

Focusing on gene therapy success. Annual report and accounts 2013

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Overview

- 01 Strongly positioned for success
- 02 A well-rounded investment proposition
- 08 Product pipeline
- 10 Chairman's message
- 12 Operational highlights

Strategic report

- 13 Key financial performance indicators
- 14 Market opportunity
- 15 Our business model
- 18 Chief Executive's review
- 20 Strategy in action
- 22 Progress against strategy
- 26 Chief Financial Officer's review
- 30 Corporate social responsibility
- 33 Principal risks and uncertainties

Corporate governance

- 38 The Board of Directors
- 40 Corporate governance
- 44 Directors' remuneration report
- 56 Directors' report
- 60 Independent auditors' report

Group financial statements

- 65 Consolidated statement of comprehensive income
- 66 Balance sheets
- 67 Statements of cash flows
- 68 Statements of changes in equity attributable to owners of the parent
- 69 Notes to the consolidated financial statements
- 94 Glossary
- 96 Advisers and contact details

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

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

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

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

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

"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."

£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

+60%

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

Operational highlights

£1.8m

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

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

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

£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

£5m

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

£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

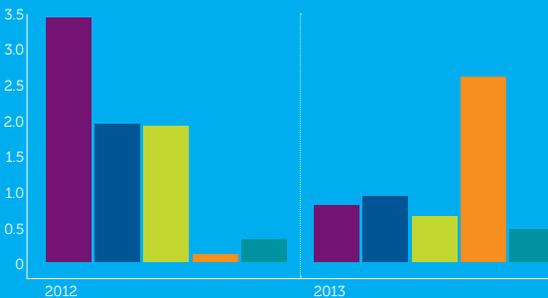
Cash burn (net cash used in/generated from operations plus sales and purchases of non-current assets and interest received) £11.9 million (2012: £10.5 million)

£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)

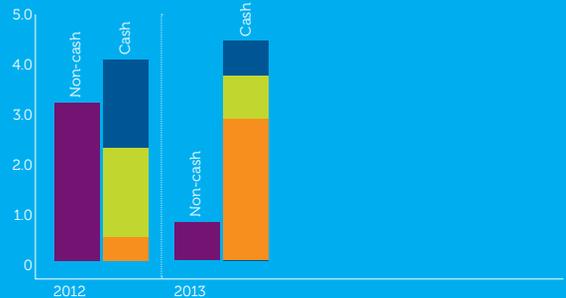
106 people

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

€16bn

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

\$6.5bn

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

90%

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

\$3.5bn

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

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

30,000

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

\$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

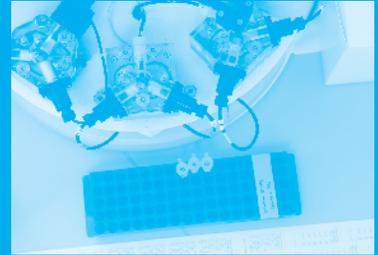
We are building our business on our unique platform – a combination of our intellectual property, the range and skills of our workforce, and our facilities which include our GMP-approved manufacturing site.

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.

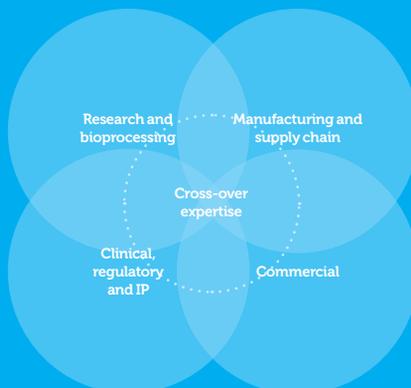
Exploiting our platform...

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.

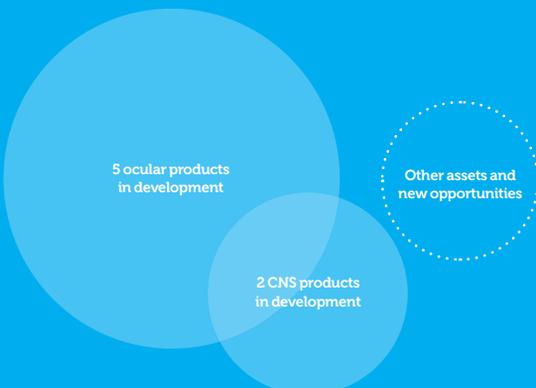
LentiVector® is one of the best delivery systems available...

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.

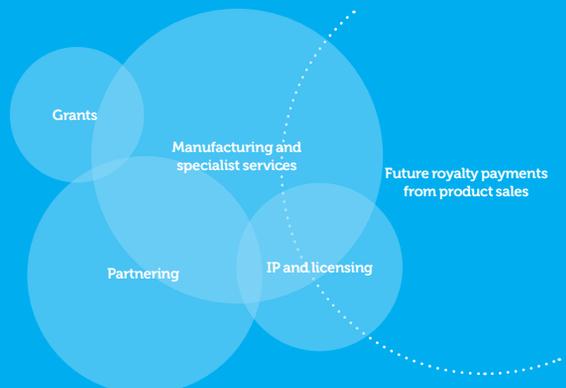
TroVax® is a therapeutic vaccine that stimulates the immune system to destroy cancerous cells expressing the 5T4 tumour antigen. We have out-licensed the technology to Pfizer, which is developing a 5T4-targeted antibody therapy.



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

"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."

£1.8m

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

£5m

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

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.

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

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

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[®], StarGen[™] and UshStat[®]. In April 2013, the Drug Safety Monitoring Board (DSMB) for StarGen[™] 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[®], we will receive an undisclosed option fee...

We have now completed the recruitment and dosing of the 21 patients required for the RetinoStat[®] 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[™] and UshStat[®] 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[®] which was originally included in our 2009 collaboration with Sanofi. We are excited about regaining control of EncorStat[®]. It is a gene-based, tissue-engineered product for preventing corneal graft rejection. EncorStat[®] uses our LentiVector[®] 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[®] 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[®] 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[®] 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[®] 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.

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.



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

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

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

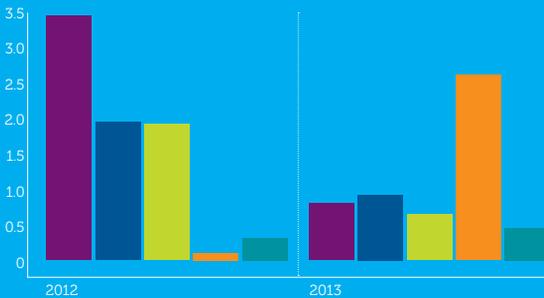
Cash burn (net cash used in/generated from operations plus sales and purchases of non-current assets and interest received) £11.9 million (2012: £10.5 million)

£2.2m

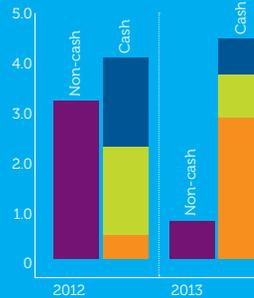
Cash balance (total of cash, cash equivalents and current financial investments) £2.2 million (£14.1 million at the start of the year)

106 people

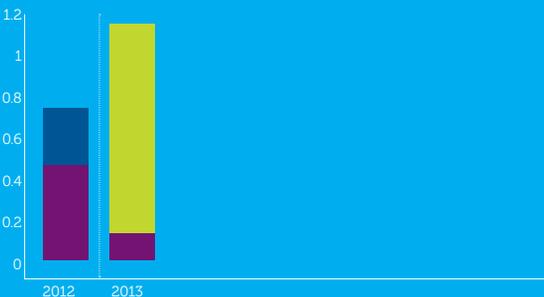
Headcount increased to 106 employees (81 at the start of the year) to support manufacturing revenue generation



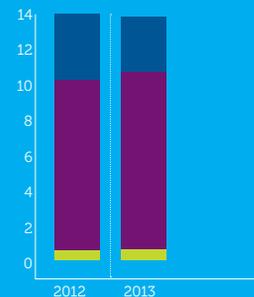
Revenue analysis £m
 ■ Deferred
 ■ R&D reimbursement
 ■ Milestones/options
 ■ Development/manufacturing
 ■ Licence/other



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.

£3m

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

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) provides information on ongoing clinical trials, and we also disclose our trials on a US government-sponsored website (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

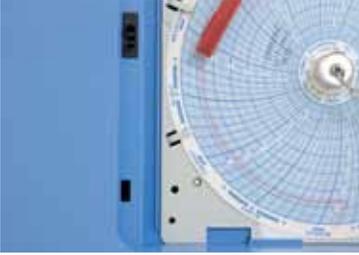
It is legally mandated by regulatory authorities worldwide that all new therapeutic products must be extensively tested for safety before they are administered to patients, and there is currently no alternative to using animal models as part of this process. We are committed to following the principles 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 CO₂ 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 CO₂ 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 ₂ 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
Total				2,297

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.

"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