p	13,600,219	9.1p
Exercisable at 31 December	794,883	5.9p	3,958,485	19.5p
Exercisable and where market price exceeds exercise price at 31 December	–	N/A	–	N/A

	2013 Number	2012 Number
<b>LTIP awards (options exercisable at par value 1p)</b>		
Outstanding at 1 January	38,845,000	18,779,000
Granted	19,501,808	25,590,000
Expired	(5,568,000)	(5,524,000)
Outstanding at 31 December	52,778,808	38,845,000
Exercisable at 31 December	1,150,000	1,150,000

	2013			2012		
	Weighted average exercise price	Number of shares	Weighted average remaining life (years) Contractual	Weighted average exercise price	Number of shares	Weighted average remaining life (years) Contractual
<b>Range of exercise prices</b>						
LTIP:						
Exercisable at par	1.0p	52,778,808	8.6	1.0p	38,845,000	8.9
Options:						
Under 10p	3.04p	16,187,476	8.7	4.9p	10,461,617	8.6
10p to 20p	–	–	–	10.6p	1,562,446	6.6
20p to 30p	–	–	–	26.2p	604,669	4.1
30p to 40p	–	–	–	33.6p	468,616	4.1
40p to 50p	–	–	–	48.2p	502,871	4.2
		68,966,284			52,445,219	

## 26. Accumulated losses

	Group		Company	
	2013 £'000	2012 £'000	2013 £'000	2012 £'000
At 1 January	(138,451)	(130,061)	(130,135)	(119,035)
Loss for the year	(11,096)	(8,730)	(513)	(11,100)
Share based payments (note 25)	351	340	–	–
<b>At 31 December</b>	<b>(149,196)</b>	<b>(138,451)</b>	<b>(130,648)</b>	<b>(130,135)</b>

Neither the Company nor its subsidiary undertakings had reserves available for distribution at 31 December 2013 or 31 December 2012.

# Notes to the consolidated financial statements

for the year ended 31 December 2013

## 27, Other reserves

Group	Translation reserve £'000	Merger reserve £'000	Total £'000
At 1 January 2013	(682)	14,310	13,628
<b>At 31 December 2013</b>	<b>(682)</b>	<b>14,310</b>	<b>13,628</b>
At 1 January 2012	(682)	14,310	13,628
<b>At 31 December 2012</b>	<b>(682)</b>	<b>14,310</b>	<b>13,628</b>

The Group merger reserve at 31 December 2013 and 2012 comprised £711,000 arising from consolidation of Oxford BioMedica (UK) Limited using the merger method of accounting in 1996 and £13,599,000 from the application of merger relief to the purchase of Oxxon Therapeutics Limited in 2007.

Company	Merger reserve £'000	Share scheme reserve £'000
At 1 January 2013	13,599	4,642
Credit in relation to employee share schemes	–	351
<b>At 31 December 2013</b>	<b>13,599</b>	<b>4,993</b>
At 1 January 2012	13,599	4,302
Credit in relation to employee share schemes	–	340
<b>At 31 December 2012</b>	<b>13,599</b>	<b>4,642</b>

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 25). In accordance with IFRIC 11, the Company has treated the awards as a capital contribution to the subsidiaries, resulting in an increase in the cost of investment of £351,000 (2012: £340,000) (see note 13) and a corresponding credit to reserves.



## 28, Cash flows from operating activities

Reconciliation of loss before tax to net cash used in operations:

	Group		Company	
	2013 £'000	2012 £'000	2013 £'000	2012 £'000
<b>Continuing operations</b>				
Loss before tax	(12,763)	(10,349)	(513)	(11,100)
Adjustment for:				
Depreciation	671	601	–	–
Amortisation of intangible assets	396	370	–	–
Loss on disposal of property, plant and equipment	–	26	–	–
Charge for impairment	–	–	–	10,840
Finance income	(64)	(141)	–	–
Finance expense	4	3	–	–
Charge in relation to employee share schemes	351	340	–	–
Changes in working capital:				
(Increase)/decrease in trade and other receivables	(886)	1,224	8	(10)
Increase/(decrease) in trade and other payables	232	(524)	13	(23)
(Decrease) in deferred income	(288)	(2,988)	–	–
Increase/(decrease) in provisions	22	(32)	–	–
(Increase) in inventory	(680)	–	–	–
<b>Net cash used in operations</b>	<b>(13,005)</b>	<b>(11,470)</b>	<b>(492)</b>	<b>(293)</b>

## 29, 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 £346,000 (2012: £342,000) represents amounts payable by the Group to the scheme. Contributions of £38,000 (2012: £8,000), included in accruals, were payable to the scheme at the year-end.

## 30, Operating lease commitments – minimum lease payments

The future aggregate minimum lease payments under non-cancellable operating leases are as follows:

Group	2013 £'000	2012 £'000
Not later than one year	652	583
Later than one year and not later than five years	805	1,298
<b>Total lease commitments</b>	<b>1,457</b>	<b>1,881</b>

The Group leases equipment under non-cancellable operating lease agreements. The Group also leases its Medawar Centre laboratories and offices under non-cancellable operating lease agreements. The leases have various terms, escalation clauses and renewal rights.

The Company had no operating lease commitments during the year (2012: none).

# Notes to the consolidated financial statements

for the year ended 31 December 2013

## 31, Contingent liabilities and capital commitments

The Group had commitments of £25,000 for capital expenditure for leasehold improvements, plant and equipment not provided in the financial statements at 31 December 2013 (2012: £148,000).

## 32, 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, 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, and BioMedica Inc., which stopped trading and became inactive in 2013.

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.

<b>Company: transactions with subsidiaries</b>	<b>2013</b>	<b>2012</b>
	<b>£'000</b>	<b>£'000</b>
<b>Purchases:</b>		
Parent company expenses paid by subsidiary	<b>(492)</b>	(969)
<b>Transactions involving parent company shares:</b>		
Subsidiary royalty liability settled by issue of parent company shares	–	195
<b>Cash management:</b>		
Cash loaned by parent to subsidiary	<b>700</b>	10,000

The loan from Oxford BioMedica plc to Oxford BioMedica (UK) Limited is unsecured and interest free. The loan is not due for repayment within 12 months of the year end. The year-end balance on the loan was:

<b>Company: year-end balance of loan</b>	<b>2013</b>	<b>2012</b>
	<b>£'000</b>	<b>£'000</b>
Loan to subsidiary	<b>138,290</b>	138,082

In addition to the transactions above, options over the Company's shares have been awarded to employees of subsidiary companies. In accordance with IFRIC 11, the Company has treated the awards as a capital contribution to the subsidiaries, resulting in a cumulative increase in the cost of investment of £4,993,000 (2012: £4,642,000).

There were no transactions (2012: none) with Oxxon Therapeutics Limited.

### **Transactions with Directors and connected persons**

Dr Alan Kingsman (former group chairman) was paid a consultancy fee of £37,500 in 2013 (2012: £75,000).

On 6 January 2014, shareholders approved a £5 million secured loan facility provided by Vulpes Life Sciences Fund to the Group. Martin Diggle, a non-Executive Director of the Company is a founder of Vulpes Investment Management which manages Vulpes Life Sciences Fund.

There were no outstanding balances in respect of transactions with Directors and connected persons at 31 December 2013 (2012: none).

Key person remuneration can be seen in the Directors' remuneration report on pages 44 to 55.

### **33, Subsequent events**

On 6 January 2014 shareholders approved a £5 million secured loan facility provided by Vulpes Life Sciences Fund to the Group. Under the facility, the Group may draw down the loan in tranches of at least £1 million, as necessary, at any time from 1 January 2014 until 10 days before the maturity of the facility on 31 December 2014. £1.5 million of this facility has been drawn down at the date of this report.

# 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.

### **ProSavin®/OXB-102: Parkinson's disease**

ProSavin® 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. ProSavin® 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.

### **RetinoStat®: "wet" age-related macular degeneration**

RetinoStat® is a gene-based treatment for neovascular "wet" age-related macular degeneration (AMD) and diabetic retinopathy (DR). RetinoStat® 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.

### **StarGen™: Stargardt disease**

StarGen™ 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. StarGen™ 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.

### **UshStat®: Usher syndrome type 1B**

UshStat® 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. UshStat® 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.

### **EncorStat®: corneal graft rejection**

EncorStat® 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. EncorStat® 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.

### **Glaucoma-GT: chronic glaucoma**

Glaucoma-GT is a gene based treatment for the treatment of chronic glaucoma. Chronic glaucoma results from a partial blockage within trabecular meshwork of the eye, the tissue mainly responsible for draining the internal fluid of the eye (aqueous humour). As the aqueous humour builds up, it causes increased intraocular pressure which can damage the optic nerve and lead to premature patches of vision loss or, in some cases blindness.

Glaucoma-GT uses the LentiVector® platform technology expressing a COX-2 gene and a PGF-2 $\alpha$  receptor gene in order to reduce intraocular pressure and minimise the risk of disease progression.

### **MoNuDin®: motor neuron disease**

MoNuDin® is a gene-based treatment for motor neuron disease. This progressive, usually fatal, neurodegenerative disease is caused by the degeneration of motor neurons, the nerve cells in the central nervous system that control voluntary muscle movement. MoNuDin® uses the Company's LentiVector® platform technology to deliver a neuroprotective gene, vascular endothelial growth factor (VEGF), to prevent further degeneration of the motor neurons and potentially restore motor function.

### **5T4 tumour antigen**

The 5T4 tumour antigen is a unique protein found on most common types of solid cancer. It is potentially a valuable target for novel anti-cancer interventions given its restricted expression in normal tissues and its high prevalence on the surface of both primary and metastatic cancerous cells. The 5T4 tumour antigen was identified through research into the similarities between the development of the placenta during pregnancy and the progression of cancer. 5T4 is produced by both cancerous cells and also by placental and foetal cells, suggesting that the process of immunological escape in pregnancy and cancer is based on similar mechanisms.

### **TroVax® (MVA-5T4): cancer**

TroVax® is a therapeutic vaccine that stimulates the immune system to destroy cancerous cells expressing the 5T4 tumour antigen which is present on most solid tumours. The product is based on an attenuated modified vaccinia virus Ankara (MVA), engineered to deliver the 5T4 antigen. Vaccinia viruses are commonly used as delivery systems for the development of antigen-specific vaccines. MVA is the vaccinia strain of choice because of its excellent safety profile.

### **Anti-5T4 antibodies**

A 5T4-targeted antibody drug conjugate which binds to the 5T4 antigen on the surface of cancerous cells. Once bound, the complex is internalised by the tumour cell, the anti cancer agent is released from the antibody, and the free drug kills the cancerous cell.

### **PrimeBoost**

Heterologous prime-boost immunotherapy involves priming the immune system to target an antigen using one vector and then boosting the response by administration of the same antigen using a different vector. In many cases this can elicit immune responses of greater magnitude and breadth than can be achieved by priming and boosting with the same vector. Oxford BioMedica's PrimeBoost technology can stimulate potentially potent and specific cellular immune responses against diseased cells, even those expressing very low levels of the antigen.

### **OXB Solutions**

Our name for our business which provides development and manufacturing services to third parties.

### **Terminology not specific to Oxford BioMedica**

#### **Advanced Therapy Medicinal Products (ATMP)**

ATMPs cover gene and cell therapy medicinal products and tissue engineered products.

### **Anti-angiogenesis**

The creation of new blood vessels, known as angiogenesis, is a critical element in tumour formation and growth. Endostatin and angiostatin were discovered by one of the best known researchers in the field of angiogenesis, Dr Judah Folkman of Children's Hospital and the Harvard Medical School in Boston. The proteins have shown potent anti-cancer activity in preclinical models and a potentially additive effect when used in combination.

### **Gene therapy**

Gene therapy is the use of DNA to treat disease by delivering therapeutic DNA into a patient's cells. 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.

### **Investigational Medicinal Product (IMP)**

A pharmaceutical substance being tested in a clinical trial.

### **Cell therapy**

Cell therapy is defined as the administration of live whole cells in a patient for the treatment of a disease.

### **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 1: Screening for safety
- Phase 2: Establishing the efficacy of the drug, usually against a placebo
- Phase 3: Final confirmation of safety and efficacy

### **Preclinical studies**

Preclinical studies (also known as nonclinical 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.

### **Technology Strategy Board (TSB)**

The Technology Strategy Board is the UK's innovation agency. Its role is to stimulate innovation, working with business and other partners, in order to accelerate economic growth.

### **Advanced Manufacturing Supply Chain Initiative (AMSCI)**

The Advanced Manufacturing Supply Chain Initiative is a funding competition designed to improve the global competitiveness of UK advanced manufacturing supply chains.

### **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.

### **CTL019**

CTL019 is a clinical trial of T cell therapy for patients with B cell cancers such as acute lymphoblastic leukemia (ALL), B cell non-Hodgkin lymphoma (NHL), and the adult disease chronic lymphocytic leukemia (CLL).

### **CD19**

CD19 is a protein that in humans is encoded by the CD19 gene. It is found on the surface of B-cells, a type of white blood cell.

### **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.

### **ANSM**

Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM) is the French National Security Agency of Medicines and Health Products.

### **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.

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