

#### **Strategy**

Synairgen leverages its deep understanding of respiratory biology to discover and develop novel therapies in the areas of highest unmet respiratory medical need, including severe asthma, COPD and IPF. Using our BioBank platform (our human tissue models of respiratory disease), and our clinical trial capabilities, Synairgen's strategy is to identify novel drug targets, progress them through early stage clinical trials and out-license them to partners for progression to market.

#### **Contents**

#### Introduction

Strategy	l
Highlights	2
Business Review	
Strategic Report	3
Governance	
Synairgen's Founders	16
Directors	17
Directors' Report	19
Corporate Governance	20
Directors' Remuneration Report	22
Financials	
Statement of Directors' Responsibilities	27
Independent Auditor's Report to the members of Synairgen plc	28
Consolidated Statement of Comprehensive Income	29
Consolidated Statement of Changes in Equity	29
Consolidated Statement of Financial Position	30
Consolidated Statement of Cash Flows	31
Notes to the Consolidated Financial Statements	32
Parent Company Balance Sheet	43
Parent Company Statement of Changes in Equity	43
Notes to the Parent Company Financial Statements	44
Other	
Corporate Directory	47
Glossary	47



www.synairgen.com

Cover image is a section of lung tissue from an IPF patient, with fibroblast cells stained in red and scar tissue stained blue.

#### **Operational** highlights

- In July, AstraZeneca commenced its Phase IIa study of AZD9412 (inhaled interferon beta, developed by Synairgen). The study is progressing according to plan and results are expected in 2017
- In August, a research collaboration was signed with Pharmaxis to develop a selective inhibitor of the lysyl oxidase type 2 enzyme (LOXL2) to treat the fatal lung disease idiopathic pulmonary fibrosis (IPF)
- · Continued screening of new development opportunities using Synairgen's proprietary 'BioBank' platform, leveraging Synairgen's world-class founder and respiratory drug discovery and development expertise

#### **Financial** highlights

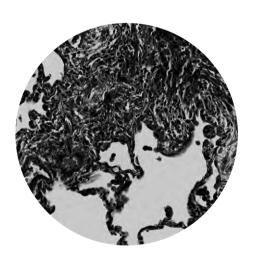
- Loss from operations for the year ended 31 December 2015 was £2.61 million (2014: profit £1.09 million). The prior vear profit was driven by the one-off upfront licensing payment from AstraZeneca of £4.25 million
- Research and development expenditure for the year was £1.36 million (2014: £1.65 million)
- · Cash, cash equivalents and deposit balances of £7.71 million at 31 December 2015 (2014: £9.60 million). The Group remains debt free
- · Current funds support the ongoing search and identification of new potential molecules opportunities

#### **Post** period-end

 Positive results from Pharmaxis collaboration with LOXL2 inhibitors







# Strategic Report

The directors present their Strategic Report for the year ended 31 December 2015.

#### **Principal activities**

Synairgen plc (the 'Company') is the holding company for Synairgen Research Limited, a respiratory drug discovery and development company.

#### **Operating Review**

#### **Summary**

Our business model is centred around a deep understanding of respiratory biology. Our focus is on the discovery and development of novel therapies for respiratory diseases, particularly in the areas of highest unmet medical need, including severe asthma, COPD and IPF. Our strategy is to take drugs through to proof of concept stage and then partner them. Synairgen's first novel development programme to enter the clinical stage (AZD9412) is an inhaled interferon beta (IFN-beta) therapy which was outlicensed to AstraZeneca for further clinical development and commercialisation. AstraZeneca started a confirmatory Phase II clinical trial in July 2015 and results are expected in 2017.

In August 2015 we announced a research collaboration with Pharmaxis Ltd (Pharmaxis), based in Sydney, Australia, to progress their anti-fibrotic LOXL2 inhibitor compounds for idiopathic pulmonary fibrosis (IPF). Since that time the two companies have been working well together to progress the programme and positive data was reported in March 2016.

Our strategy is to continue to build a portfolio of assets, to which we can add value, in collaboration with market leaders and other specialist biotechnology companies, all with the common goal of improving the health and well-being of respiratory disease sufferers.

#### Inhaled IFN-beta being developed by AstraZeneca

In June 2014, Synairgen signed a global exclusive licence agreement with AstraZeneca worth up to \$232 million in milestone payments plus tiered royalties. AstraZeneca is responsible for all development, regulatory and commercial activities and on-going costs associated with this programme. The licence agreement with AstraZeneca also provides the opportunity to expand the clinical programme into other pulmonary diseases, including COPD.

In July 2015 AstraZeneca enrolled the first patient into a Phase II clinical trial which is designed to confirm the efficacy signal in the target population which was first observed in our pilot Phase II study SG005. The global trial will dose approximately 220 asthmatic patients who develop cold symptoms and is expected to complete in 2017. Half of the patients will receive placebo, and half AZD9412, which is designed to boost antiviral defences in the lungs to prevent these common viruses 'taking hold'

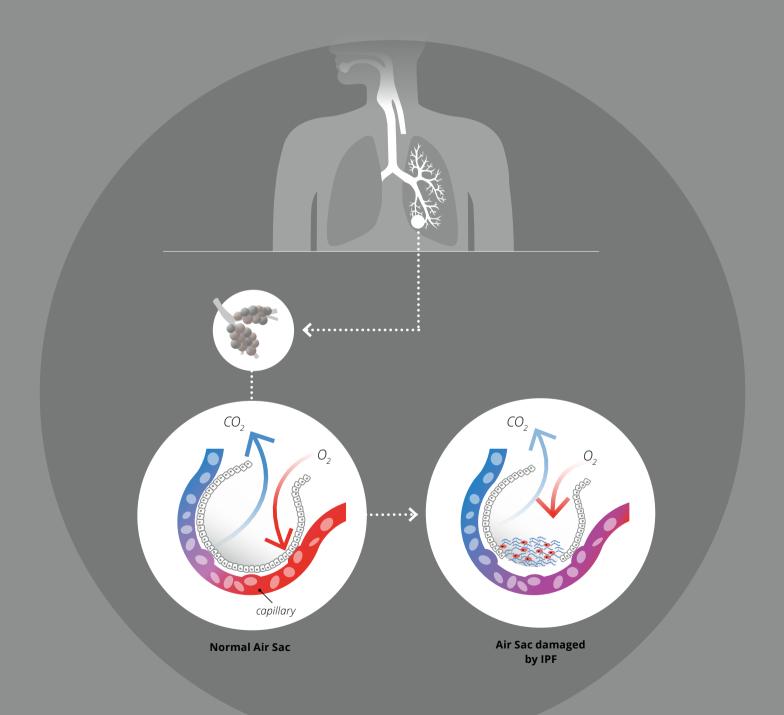
and causing a deterioration in asthma symptoms, known as exacerbations. The primary outcome for the trial is the number of severe asthma exacerbations. Secondary outcomes will include lung function, asthma symptoms, safety and biomarkers relevant to the underlying biology.

AstraZeneca is a world leader in the respiratory sector, with a strong market presence and pipeline. This strength in respiratory medicine is of great benefit to Synairgen, and considerable effort and expertise is being applied to this programme over and beyond the ongoing clinical trial.

During the year, various academic groups from universities around the world have generated data that is helpful in understanding not only the problem that these common respiratory viruses cause to patients with asthma, but also to patients with the other major lung disease of chronic obstructive pulmonary disease (COPD). COPD affects approximately 25% of people who have smoked. The common cold virus is similarly implicated in causing exacerbations of COPD and is an unmet area of clinical need that is of great interest to AstraZeneca. In particular these studies have focussed on the mechanisms which may contribute to a deficiency in antiviral defences caused by lower or delayed production of IFN-beta. In the first study<sup>1</sup>, lung samples from asthmatic patients expressed more of the SOCS1 protein, which is known to suppress IFN-beta production. This may explain the lower levels of IFN-beta observed in cells from asthmatic patients when they are exposed to the common cold virus. In a second study<sup>2</sup>, it was shown that corticosteroids (an essential antiinflammatory asthma therapy) may be compromising the lung's antiviral defences, an unwanted effect that could be overcome through application of IFN-beta. A third paper<sup>3</sup> describes why lung cells from COPD patients may be more susceptible to flu infection. These papers further support Synairgen's original work in establishing the rationale for using inhaled AZD9412 to boost antiviral defences in asthmatic and COPD patients when they are infected with common respiratory viruses. This makes us increasingly confident that AZD9412 should be of significant benefit to such patients in an area of unmet need worldwide.

With its inhaled interferon beta programme, Synairgen has a particular interest in the common cold and how it affects asthma and COPD patients. In June 2014, Synairgen signed a global exclusive licence agreement with AstraZeneca worth up to \$232 million in milestone payments plus tiered royalties. AstraZeneca is responsible for all development, regulatory and commercial activities and on-going costs associated with this programme.

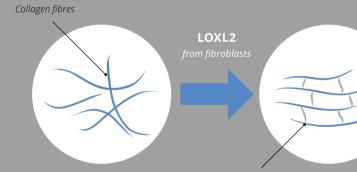
Idiopathic Pulmonary Fibrosis (IPF) is a rare and poorly understood lung condition that manifests in scarring (fibrosis) of the lungs. As this scarring gets worse, the lungs find it more difficult to function, compromising the uptake of oxygen into the blood, resulting in the symptoms of IPF.



## Strategic Report

(continued)

#### Role of LOXL2 in fibrosis



Excessive production and cross-linking of collagen fibres results in fibrosis

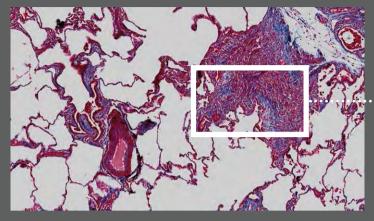
#### LOXL2 inhibitor to reduce fibrosis in patients with idiopathic pulmonary fibrosis (IPF)

In August 2015, Synairgen entered into a collaboration with Pharmaxis to identify and develop an oral inhibitor of the LOXL2 enzyme which has been implicated in lung fibrosis, in particular IPF, and other fibrotic conditions.

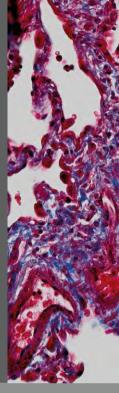
Idiopathic Pulmonary Fibrosis (IPF) is a rare and poorly understood lung condition that manifests in scarring (fibrosis) of the lungs. As this scarring gets worse, the lungs find it more difficult to function, compromising the uptake of oxygen into the blood, resulting in the symptoms of IPF. Symptoms include shortness of breath (even when performing day-to-day activities), which gets worse over time, and a persistent dry cough. The median survival is two to five years from the time of diagnosis<sup>4</sup>. IPF affects in the region of 100,000 people in the US<sup>5</sup> and at least this number in Europe<sup>6</sup>.

Inhibition of Lysyl Oxidase-like protein 2 (LOXL2) is an attractive target in treatment of IPF. Scar tissue is composed of collagen fibres, which are produced by a type of cell called a fibroblast. LOXL2 is an enzyme released from fibroblasts that links collagen fibres together to stiffen scar tissue. Excessive production and linking of collagen fibres results in fibrosis. LOXL2 levels are increased in the lungs of patients with IPF, and higher levels are associated with more rapid disease progression. Pharmaxis has identified a novel family of compounds that selectively inhibit the LOXL2 enzyme.

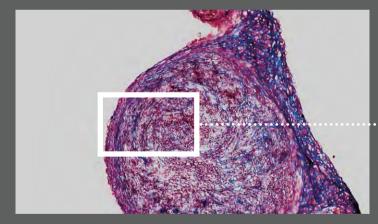
## A section of lung from a diagnostic biopsy from an IPF patient



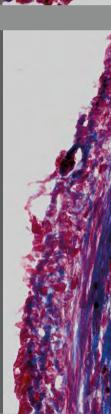
The majority of this image shows normal lung tissue. However in the top right quadrant (and enlarged to the right) is a fibroblastic focus, comprising fibroblast cells (stained red), which make scar tissue (stained blue). The fibroblastic focus is the hallmark of IPF.



## A section from an *in vitro* model of a fibroblastic focus



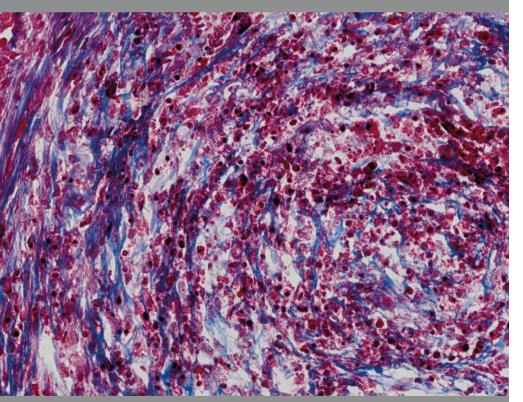
The model (developed in collaboration with the University of Southampton) uses fibroblast cells taken from an IPF patient.



# Strategic Report

Two new treatments have recently been approved for the treatment of IPF: pirfenidone (Roche); and nintedanib (Boehringer Ingelheim). However, there remains a clear unmet need for more effective and better tolerated drugs. Importantly, LOXL2 inhibitors, due to their differentiated mechanism of action, have the potential to provide additional benefit to these treatments.

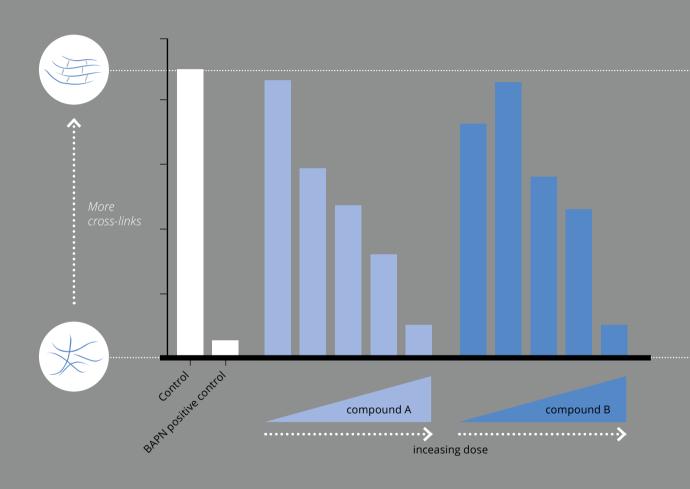
The deal terms with Pharmaxis recognise the extensive work already completed in building up the library of compounds. The objective of the collaboration is to build value through application of our pre-clinical models and clinical expertise, and to license the programme to a large pharmaceutical company at the end of Phase I or Phase IIa. Pharmaxis and Synairgen will share any licensing revenues in accordance with the ratio of total investment by the two companies at that time. The share of licensing revenues is expected to be approximately equal for a compound licensed for IPF after early clinical development. Synairgen will also receive a share of the licensing revenues paid by a licensee to Pharmaxis for collaboration compounds developed in other fibrotic indications outside the respiratory field such as non-alcoholic steatohepatitis (NASH) or kidney fibrosis.



As can be seen by comparing the two images above, the in vitro model replicates structures seen in IPF tissue. This fibroblastic focus model has been used to profile the LOXL2 inhibitors being developed in collaboration with Pharmaxis, with the results being shown on pages 9 and 10 overleaf.

## Strategic Report (continued)

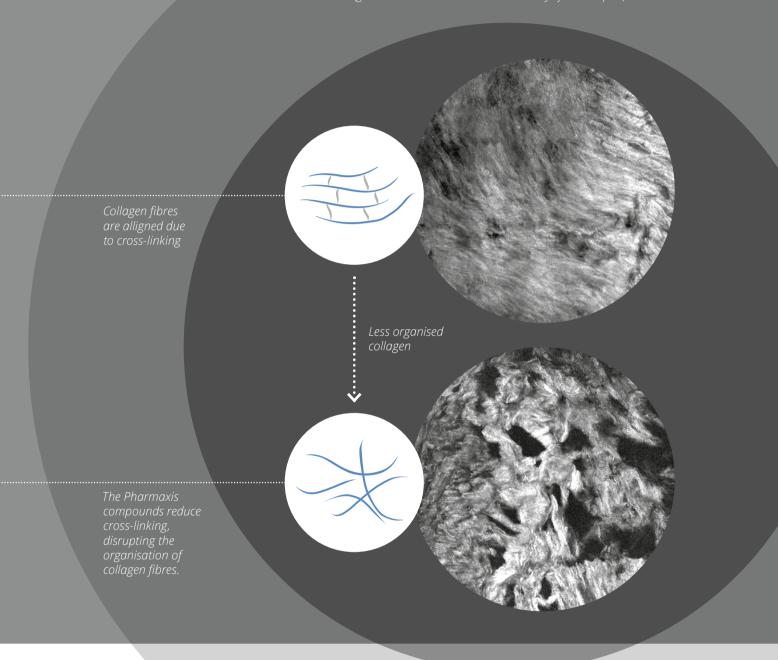
#### Disease-relevant activity of the Pharmaxis inhibitors measured in the fibroblastic focus in vitro model



To date we have used our proprietary in vitro models (using lung cells from IPF patients) to demonstrate the ability of the Pharmaxis compounds to inhibit the cross-linking of collagen fibres. We are currently conducting numerous pre-clinical tests prior to the selection of a candidate. In March 2016, we provided an update which shows that the Pharmaxis enzyme inhibitors, by inhibiting LOXL2, are able to reduce cross-linking of collagen fibres in a dose dependent manner.

Additionally it has also been found that collagen fibres were less organised in the presence of the inhibitors. It is hypothesised that this will result in less "stiff" lung tissue and that this may beneficially alter the course of this devastating disease. We are very excited at the prospect of progressing one of the Pharmaxis compounds into a Phase I clinical trial, which we anticipate commencing during 2017.

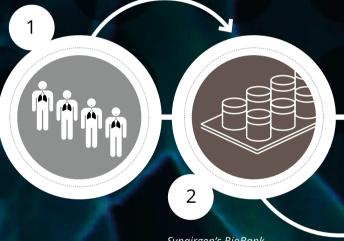
## Second harmonic generation images showing collagen structure within the fibroblastic focus in vitro model



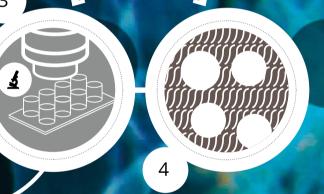
We use our BioBank and tissue models to increase confidence in the rationale for progressing such an asset and work to produce the scientific data required by large pharma licensees.

BioBank samples are obtained from volunteer patients attending specialist clinical research facilities at Southampton General Hospital

BioBank samples are used to create in vitro human respiratory cell and tissue models to discover, develop and validate novel drug targets



Synairgen's BioBank contains blood, sputum, lung cells and tissue samples collected from subjects with and without specific respiratory diseases



Cultured epithelial cells grown at an air-liquid interface showing cilia and mucus-secreting

### Strategic Report (continued)

#### Synairgen's new pipeline developments

We continue to assess new opportunities in our laboratories in parallel to discussing commercial terms and conducting due diligence in relation to bringing such opportunities into the Group. The ideal programme for us:

- has sufficient novelty such that it could achieve sales exceeding \$1 billion per annum;
- has been progressed and produced promising initial data; and
- needs the validation of our BioBank technology platform and Synairgen's wider clinical and commercial competence to progress to a proven value inflection point, ready for licensing to a large pharma company.

We use our BioBank and tissue models to increase confidence in the rationale for progressing such an asset and work to produce the scientific data required by large pharma licensees. We have a high due diligence threshold and a number of potential assets have been explored but declined. There are a number of opportunities from academic groups, small biotech companies, and some currently residing within large pharma, which we are continuing to review in depth. A number of these assets are at the clinical stage.

We expect to be able to bring at least one such collaboration into the Group in the coming year.

#### **Key performance** indicators (KPIs)

The Board considers that the most important KPIs are non-financial and relate to the progress of the scientific programmes which are discussed in the preceding section of this report.

The most important financial KPIs are the cash position and operating result of the Group. At 31 December 2015 cash and deposit balances amounted to £7.71 million (2014: £9.60 million) and were above budgeted levels. The operating loss of £2.61 million (2014: profit of £1.09 million) was also favourable to the budgeted result for the year.

#### References

- 1. Gielen V et al. Increased nuclear suppressor of cytokine signaling 1 in asthmatic bronchial epithelium suppresses rhinovirus induction of innate interferons. J Clin Immunol. 2015;136(1):177-188
- 2. Singanayagam A et al. Effect of fluticasone propionate on virus-induced airways inflammation and anti-viral immune responses in mice. Lancet. 2015;385
- 3. Hsu AC et al. Impaired antiviral stress granule and IFN-β enhanceosome formation enhances susceptibility to influenza infection in COPD epithelium. Am [ Respir Cell Mol Biol. 2016; [Epub ahead of print]
- 4. Meltzer E and Noble P. Idiopathic pulmonary fibrosis. Orphanet J Rare Dis. 200; 3:8
- $5. \ https://ghr.nlm.nih.gov/condition/idiopathic-pulmonary-fibrosis. Accessed March 2016$
- $6. \ \ http://www.pulmonary-fibrosis.net/index.php?option=com\_content\&view=category\&layout=blog\&id=2\&ltemid=4. Accessed March 2016 and the properties of t$

## Strategic Report

(continued)

#### **Financial Review**

The Financial Review should be read in conjunction with the consolidated financial statements of the Company and Synairgen Research Limited (together the 'Group') and the notes thereto on pages 29 to 42. The consolidated financial statements are presented under International Financial Reporting Standards as adopted by the European Union. The financial statements of the Company, set out on pages 43 to 46, are, for the first time, prepared in accordance with Financial Reporting Standard 100 Application of Financial Reporting Requirements and Financial Reporting Standard 101 Reduced Disclosure Framework, having been previously prepared in accordance with UK Generally Accepted Accounting Practice. This change in the basis of preparation has not materially altered the recognition and measurement requirements previously applied.

#### **Statement of Comprehensive Income**

The loss from operations for the year ended 31 December 2015 was £2.61 million (2014; profit £1.09 million). The Group reported a profit in 2014 on account of the recognition of the AstraZeneca licensing transaction £4.25 million upfront payment. Revenues in the current year to 31 December 2015, representing scientific fee for service work for AstraZeneca, amounted to £0.03 million, were down from the 2014 revenues of £4.29 million (comprising the licence receipt of £4.25 million and fee for service income of £0.04 million). Research and development expenditure for the year amounted to £1.36 million (2014: £1.65 million), with a higher rate of expenditure in the second half of the year following the commencement of the LOXL2 programme with Pharmaxis in August 2015. There has been continuing expenditure during the year on research into new opportunity candidates.

Other administrative costs for the year amounted to £1.28 million (2014: £1.55 million), with the reduction over the prior year being attributable to lower staff costs. The research and development tax credit amounted to £0.30 million (2014: £0.06 million). The 2014 tax research and development tax credit was restricted on account of the Group being in profit. The loss after tax for 2015 was £2.26 million (2014: profit of £1.19 million) and the basic loss per share amounted to 2.47p (2014: basic earnings per share of 1.42p).

#### Statement of Financial Position and cash flows

At 31 December 2015, net assets amounted to £7.35 million. (2014: £9.44 million), including net funds, as detailed below in Capital structure and funding, of £7.71 million (2014: £9.60 million).

The principal elements of the £1.89 million decrease over the year ended 31 December 2015 (2014: £8.31 million increase) in net funds were:

- cash used in operations of £1.99 million (2014: £1.61 million inflow);
- research and development tax credits received of £0.06 million (2014: £0.20 million); and
- share issue proceeds (net of costs) £nil (2014: £6.51 million)

#### **Capital structure and funding**

The Group is funded by equity capital, reflecting the early stage nature of its discovery and development programmes.

The Group considers its capital to be its total equity, which at 31 December 2015 amounted to £7.35 million (2014: £9.44 million). The Group's objectives when managing capital are to safeguard the Group's ability to continue as a going concern in order to provide returns to equity holders of the Company and benefits to other stakeholders and to maintain an optimal capital structure to reduce the cost of capital. The Group manages this objective through tight control of its cash resources and, upon reaching significant drug development programme milestones (to decrease investment risk), by raising additional equity from shareholders to meet its forecast future cash requirements.

Net funds held by the Group at 31 December 2015 amounted to £7.71 million and comprised cash and cash equivalents, short-term deposits (with original maturities of greater than three months and less than one year) as shown below:

				3	31 Dec
	2015 fm		2013 fm	2012 fm	2011 fm
Short-term deposits					
Cash and cash equivalents	3.99	2.85	0.83	1.66	0.90
Net funds	7.71	9.60	1.29	3.09	3.35

The Group did not have any bank borrowings as at 31 December 2015 (2014: £nil).

There have been seven significant issues of shares with the following amounts (net of costs) raised: £0.62 million (August 2003); £8.98 million (from IPO on AIM in October 2004); £6.20 million (June 2009); £2.50 million (June 2011); £2.35 million (July 2012); £1.42 million (March 2014); and £4.98 million (July 2014). The other major sources of funding received by the Group from the formation of the business until 31 December 2015 have been: revenues from licensing transactions of £4.25 million, research and development tax credits of £2.72 million, bank interest of £1.69 million, and revenues from collaborative work of £0.67 million.

#### Treasury policy and financial risk management

#### Credit risk

The Group follows a risk-averse policy of treasury management. Sterling deposits are held with one or more approved UK-based financial institutions and in the Institutional Cash Series plc Institutional Sterling Liquidity Fund managed by BlackRock Investment Management (UK) Limited. The Group's primary treasury objective is to minimise exposure to potential capital losses whilst at the same time securing prevailing market rates.

#### Interest rate risk

The Group's cash held in current bank accounts is subject to the risk of fluctuating base rates. An element of the Group's financial assets is placed on fixed-term interest deposits. The interest rate profile of financial assets is illustrated in note 16 to the financial statements.

#### Currency risk

During the year under review, the Group was exposed to Australian dollar, Euro and US dollar currency movement as the Pharmaxis collaboration involves expenditure in all these currencies. The largest exposure relates to the Australian dollar on account of work undertaken by Pharmaxis and which is billed on a quarterly basis. To hedge against currency movement the Group purchases Australian dollars during the quarter before the payment is due.

## and uncertainties

The Board considers that the principal risks and uncertainties facing the Group may be summarised as follows:

· Reliance on the interferon beta programme The Group's most significant and advanced drug development programme is the interferon beta programme, which is now being developed by AstraZeneca, following the significant investment by the Group.

During the year under review the Group has entered into the LOXL2 collaboration agreement with Pharmaxis Ltd. It continues to review a number of additional development opportunities which it hopes will enable it to broaden and diversify its portfolio further.

 Failure to generate innovative discoveries There can be no guarantee that the Group will successfully develop new pharmaceutical products.

#### · Loss of the BioBank

The Group's BioBank of well-characterised human tissue, which has been built up over several years, is a key element of its technology platform and is very important in relation to the development of future opportunities.

The Group follows a defined policy to minimise the chances of loss of the BioBank, including storing it in a number of different locations at Southampton General Hospital and monitoring the storage temperature 24 hours a day.

#### · Clinical development and regulatory risk

The development of pharmaceutical drugs requires the necessary safety and efficacy to be demonstrated in clinical programmes in order to meet the requirements of the appropriate regulatory bodies. There can be no guarantee that the necessary safety or efficacy will be demonstrated or that the clinical trials will not be delayed or extended. There can be no guarantee that any of the Group's therapies will be able to obtain or maintain the necessary regulatory approvals.

The Group seeks to reduce this risk by closely monitoring the progress of recruitment on clinical trials, drawing on the experience of its Founders, seeking advice from regulatory advisers, and holding consultations with the appropriate regulatory bodies.

## Strategic Report

(continued)

#### · Intellectual property risk

The commercial success of the Group depends on its ability to obtain patent protection for its pharmaceutical discoveries in the US, Europe and other countries and to preserve the confidentiality of its know-how. There is no guarantee that patent applications will succeed or be broad enough to provide protection for the Group's intellectual property rights and exclude competitors with similar pharmaceutical products. The success of the Group is also dependent on non-infringement of patents, or other intellectual property rights, held by third parties. Competitors and third parties may hold intellectual property rights which the Group may not be able to license upon favourable terms, potentially inhibiting the Group's ability to develop and exploit its own business. Litigation may be necessary to protect the Group's intellectual property which may result in substantial costs.

The Group seeks to reduce this risk by seeking patent attorney advice that patent protection will be available prior to investing in a project, by seeking patent protection where appropriate and by minimising disclosure to third parties.

#### Commercial risk

There can be no guarantee that the Group will succeed in securing and maintaining the necessary contractual relationships with licensing partners for its programmes under development. Even if the programmes are successfully out-licensed and pharmaceutical products are brought to market by a partner, there is no guarantee that such products will succeed in the marketplace.

The Group seeks to reduce this risk by structuring its development programmes to meet the needs and requirements of its potential partners and by engaging with partners who have the appropriate experience, resource and interest to bring such pharmaceutical products to the global marketplace.

#### Competition risk

The Group's current and potential competitors include pharmaceutical and biotechnology companies and academic institutions, many of whom have significantly greater financial resources than the Group. There can be no assurance that competitors will not succeed in developing products that are more effective or economic than any developed by the Group, or which would render the Group's products non-competitive or obsolete.

#### Funding risk

The Group continues to consume cash resources. Until the Group generates positive net cash inflows from successful out-licensing transactions and commercialisation of its products, it remains dependent upon securing additional funding through the injection of capital from share issues. The Group may not be able to generate positive net cash flows in the future or attract such additional funding required at all, or on suitable terms. In such circumstances, the Group's discovery and development programmes may be delayed or cancelled and the business operations curtailed.

The Group seeks to reduce this risk through tight financial control, prioritising programmes which will generate the best returns and keeping shareholders informed on progress.

#### Dependence on Founders, senior management and kev staff

The Founders and certain members of staff are highly skilled scientists and clinicians. The Group has deliberately pursued a lean headcount policy to conserve financial resources. Failure to continue to attract and retain such individuals could adversely affect operational results.

The Group seeks to reduce this risk by appropriate incentivisation of staff through participation in long term equity incentive schemes.

#### Outlook

Our primary asset, AZD9412, is in a confirmatory Phase II trial being conducted by AstraZeneca, with results from this trial expected in 2017.

During 2016, we expect to increase the data package around the LOXL2 inhibitor, building on the positive data already announced, and prepare for a Phase I clinical trial to start during 2017. Jointly with Pharmaxis, we have started to engage with large pharma companies, who are showing a strong interest in this programme.

We retain a strong balance sheet to enable us to continue to both develop existing programmes and screen new opportunities.

By order of the Board

#### **John Ward**

Company Secretary

21 March 2016

# Synairgen's Founders



**Prof. Stephen Holgate CBE** is MRC Clinical Professor of Immunopharmacology at the University of Southampton



Prof. Ratko Djukanovic is Professor of Medicine at the University of Southampton and Director of the Southampton NIHR Respiratory Biomedical Research Unit



**Prof. Donna Davies** is Professor of Respiratory Cell and Molecular Biology at the University of Southampton

## Directors

#### **Simon Shaw**

Non-executive Chairman

Simon Shaw joined Synairgen as executive Chairman on its inception in June 2003 and became non-executive Chairman in October of that year. He is Group Chief Financial Officer of Savills plc. He was Chief Financial Officer of Gyrus Group PLC from 2003 until its sale to Olympus Corporation in 2008, having previously been Chief Operating Officer of Profile Therapeutics plc between 1998 and 2003. Between 1991 and 1997 he was a corporate financier, latterly at Hambros Bank Limited. He is a chartered accountant.

#### **Richard Marsden**

Chief Executive Officer

Richard Marsden joined Synairgen in a consulting role as General Manager in November 2003, was appointed to the Board as Managing Director in June 2004 and appointed Chief Executive Officer in September 2009. Between 1998 and 2003 he worked as Projects Manager and Cystic Fibrosis Business Development Manager at Profile Therapeutics plc, where he managed the Cystic Fibrosis business and played a major role in the development of its proprietary pharmaceutical unit, Profile Pharma Limited. Prior to this, he worked for Zimmer Limited, Genentech (UK) Limited and Roche Products Limited.

#### **Dr Phillip Monk**

Chief Scientific Officer

Phillip Monk joined Synairgen in October 2006 as Head of Bioscience Development and was appointed to the Board as Chief Scientific Officer in September 2009. Phillip was previously Director of the Respiratory and Inflammation Biology group at Cambridge Antibody Technology (CAT) and led the scientific development of tralokinumab, an anti-IL-13 antibody being developed for the treatment of severe asthma. Prior to joining CAT, he worked at Bayer AG within the respiratory disease therapeutic area, focusing on the development of novel therapies for asthma, COPD and cystic fibrosis.

#### John Ward

Finance Director

John Ward joined Synairgen in October 2004 as Finance Director. From December 1999 to July 2004 he was Chief Financial Officer and Company Secretary of Profile Therapeutics plc and was appointed to the Profile Therapeutics board in March 2003. From 1996 to 1999 he was Finance Director of Rapid Deployment Group Limited, the UK holding company for the healthcare operations of Ventiv Health, Inc. Prior to joining Rapid Deployment he was a Director of Corporate Finance at Price Waterhouse. He is a chartered accountant.

#### **Iain Buchanan**

Non-executive Director

lain Buchanan was appointed as a non-executive director in June 2010 and brings to the company over 40 years of management experience in the pharmaceutical and biotech industries. Most recently he was CEO of NOXXON Pharma AG based in Berlin and previously he was CEO of Novexel S.A. based in Paris. He joined Novexel from Vertex Pharmaceuticals where he established the European affiliate. Prior to Vertex, lain managed the international licensee business of Cilag AG - a subsidiary of Johnson and Johnson - based in Switzerland. lain serves as a member of the supervisory board of NOXXON Pharma AG.

#### **Paul Clegg**

Non-executive Director

Paul Clegg was appointed as a non-executive director of Synairgen in September 2009. He is Chief **Executive Officer of Accsys** Technologies PLC, Chairman of Tricoya Technologies Ltd and a non-executive director of Peel Hunt LLP. Paul was previously Managing Director and Chief Executive Officer of Cowen International Limited and director of Cowen Asset Management Limited until June 2008. After over twenty years working in the investment banking industry, Paul joined Accsys Technologies PLC, a UK publicly quoted company which has developed the process and the commercial industrialisation of wood acetylation, as Chief Executive Officer.

#### **Dr Bruce Campbell**

Non-executive Director

Bruce Campbell joined Synairgen as a non-executive Director in April 2006. He has 45 years of drug development experience and has developed many drugs in a wide range of indications which are now on the market. He currently acts as a consultant to various companies including Proximagen Limited. Formerly he was Senior VP of International Development at Neurocrine Biosciences, Inc. (Neurocrine). Prior to joining Neurocrine he worked for 27 years at Servier (United Kingdom), latterly as Scientific Director. In addition, he has also been a director and European Chairman of the Drug Information Association, a member of the European ICH Safety Working Party and a scientific advisor to IP Group plc. He is a visiting Professor in Pharmacology at King's College, London.

**Prof. Stephen Holgate CBE** 

Non-executive Director

Stephen Holgate is a co-founder of Synairgen and was appointed a non-executive director in June 2003. After qualifying in Medicine at Charing Cross Hospital Medical School, London he has pursued an academic career leading to his appointment in 1987 to his current position as Medical Research Council Clinical Professor of Immunopharmacology at the University of Southampton. His research interests have been largely focused on the cellular and molecular mechanisms of asthma that has involved use of both epidemiological and genetic approaches. He has published over 1000 papers in peer-reviewed literature. He is currently: Chairman of the MRC Translational Research Group; Member of the MRC Strategy Board; Member of the Science Europe Medical Science Committee and Horizon 2020 Health Science Panel; Chairman of the European Respiratory Society Scientific Council; Board Chair of the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs); Chairman of Defra's Hazardous Substances Advisory Committee; Trustee of Cancer Research UK, the British Lung Foundation and The Kennedy Trust for Rheumatology Research; and a scientific board member or advisor to a number of companies, including Amgen, Takeda, Merck, and Novartis. In 2010, he was appointed by the Higher Education Funding Council for England to be the Chair of the Research Excellence Framework (REF2014) Main Panel A covering Medicine, Health and Life Sciences.





Dr Phillip Monk



John Ward







Paul Clegg



Prof. Stephen Holgate CBE

## Directors' Report

The directors present their report and the audited financial statements for Synairgen plc (the 'Company') and its subsidiary (together the 'Group') for the year ended 31 December 2015.

The review of future developments and the use of financial instruments and financial risk management policies are covered in the Strategic Report. Details of directors' remuneration and share options are given in the Directors' Remuneration Report.

#### Research and development

During the year ended 31 December 2015, the Group has invested £1,355,000 (2014: £1,649,000) in research and development activities and a review of this expenditure is included in the Strategic Report.

#### **Dividends**

The directors do not propose the payment of a dividend.

#### **Substantial shareholdings**

As at 21 March 2016, the Company had been advised of the following shareholders with interests of 3% or more in its ordinary share capital:

Name of shareholder	Number of ordinary shares	% of share capital
Woodford Investment Management LLP	20,386,651	22.3%
Lansdowne Partners International Limited	16,923,111	18.5%
Richard Griffiths	9,117,012	10.0%
Southampton Asset Management Limited	3,600,000	3.9%

#### **Directors**

The directors of the Company during the year ended 31 December 2015 were:

Executive directors:

Richard Marsden (Chief Executive Officer) Dr Phillip Monk (Chief Scientific Officer) John Ward (Finance Director)

Non-executive directors:

Simon Shaw (Chairman) Iain Buchanan Dr Bruce Campbell Paul Clegg Prof. Stephen Holgate CBE

#### **Directors' interests in ordinary shares**

The directors, who held office at 31 December 2015, had the following interests in the ordinary shares of the Company:

	31 December 2015 Number of shares	1 January 2015 Number of shares
Richard Marsden	154,432	110,972
Dr Phillip Monk	183,439	161,710
John Ward	276,506	243,912
Simon Shaw (i)	1,474,096	1,408,879
lain Buchanan	112,741	112,741
Dr Bruce Campbell (ii)	294,259	294,259
Paul Clegg (iii)	204,244	204,244
Prof. Stephen Holgate (iv)	858,360	858,360

- (i) Simon Shaw's shareholding includes 105,516 shares held in his pension plan.
- (ii) Dr Bruce Campbell's shareholding includes 40,299 owned by his wife, Susan
- (iii) Paul Clegg's shareholding includes 180,149 shares held in his pension plan.
- (iv) Prof. Stephen Holgate's shareholding includes 1,923 shares owned by his wife, Elizabeth Holgate.

Between 31 December 2015 and the date of this report there has been no change in the interests of directors in shares as disclosed in this report. The interests of directors in share options as set out in the Directors' Remuneration Report on pages 24 and 25 have changed since 31 December 2015 as the options granted on 11 March 2013 under the Synairgen Long Term Incentive Plan have now lapsed as the performance criteria were not met.

#### Directors' and officers' liability insurance

Qualifying indemnity insurance cover has been arranged in respect of the personal liabilities which may be incurred by directors and officers of the Group during the course of their service with the Group. This insurance has been in place during the year and on the date of this report.

#### **Auditors**

All of the current directors have taken all the steps that they ought to have taken to make themselves aware of any information needed by the Company's auditors for the purposes of their audit and to establish that the auditors are aware of that information. The directors are not aware of any relevant audit information of which the auditors are unaware.

By order of the Board

#### John Ward

Company Secretary 21 March 2016

## Corporate Governance

The Board is accountable to the Company's shareholders for good corporate governance and it is the objective of the Board to attain a high standard of corporate governance. As an AIM-quoted company, full compliance with The UK Corporate Governance Code (the 'Code') is not a formal obligation. The Company has not sought to comply with the full provisions of the Code, however it has sought to adopt the provisions that are appropriate to its size and organisation and establish frameworks for the achievement of this objective. This statement sets out the corporate governance procedures that are in place.

#### **Board of Directors**

On 31 December 2015 the Board of directors (the 'Board') consisted of a non-executive Chairman (Simon Shaw), three executive directors (Richard Marsden, Dr Phillip Monk and John Ward), and four nonexecutive directors (lain Buchanan, Dr Bruce Campbell, Paul Clegg and Prof. Stephen Holgate). Brief details about the directors are given on pages 17 and 18. The responsibilities of the non-executive Chairman and the Chief Executive Officer are clearly divided. The non-executive directors bring relevant experience from different backgrounds and receive a fixed fee for their services and reimbursement of reasonable expenses incurred in attending meetings.

The Board retains full and effective control of the Group. This includes responsibility for determining the Group's strategy and for approving budgets and business plans to fulfil this strategy. The full Board ordinarily meets seven times a year ('Scheduled Board meetings'). It also meets on any other occasions it considers necessary. During the year ended 31 December 2015, the Board met seven times for Scheduled Board meetings, with each member attending as follows:

Director	Number of meetings held whilst a Board member	Number of meetings attended
Simon Shaw	7	7
Richard Marsden	7	7
Dr Phillip Monk	7	7
John Ward	7	7
lain Buchanan	7	7
Dr Bruce Campbell	7	6
Paul Clegg	7	7
Prof. Stephen Holgate	7	4

In addition there were two other meetings, to which Board members were invited, during the year.

It is the duty of the Chairman to ensure that all directors are properly briefed on issues arising at Board meetings. Prior to each Board meeting, directors are sent an agenda and Board papers for each agenda item to be discussed. Additional information is provided when requested by the Board or individual directors

The Company Secretary is responsible to the Board for ensuring that Board procedures are followed and that the applicable rules and regulations are complied with. All directors have access to the advice and services of the Company Secretary, and independent professional advice, if required, at the Company's expense. Removal of the Company Secretary would be a matter for the Board.

As appropriate, the Board has delegated certain responsibilities to Board committees.

#### **Audit Committee**

The Audit Committee currently comprises Simon Shaw (Chairman), lain Buchanan and Dr Bruce Campbell. Whilst it is not normal in larger companies for the chairman of the Company to chair the Audit Committee, the Company considers it appropriate for Simon Shaw to be Chairman as he is considered to have the most significant, recent and relevant financial experience of the non-executive directors.

The committee has primary responsibility for ensuring that the financial performance of the Group is properly measured and reported on and it reviews the interim financial information and annual financial statements before they are submitted to the Board. The committee reviews accounting policies and material accounting judgements. The committee also reviews, and reports on, reports from the Group's auditors relating to the Group's accounting controls. It makes recommendations to the Board on the appointment of auditors and the audit fee. The committee monitors the scope, results and cost-effectiveness of the audit. It has unrestricted access to the Group's auditors. In certain circumstances it is permitted by the Board for the auditors to supply non-audit services (in the provision of tax advice, or on specific projects where they can add value). The committee has approved and monitored the application of this policy in order to safeguard auditor objectivity and independence. The overall fees paid to the auditors are not deemed to be of such significance to them as to impair their independence. The Group does not have an internal audit function, but the Board considers that this is appropriate, given the size of the Group. The committee keeps this matter under review annually. During the year ended 31 December 2015, the committee met four times with each member attending all meetings.

#### **Remuneration and Nomination Committee**

The Remuneration and Nomination Committee currently comprises Paul Clegg (Chairman), Dr Bruce Campbell and Simon Shaw. The committee is responsible for making recommendations to the Board on remuneration policy for executive directors and the terms of their service contracts, with the aim of ensuring that their remuneration, including any share options and other awards, is based on their own performance and that of the Group generally. The committee administers the Long Term Incentive Plan, the staff share option scheme and the Qualifying Non-Employee Option Scheme and approves grants under all three schemes.

## Corporate Governance (continued)

It also advises on the remuneration policy for the Group's employees. The committee is responsible for all senior appointments that are made within the Group. During the year ended 31 December 2015, the committee met twice with each member attending both meetings.

#### **Investor relations**

The directors seek to build a mutual understanding of objectives between the Company and its shareholders by meetings with major institutional investors and analysts after the Company's preliminary announcement of its year-end results and its interim results. The Company also maintains investor relations pages on its website (www.synairgen.com) to increase the amount of information available to investors.

There is an opportunity at the Annual General Meeting for individual shareholders to guestion the Chairman, the Chairmen of the Audit and Remuneration and Nomination committees, and the executive directors. Notice of the meeting is sent to shareholders at least 21 clear days before the meeting. Shareholders are given the opportunity to vote on each separate issue. The Company counts all proxy votes and will indicate the level of proxies lodged on each resolution, after it has been dealt with by a show of hands. Details of the resolutions and explanations thereto are included with the notice.

#### **Internal control**

The directors are responsible for establishing and maintaining the Group's system of internal control and reviewing its effectiveness. The system of internal control is designed to manage, rather than eliminate, the risk of failure to achieve business objectives and can only provide reasonable but not absolute assurance against material misstatement

The main features of the internal control system are as follows:

- · a control environment exists through the close management of the business by the executive directors. The Group has a defined organisational structure with delineated approval limits. Controls are implemented and monitored by personnel with the necessary qualifications and experience;
- · a list of matters reserved for board approval;
- monthly management reporting and analysis of variances;
- financial risks for each major transaction are identified and evaluated by the Board; and
- standard financial controls operate to ensure that the assets of the Group are safeguarded and that proper accounting records are maintained.

By order of the Board

#### John Ward

Company Secretary 21 March 2016

## Directors' Remuneration Report

This report is non-mandatory for AIM-quoted companies and has been produced on a voluntary basis. It includes and complies with the disclosure obligations of the AIM Rules.

#### **Remuneration Committee**

The Company's remuneration policy is the responsibility of the Remuneration and Nomination Committee (the 'Committee'), which was established in October 2004. The terms of reference of the Committee are outlined in the Corporate Governance Statement on page 20. The members of the Committee are Paul Clegg (Chairman), Dr Bruce Campbell and Simon Shaw.

The Committee, which is required to meet at least twice a year, met twice during the year ended 31 December 2015. The Chief Executive Officer and certain executives may be invited to attend meetings of the Committee to assist it with its deliberations, but no executive is present when his or her own remuneration is discussed.

During the year, the Committee has been advised on director remuneration by its retained independent remuneration adviser, FIT Remuneration Consultants LLP. No other advice has been provided to the Group by this firm during the year.

#### **Remuneration policy**

#### (i) Executive remuneration

The Committee has a duty to establish a remuneration policy which will enable it to attract and retain individuals of the highest calibre to run the Group. Its policy is to ensure that the executive remuneration packages of executive directors and the fee of the Chairman are appropriate given performance, scale of responsibility, experience, and consideration of the remuneration packages for similar executive positions in companies it considers to be comparable. Packages are structured to motivate executives to achieve the highest level of performance in line with the best interests of shareholders. A significant element of the total remuneration package, in the form of bonus and long term incentive plan ('LTIP') awards, is performance driven.

Executive remuneration currently comprises a base salary, an annual performance-related bonus, LTIP participation, a pension contribution to the executive director's individual money purchase scheme (at 9% of base salary), family private health cover, permanent health and life assurance.

The previous salary and benefit review took effect from 1 December 2014 and, as reported in the previous Directors' Remuneration Report, there was no review during 2015. Salaries and benefits have been reviewed in January 2016 taking into account Group and individual performance, external benchmark information and internal relativities.

As a consequence of the 2016 review, the following changes were made with effect from 1 January 2016:

		1 December 2014 to	31 December 2015			From 1 January 2016
	Salary per annum (£000)	Employer pension contribution as a % of salary	Maximum bonus as a % of salary	Salary per annum (£000)	Employer pension contribution as a % of salary	Maximum bonus as a % of salary
Richard Marsden	180	9%	100%	182	9%	100%
Dr Phillip Monk	130	9%	100%	131	9%	100%
John Ward	140	9%	100%	141	9%	100%

## Directors' Remuneration Report (continued)

Executive directors are also rewarded for improvements in the performance of the Group sustained over a period of years in the form of Long Term Incentive Plan share awards granted on a discretionary basis by the Committee.

Directors' remuneration for the year ended 31 December 2015 is set out on page 26 of this document.

#### (ii) Chairman and non-executive director remuneration

The Chairman and the non-executive directors receive a fixed fee of £25,000 per annum (prior to 1 December 2014, Dr Campbell and Professor Holgate received a fixed fee of £15,000 per annum). The fixed fee covers preparation for and attendance at meetings of the full Board and committees thereof. A fee of £5,000 per annum is also paid for chairing each of the audit and remuneration committees. The Chairman and the executive directors are responsible for setting the level of non-executive remuneration. The non-executive directors are also reimbursed for all reasonable expenses incurred in attending meetings.

#### (iii) Annual bonus plan

The Company operates a discretionary bonus scheme for executive directors for delivery of exceptional performance against relevant corporate objectives. The following bonuses, representing 40% of annual salary, were awarded for the year ended 31 December 2015: Richard Marsden: £72,000; Dr Phillip Monk: £52,000; and John Ward: £56,000.

#### (iv) Equity-based incentive schemes

The Committee strongly believes that long term equity-based incentive schemes increase the focus of employees in improving Group performance, whilst at the same time providing a strong incentive for retaining and attracting individuals of a high calibre.

#### Long Term Incentive Plan (LTIP)

The Synairgen Long Term Incentive Plan, comprising conditional (performance-related) share awards (technically structured as nominal cost options pursuant to which participants must pay 1p per share on the exercise of their awards), was introduced in 2005 as the sole on-going long-term incentive vehicle for executive directors. The authority for this original plan expired in 2015. At the Company's Annual General Meeting ('AGM') in June 2015 shareholders approved the introduction of a new LTIP plan (the Synairgen Long Term Incentive Plan 2015 or '2015 LTIP'). In all material respects, the rules of the new LTIP are the same as those of the previous plan, except where it has been clarified:

- a) That a participant who ceases to be employed whilst holding a vested LTIP award will ordinarily have an opportunity to exercise that vested award in the succeeding 12 months before the award lapses;
- b) Consistent with evolving best practice, provisions for malus and clawback were introduced; and
- c) If regulatory restrictions prevent the grant of an LTIP award in any year, the 100% of base salary individual award limit for that financial year may be carried forward to the following financial year and used in addition to the following year's annual individual award limit when awards are made.

Senior executives and other employees may be granted an award which will normally vest if demanding performance conditions are achieved over a three-year period and if the grantee remains an employee of the Group.

Grants under the 2015 LTIP in any financial year are capped at a maximum of 100% of base salary.

In October 2015, Richard Marsden, Dr Phillip Monk and John Ward were granted awards over shares worth 62.5% of base salary. This level is lower than past practice to reflect both the increase in salaries awarded in 2014 and that new awards will be made on the more common basis of the Company bearing employers' NICs (with such liability mitigated through the use of EMI qualified awards to the extent feasible).

Executive directors are expected to retain no fewer than 50% of shares acquired upon vesting of awards under the LTIP, net of shares sold to pay taxes, until such time as, in combination with any other shares the executives may have acquired, they hold shares with a value equivalent to 100% of base salary.

All awards will lapse at the end of the applicable performance period to the extent that the applicable performance criteria conditions have not been satisfied with no opportunity for retesting. In the event of a good leaver event or a change of control of the Company, the LTIP awards may vest early, but only to the extent that, in the opinion of the Committee, the performance conditions have been satisfied at that time. The awards will generally also be subject to a time pro-rated reduction to reflect the reduced period of time between the grant of the awards and the time of vesting although this reduction may not be applied in certain cases.

Performance conditions for the 2013, 2014 and 2015 LTIP awards The performance conditions for all three awards were the same. The awards are subject to two conditions. Firstly, awards will only vest to the extent that the percentage increase in the total shareholder return ('TSR', being the return earned by a shareholder over the performance period in terms of change in the share price and assuming re-investment of any dividends in more shares at the prevailing price on the relevant ex-dividend date) of the Company over the three year performance period is equal or greater than the percentage increase in the techMARK mediscience™ index over the same period as follows:

TSR growth over the performance period less percentage increase in the techMARK mediscience™ index over the same period	Vesting percentage of total number of shares subject to award
Less than 0%	0%
0%	25%
10%	50%
20%	100%
Performance between the steps	Pro-rata on a straight-line basis

Secondly, no award will vest unless the average annual growth in the TSR of the Company over the performance period is equal to or greater than RPI plus 2% or, for more than 75% of an award to vest, annual average TSR must exceed RPI by at least 5% rather than 2%.

No awards became exercisable during 2015 as, given regulatory constraints in 2012, no grants reached the end of their 3 year performance period during the year.

#### Qualifying Non-Employee Option Scheme (QNEOS)

On 12 June 2009 shareholders in General Meeting approved the adoption of the ONEOS. This plan was a discretionary share scheme which enabled the Committee to grant market value share options to consultants and non-executive directors who, in the opinion of the Committee, make, or, in the case of new appointments, will make, a significant contribution to the Group and where the Committee considers it to be in the interests of shareholders to make such grants. The ability to make further option grants under the QNEOS expired in June 2014. Following a review by the Committee during 2015, shareholder approval was sought and given by shareholders at the 2015 AGM to continue to operate the Synairgen Non-Employee Share Option Plan 2015 ('QNEOS 2015'). QNEOS 2015 operates similarly to QNEOS except:

a) The list of those eligible to receive new grants will be limited to nonemployee consultants of the Group who are not also directors (so non-executive directors will not be eligible to participate without further recourse to shareholders); and

b) Consistent with developments in best practice and for consistency with the 2015 LTIP, the leaver rules have been clarified to ensure that vested but unexercised options are retained for a period post a participant ceasing to be engaged by the Group.

During the year under review no options were granted under ONEOS 2015.

#### (v) Service contracts and letters of appointment

The executive directors have entered into service agreements which can be terminated on six months' notice by either party.

During the year ended 31 December 2015, the executive directors did not hold any non-executive directorships with other companies.

The Chairman and non-executive directors have entered into letters of appointment for an initial fixed period of twelve months, which renew automatically for a further twelve month period on the anniversary of commencement. The appointment can be terminated on three months' notice by either party.

#### Directors' interests in share options

The interests of directors in share options over ordinary shares during the year were as follows:

Synairgen Long Term Incentive Plan

Date of grant	At 1 January 2015	Granted during the year	At 31 December 2015	Exercise price	Earliest exercise date	Expiry date
Richard Marsden						
7 September 2009	605,000	_	605,000	1p	7 Sept 2012	6 Sept 2019
8 September 2010	246,889	-	246,889	1p	8 Sept 2013	7 Sept 2020
21 September 2011	538,063	-	538,063	1p	21 Sept 2014	20 Sept 2021
11 March 2013	245,732	-	245,732	1p	11 Mar 2016	10 Mar 2023
3 November 2014	313,827	-	313,827	1p	3 Nov 2017	2 Nov 2024
27 October 2015	_	387,931	387,931	1p	27 Oct 2018	26 Oct 2025
Dr Phillip Monk						
21 September 2011	400,212	_	400,212	1р	21 Sept 2014	20 Sept 2021
11 March 2013	182,776	_	182,776	1р	11 Mar 2016	10 Mar 2023
3 November 2014	233,425	-	233,425	1p	3 Nov 2017	2 Nov 2024
27 October 2015	-	280,172	280,172	1p	27 Oct 2018	26 Oct 2025
John Ward						
7 September 2009	100,000	-	100,000	1p	7 Sept 2012	6 Sept 2019
8 September 2010	224,445	-	224,445	1p	8 Sept 2013	7 Sept 2020
21 September 2011	489,148	-	489,148	1p	21 Sept 2014	20 Sept 2021
11 March 2013	223,393	_	223,393	1p	11 Mar 2016	10 Mar 2023
3 November 2014	285,297	_	285,297	1p	3 Nov 2017	2 Nov 2024
27 October 2015	_	301,724	301,724	1p	27 Oct 2018	26 Oct 2025
		'				

No options were exercised by directors during the year.

## Directors' Remuneration Report (continued)

#### Other options granted under the Synairgen plc Staff Option Scheme

Date of grant	At 1 January and 31 December 2015	Exercise price	Earliest exercise date	Expiry date
<b>Dr Phillip Monk</b> 2 October 2006	50,000	85.5p	2 Oct 2009	1 Oct 2016

The vesting and exercise of these other options is generally subject to the relevant option holder continuing to be an employee or director of a company in the same Group as the Company at the relevant time. There are no further performance criteria.

#### Synairgen Qualifying Non-Employee Option Scheme

Date of grant	At 1 January and 31 December 2015	Exercise price	Earliest exercise date	Expiry date
lain Buchanan				
28 June 2010	212,765	23.5p	28 June 2013	27 June 2020
Paul Clegg				
7 September 2009	250,000	20p	7 Sept 2012	6 Sept 2019

The exercise of the options awarded in September 2009 (which vested in 2012) and in June 2010 (which vested in 2013) is subject to the rules of the scheme.

There were no other options granted to directors or which were exercised or lapsed during the year.

The mid-market price of the Company's shares at 31 December 2015 was 22.5p. During the year then ended, the mid-market price ranged from 22.5p. to 39.5p. On 21 March 2016 the closing price was 22.0p.

#### **Audited information**

The following section (Directors' remuneration) contains the disclosures required by Schedule 5 to the Large and Medium-sized Companies and Groups (Accounts and Reports) Regulations 2008, forms part of the financial statements for the year ended 31 December 2015 and has been audited by the Company's auditor, BDO LLP.

#### **Directors' remuneration**

The remuneration received by directors who served during the years ended 31 December 2015 and 2014 was as follows:

					Year e	nded 31 Dec	ember 2015	Year	ended 31 Ded	cember 2014
		Salary/		_	Total (excl.		Total (incl.	Total (excl.		Total (incl.
£000	Note	fee	Bonus	Benefits	pension)	Pension	pension)	pension)	Pension	pension)
<b>Executive Directors</b>										
Richard Marsden	(i)	180	72	3	255	16	271	396	12	408
Dr Phillip Monk		130	52	-	182	12	194	294	9	303
John Ward		140	56	2	198	13	211	359	11	370
Non-executive Directors										
Simon Shaw		30	-	_	30	_	30	30	-	30
lain Buchanan		25	-	-	25	-	25	25	-	25
Dr Bruce Campbell		25	-	-	25	-	25	16	-	16
Paul Clegg		30	-	-	30	-	30	30	-	30
Prof. Stephen Holgate		25	_	-	25	-	25	16	_	16
Total		585	180	5	770	41	811	1,166	32	1,198

Richard Marsden was the highest paid director during the year ended 31 December 2015. He did not exercise any options during that year. Dr Phillip Monk was the highest paid director during the year ended 31 December 2014, earning a total of £596,000, comprising emoluments as set out above of £303,000 and gains on the exercise of options amounting to £293,000.

In respect of key management personnel, for the year ended 31 December 2015, total share-based payment amounted to £137,000 (2014: £123,000) and total social security costs were £86,000 (2014: £142,000).

By order of the Board

#### **Paul Clegg**

Chairman of the Remuneration and Nomination Committee

21 March 2016

<sup>(</sup>ii) The total amount paid to third parties amounted to £nil (2014: £15,000).

# Statement of Directors' responsibilities in respect of the Annual Report and the Financial Statements

The directors are responsible for preparing the annual report and the financial statements in accordance with applicable law and regulations.

Company law requires the directors to prepare financial statements for each financial period. Under that law the directors have elected to prepare the Group financial statements in accordance with International Financial Reporting Standards (IFRSs) as adopted by the European Union and the Company financial statements in accordance with Financial Reporting Standard 100 Application of Financial Reporting Requirements and Financial Reporting Standard 101 Reduced Disclosure Framework and applicable law. Under company law the directors must not approve the financial statements unless they are satisfied that they give a true and fair view of the state of affairs of the Group and Company and of the profit or loss of the Group for that period. The directors are also required to prepare financial statements in accordance with the rules of the London Stock Exchange for companies trading securities on the Alternative Investment Market.

In preparing these financial statements, the directors are required to:

- select suitable accounting policies and then apply them consistently;
- · make judgements and accounting estimates that are reasonable and prudent;
- state whether they have been prepared in accordance with IFRSs as adopted by the European Union, subject to any material departures disclosed and explained in the financial statements; and
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that the Company will continue in business.

The directors are responsible for keeping adequate accounting records that are sufficient to show and explain the Company's transactions and disclose with reasonable accuracy at any time the financial position of the Company and enable them to ensure that the financial statements comply with the requirements of the Companies Act 2006. They are also responsible for safeguarding the assets of the Company and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

#### Website publication

The directors are responsible for ensuring the annual report and financial statements are made available on a website. Financial statements are published on the Group's website in accordance with AIM rules for companies and legislation in the United Kingdom governing the preparation and dissemination of financial statements, which may vary from legislation in other jurisdictions. The maintenance and integrity of the Group's website is the responsibility of the directors. The directors' responsibility also extends to the ongoing integrity of the financial statements contained therein.

#### **Going concern**

The directors have prepared and reviewed financial forecasts. After due consideration of these forecasts and current cash resources, the directors consider that the Company and the Group have adequate financial resources to continue in operational existence for the foreseeable future (being a period of at least twelve months from the date of this report), and for this reason the financial statements have been prepared on a going concern basis.

By order of the Board

#### John Ward

Company Secretary 21 March 2016

# Independent Auditor's Report to the members of Synairgen plc

We have audited the financial statements of Synairgen plc for the year ended 31 December 2015 which comprise the Consolidated Statement of Comprehensive Income, the Consolidated Statement of Changes in Equity, the Consolidated Statement of Financial Position, the Consolidated Statement of Cash Flows, the Parent Company Balance Sheet, the Parent Company Statement of Changes in Equity and the related notes. The financial reporting framework that has been applied in the preparation of the group financial statements is applicable law and International Financial Reporting Standards (IFRSs) as adopted by the European Union. The financial reporting framework that has been applied in preparation of the parent company financial statements is applicable law and United Kingdom Accounting Standards (United Kingdom Generally Accepted Accounting Practice), including Financial Reporting Standard 101 'Reduced Disclosure Framework'.

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

#### Respective responsibilities of directors and auditors

As explained more fully in the statement of directors' responsibilities, the directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view. Our responsibility is to audit and express an opinion on the financial statements in accordance with applicable law and International Standards on Auditing (UK and Ireland). Those standards require us to comply with the Financial Reporting Council's (FRC's) Ethical Standards for Auditors.

#### Scope of the audit of the financial statements

A description of the scope of an audit of financial statements is provided on the FRC's website at www.frc.org.uk/auditscopeukprivate.

#### **Opinion on financial statements**

In our opinion:

- the financial statements give a true and fair view of the state of the group's and the parent company's affairs as at 31 December 2015 and of the group's loss for the year then ended;
- the group financial statements have been properly prepared in accordance with IFRSs as adopted by the European Union;
- the parent company's financial statements have been properly prepared in accordance with United Kingdom Generally Accepted Accounting Practice: and
- the financial statements have been prepared in accordance with the requirements of the Companies Act 2006.

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

In our opinion the information given in the strategic report and directors' report for the financial year for which the financial statements are prepared is consistent with the financial statements.

#### Matters on which we are required to report by exception

We have nothing to report in respect of the following matters where the Companies Act 2006 requires us to report to you if, in our opinion:

- adequate accounting records have not been kept by the parent company, or returns adequate for our audit have not been received from branches not visited by us; or
- the parent company financial statements are not in agreement with the accounting records and returns; or
- certain disclosures of directors' remuneration specified by law are not made: or
- we have not received all the information and explanations we require for our audit.

#### Kim Hayward (senior statutory auditor)

For and on behalf of

#### **BDO LLP, statutory auditor**

Southampton United Kingdom

21 March 2016

BDO LLP is a limited liability partnership registered in England and Wales (with registered number OC305127).

## Consolidated Statement of Comprehensive Income

for the year ended 31 December 2015

No Revenue	tes	Year ended 31 December 2015 £000	Year ended 31 December 2014 £000 4,290
Research and development expenditure		(1,355)	(1,649)
Other administrative expenses		(1,279)	(1,547)
Total administrative expenses		(2,634)	(3,196)
(Loss)/Profit from operations	4	(2,609)	1,094
Finance income	6	50	31
(Loss)/Profit before tax		(2,559)	1,125
Tax	7	304	63
(Loss)/Profit and total comprehensive (loss)/income for the period attributable to equity holders of the parent		(2,255)	1,188
(Loss)/Earnings per ordinary share	8		
Basic (loss)/earnings per share pence		(2.47p)	1.42p
Diluted (loss)/earnings per share pence		(2.47p)	1.35p

## Consolidated Statement of Changes in Equity

for the year ended 31 December 2015

	Share capital £000	Share premium £000	Merger reserve £000	Retained deficit £000	Total £000
Note	18a	18b	18c	18d	
At 1 January 2014	752	19,422	483	(19,078)	1,579
Issuance of ordinary shares	161	6,761	-	-	6,922
Transaction costs in respect of share issues	-	(412)	-	-	(412)
Recognition of share-based payments	-	_	-	159	159
Total comprehensive income for the year	-	-	_	1,188	1,188
At 31 December 2014	913	25,771	483	(17,731)	9,436
Recognition of share-based payments	-	-	_	166	166
Total comprehensive loss for the year	-	-	-	(2,255)	(2,255)
At 31 December 2015	913	25,771	483	(19,820)	7,347

## Consolidated Statement of Financial Position

as at 31 December 2015

	Notes	31 December 2015 £000	31 December 2014 £000
Assets		2000	2000
Non-current assets			
Intangible assets	9	81	102
Property, plant and equipment	10	17	17
		98	119
Current assets			
Inventories	11	56	56
Current tax receivable		303	55
Trade and other receivables	12	112	102
Other financial assets – bank deposits	13	3,722	6,752
Cash and cash equivalents	14	3,992	2,847
		8,185	9,812
Total assets		8,283	9,931
Liabilities			
Current liabilities			
Trade and other payables	15	(936)	(495)
Total liabilities		(936)	(495)
Total net assets		7,347	9,436
Equity			
Capital and reserves attributable to equity holders of the parent			
Share capital	17	913	913
Share premium	17	25,771	25,771
Merger reserve	18	483	483
Retained deficit	18	(19,820)	(17,731)
Total equity		7,347	9,436

The financial statements on pages 29 to 42 were approved and authorised for issue by the Board of directors on 21 March 2016 and signed on its behalf by:

#### **Richard Marsden**

Chief Executive Officer

#### John Ward

Finance Director

## Consolidated Statement of Cash Flows

for the year ended 31 December 2015

	Year ended 31 December 2015 £000	Year ended 31 December 2014 £000
Cash flows from operating activities	2000	2000
(Loss)/Profit before tax	(2,559)	1,125
Adjustments for:		
Finance income	(50)	(31)
Depreciation	10	12
Amortisation	21	35
Loss on derecognised intangible asset	-	164
Share-based payment charge	166	159
Cash flows from operations before changes in working capital	(2,412)	1,464
Decrease in inventories	-	143
Increase in trade and other receivables	(18)	(40)
Increase in trade and other payables	441	38
Cash (used in)/generated from operations	(1,989)	1,605
Tax credit received	56	198
Net cash (used in)/generated from operating activities	(1,933)	1,803
Cash flows from investing activities		
Interest received	58	12
Purchase of property, plant and equipment	(10)	(14)
Purchase of intangible assets	-	(4)
Decrease/(Increase) in other financial assets	3,030	(6,294)
Net cash generated from/(used in) investing activities	3,078	(6,300)
Cash flows from financing activities		
Proceeds from issuance of ordinary shares	-	6,922
Transaction costs in respect of share issues	-	(412)
Net cash generated from financing activities	-	6,510
Increase in cash and cash equivalents	1,145	2,013
Cash and cash equivalents at beginning of the period	2,847	834
Cash and cash equivalents at end of the period	3,992	2,847

for the year ended 31 December 2015

#### 1. Accounting policies

#### **Basis of preparation**

The Group financial statements have been prepared in accordance with International Financial Reporting Standards, International Accounting Standards and Interpretations (collectively 'IFRSs') as adopted by the European Union ('Adopted IFRSs') and with those parts of the Companies Act 2006 applicable to companies preparing their financial statements under IFRSs.

The accounting policies adopted are consistent with those of the previous financial year.

The following amendments to standards have been adopted and are effective for the current year:

IFRS 2	Share-based Payment (Definition of vesting and market condition)
IFRS 3	Business Combinations (Accounting for contingent consideration)
IFRS 8	Operating Segments (Disclosure of judgements made relating to the aggregations of operating segments and reconciliation of reportable segments' assets to total entity assets)

The adoption of these pronouncements has not impacted the classification or measurement of the Group's assets and liabilities.

#### New standards and interpretations not applied

IASB have issued the following relevant standards and interpretations with an effective date for periods commencing after 1 January 2016:

Standard or interpretation	Title	Effective for periods beginning on or after
IFRS 9	Financial Instruments	1 January 2018
IFRS 15	Revenue from Contracts with Customers	1 January 2018
IFRS 16	Leases	1 January 2019
IAS 1	Presentation of Financial Statements	1 January 2016
IAS 27	Equity Method in Separate Financial Statements	1 January 2016

The Directors do not anticipate that the adoption of the standards and interpretations will have a material impact on the Group's financial statements in the period of initial application.

The effective dates stated here are those given in the original IASB standards and interpretations. As the Group prepares its financial statements in accordance with IFRS as adopted by the European Union, the application of new standards and interpretations will be subject to them having been endorsed for use in the EU via the EU Endorsement mechanism. In the majority of cases this will result in an effective date consistent with that given in the original standard or interpretation but the need for endorsement restricts the Group's discretion to early adopt standards.

The Group financial statements are presented in Sterling.

for the year ended 31 December 2015 (continued)

#### 1. Accounting policies (continued)

#### **Basis of consolidation**

The consolidated financial statements incorporate the financial statements of the Company and entities controlled by the Company made up to the reporting date. Control is achieved when power can be exercised over the investee; there is exposure, or rights, to variable returns from involvement with the investee; and the ability to exercise power over the investee affects returns. All intra-group transactions, balances, income and expenses are eliminated on consolidation. Business combinations that took place prior to 1 July 2006, the date of transition to IFRS, have not been restated as permitted by IFRS 1 "First-time Adoption of International Financial Reporting". The consolidated financial statements have been prepared using the merger method of accounting.

#### Revenue

Revenue is stated net of value added tax and is recognised when products or services are supplied. Revenues from licensing agreements, including up-front and milestone payments, are recognised where the milestone has been accomplished, the payments are non-refundable, the Group's obligations to the revenues have been discharged and their collection is reasonably assured, and the transfer of risk has occurred.

#### **Research and development**

All ongoing research expenditure is currently expensed in the period in which it is incurred. Due to the regulatory and other uncertainties inherent in the development of the Group's products, the criteria for development costs to be recognised as an asset, as set out in IAS 38 "Intangible Assets", are not met until a product has been submitted for regulatory approval and it is probable that future economic benefit will flow to the Group. The Group currently has no such qualifying expenditure.

#### **Employee benefits**

All employee benefit costs, notably salaries, holiday pay, bonuses and contributions to Group stakeholder or personal defined contribution pension schemes are charged to the consolidated statement of comprehensive income on an accruals basis.

#### **Share-based payments**

Option awards and awards made under the Group's Long Term Incentive Plan ('LTIP') granted after 7 November 2002 which had not vested by 1 July 2006 are fair valued at the date of grant and charged to the consolidated statement of comprehensive income over the period from grant to vesting. The Group has fair-valued option and LTIP awards using appropriate share valuation models. At each reporting date, the Group revises its estimate of the number of options that are expected to become exercisable. The credit for any charge is taken to equity.

#### **Intangible assets**

Intangible assets are stated at cost less any accumulated amortisation and any accumulated impairment losses. Patent and licence costs are amortised over ten years on a straight-line basis and the amortisation cost is charged to research and development expenditure in the consolidated statement of comprehensive income.

#### Property, plant and equipment

Property, plant and equipment are stated at cost less any accumulated depreciation and any accumulated impairment losses. Depreciation is provided on a straight-line basis at rates calculated to write off the cost of property, plant and equipment, less their estimated residual value over their expected useful lives, which are as follows:

Computer equipment: 3 years Laboratory and clinical equipment: 5 years

The carrying values of property, plant and equipment are reviewed for impairment if events or changes in circumstances indicate that the carrying value may not be recoverable.

#### **Inventories**

Inventories are stated at the lower of cost and net realisable value.

#### **Financial instruments**

Financial assets and financial liabilities are recognised on the Group's consolidated statement of financial position when the Group becomes a party to the contractual provisions of the instrument.

#### Financial assets

The Group classifies its financial assets as loans and receivables. These assets are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. They are initially recognised at fair value plus transaction costs that are directly attributable to their acquisition or issue, and are subsequently carried at amortised cost using the effective interest rate method, less provision for impairment.

for the year ended 31 December 2015 (continued)

#### 1. Accounting policies (continued)

Impairment provisions are recognised when there is objective evidence (such as significant financial difficulties on the part of the counterparty or default or significant delay in payment) that the Group will be unable to collect all of the amounts due under the terms receivable; the amount of such a provision being the difference between the net carrying amount and the present value of the future expected cash flows associated with the impaired receivable.

The Group's loans and receivables comprise trade and other receivables, other financial assets and cash and cash equivalents in the consolidated statement of financial position. Other financial assets comprise short-term deposits not meeting the IAS 7 definition of a cash equivalent. Cash and cash equivalents includes cash in hand, deposits held at call with banks and other short-term bank deposits with a maturity period of three months or less from the date of initial deposit.

#### Financial liabilities

The Group classifies its financial liabilities as financial liabilities held at amortised cost. Trade payables are initially recognised at fair value and subsequently carried at amortised cost using the effective interest rate method.

#### **Leased assets**

Where substantially all of the risks and rewards incidental to ownership are not transferred to the Group (an 'operating lease'), the total rentals payable under the lease are charged to the consolidated statement of comprehensive income on a straight-line basis over the lease term.

#### **Taxation**

Income tax is recognised or provided at amounts expected to be recovered or to be paid using the tax rates and tax laws that have been enacted or substantively enacted at the reporting date. Research and development tax credits are included as an income tax credit under current assets.

Deferred tax balances are recognised in respect of all temporary differences that have originated but not reversed by the reporting date except for differences arising on:

- · investments in subsidiaries where the Group is able to control the timing of the reversal of the difference and it is probable that the difference could not reverse in the foreseeable future; and
- the initial recognition of an asset or liability in a transaction which is not a business combination and at the time of the transaction affects neither accounting or taxable profit.

The amount of the asset or liability is determined using tax rates that have been enacted or substantively enacted by the reporting date and are expected to apply when the deferred tax liabilities/(assets) are settled/(recovered).

Recognition of deferred tax assets is restricted to those instances where it is probable that a taxable profit will be available against which the temporary difference can be utilised. Deferred tax balances are not discounted.

#### **Foreign currencies**

Transactions entered into by Group entities in a currency other than the currency of the primary economic environment in which they operate (their "functional currency") are recorded at the rates ruling when the transactions occur. Foreign currency monetary assets and liabilities are translated at the rates ruling at the reporting date. Exchange differences arising on the retranslation of unsettled monetary assets and liabilities are recognised immediately in the consolidated statement of comprehensive income.

The functional currency of all entities in the Group is Sterling.

#### 2. Critical accounting estimates and judgements

Critical accounting estimates, assumptions and judgements are continually evaluated by management based on available information and experience. As the use of estimates is inherent in financial reporting, actual results could differ from these estimates.

#### **Share-based payment**

The critical accounting estimates, assumptions and judgements underpinning the valuation of the option and LTIP awards are disclosed in note 17.

#### 3. Segmental analysis

The Group operates in one area of activity, namely drug discovery and development. All assets of the Group are located within the United Kingdom and all losses were generated in that territory. The revenue generated in 2015 and 2014 was all generated from a single customer.

for the year ended 31 December 2015 (continued)

#### 4. (Loss)/Profit from operations

The (loss)/profit from operations has been arrived at after charging:

	2015 £000	2014 £000
Depreciation of property, plant and equipment	10	12
Amortisation of intangible assets	21	35
Loss on derecognised intangible asset	-	164
Operating lease rentals payable		
Land and buildings	78	81
Other operating lease rentals	93	93
The fees of the Group's auditor, BDO LLP, for services provided are analysed below:	2015 £000	2014 £000
Fees payable to the Company's auditor for the audit of the Group and Company financial statements	12	11
Fees payable to the Company's auditor for other services:		
The audit of the Company's subsidiary, pursuant to legislation	11	10
Audit-related assurance services	7	5
Tax compliance services	14	6
Tax advisory services	9	9
Total fees	53	41

#### 5. Employee benefit expense

The average monthly number of employees (including executive directors) was:

	2015	2014
Research	9	11
Administration	3	2
	12	13
Their aggregate remuneration comprised:	2015 £000	2014 £000
Wages and salaries	909	1,361
Social security costs	114	170
Pension costs – defined contribution plans	56	47
Total cash-settled remuneration	1,079	1,578
Accrued holiday pay	2	(4)
Share-based payment	166	159
Total remuneration	1,247	1,733

For the purpose of presentation in the Consolidated Statement of Comprehensive Income, remuneration costs of £581,000 (2014: £767,000) are included in research and development expenditure and £666,000 (2014: £966,000) are included in other administrative expenses.

#### Key management compensation

The directors represent the key management personnel and details of their remuneration are given in the Directors' Remuneration Report.

In respect of directors' remuneration, the disclosures required by Schedule 5 to the Large and Medium-sized Companies and Groups (Accounts and Reports) Regulations 2008 are included in the detailed disclosures in the audited section of the Remuneration Report on page 26, which are ascribed as forming part of these financial statements.

#### 6. Finance income

For the years ended 31 December 2015 and 2014 Finance income represents bank interest receivable.

for the year ended 31 December 2015 (continued)

#### 7. Taxation

#### **Current tax**

	2015 £000	2014 £000
UK corporation tax credit on profit/loss for the year	(303)	(55)
Adjustment in respect of prior years	(1)	(8)
Total income tax credit	(304)	(63)
The tax assessed on the profit/loss on ordinary activities for the year is different to the standard rate of corporation tax in the UK of 20.25% (2014: 21.50%). The differences are reconciled below:	2015 £000	2014 £000
(Loss)/Profit on ordinary activities before tax	(2,559)	1,125
(Loss)/Profit on ordinary activities before tax multiplied by the standard rate of corporation tax in the UK $$	(518)	242
Effects of:		
Tax relief on share option exercises	-	(221)
Expenses not deductible for tax purposes	35	34
Enhanced research & development relief	(258)	(234)
Variable rates on tax losses surrendered for research & development tax credit	120	27
Movement in unrecognised losses and temporary differences	318	97
Overprovision in respect of previous years	(1)	(8)
Total tax credit for the current year	(304)	(63)

#### **Deferred taxation**

#### Changes in tax rates and factors affecting the future tax charge

Finance Act 2015 included provision for the main rate of corporation tax to reduce from 20% to 19% on 1 April 2017, and to 18% on 1 April 2020. This will reduce the Company's future tax charge accordingly. The rate changes were substantively enacted on 26 October 2015. Accordingly, deferred tax balances have been recognised at 18%, being the rate of corporation tax expected to be in force at the time these timing difference are expected to reverse.

Recognised deferred taxation	2015 £000	2014 £000
Accelerated capital allowances	2	2
Other temporary differences	(2)	(2)
Charge for the year	-	-

#### Unrecognised deferred taxation

At 31 December 2015 the Group has trading losses carried forward which are available for offset against future profits of the Group amounting to £11,917,000 (2014: £10,599,000) and non-trading losses of £1,605,000 (2014: £1,338,000). At 31 December 2015 the Group has an unrecognised deferred tax asset in respect of these losses of £2,434,000 (2014: £2,388,000). The full utilisation of these losses in the foreseeable future is uncertain and no deferred tax asset has therefore been recognised.

In addition to the deferred tax asset on losses, the Group has a potential future tax deduction on share options of £902,000 (2014: £1,151,000) and a deferred tax asset of £162,000 (2014: £230,000) thereon. The additional tax deduction will crystallise at the point the options are exercised. As the utilisation of this additional deduction against taxable profits in the Group is uncertain, no deferred tax asset has been recognised in respect of the future tax deduction on share options.

The movement on the unrecognised deferred tax asset comprises the following:

	2015 £000	2014 £000
Unrecognised deferred tax asset at the start of the year	(2,618)	(2,907)
Movement in year	22	289
Unrecognised deferred tax asset at the year-end	(2,596)	(2,618)

for the year ended 31 December 2015 (continued)

#### 8. (Loss)/Earnings per ordinary share

Basic (loss)/earnings per share ('LPS' or 'EPS') is calculated by dividing the (loss)/profit attributable to ordinary equity holders of the parent company by the weighted average number of ordinary shares in issue during the year.

For diluted earnings per share, the weighted number of ordinary shares in issue is adjusted to assume conversion of dilutive potential ordinary shares, being share options where the exercise price is less than the average market price of the Company's ordinary shares during the year and where performance conditions have been met or, in the case of options where the performance period is not completed, are being met.

Where there is a loss (as for the year ended 31 December 2015), the loss attributable to ordinary shareholders and weighted average number of ordinary shares for the purpose of calculating the diluted earnings per ordinary share are identical to those used for basic loss per share. This is because the exercise of share options would have the effect of reducing the loss per ordinary share and is therefore antidilutive under the terms

The losses/earnings and the number of weighted average number of shares used in the calculations are as follows:

	Losses £000	Shares 000	2015 LPS pence	Earnings £000	Shares 000	2014 EPS pence
Basic (loss)/earnings per share	(2,255)	91,317	(2.47)	1,188	83,899	1.42
Effect of additional shares under option	-	-	-	-	4,279	(0.07)
Diluted (loss)/earnings per share	(2,255)	91,317	(2.47)	1,188	88,178	1.35

#### 9. Intangible assets

	Patent and licence costs £000
Cost	2000
At 1 January 2014	477
Externally-acquired additions	4
Derecognised assets	(269)
At 31 December 2014 and 2015	212
Amortisation	
At 1 January 2014	180
Derecognised assets	(105)
Charge for the year	35
At 31 December 2014	110
Charge for the year	21
At 31 December 2015	131
Net book amount	
At 31 December 2015	81
At 31 December 2014	102
At 1 January 2014	297

At 31 December 2015 £81,000 (31 December 2014: £102,000) of the net book amount relates to interferon beta patent costs, which has a remaining average amortisation period of 4 years (31 December 2014: 5 years). At 1 January 2014 £119,000 of the net book amount related to interferon beta patent costs and £178,000 to interferon lambda patent and licence costs with remaining amortisation periods of 6 and 7 years respectively. During 2014 as a consequence of the AstraZeneca transaction the Company terminated the interferon lambda licence and accordingly derecognised the interferon lambda intangible assets.

for the year ended 31 December 2015 (continued)

### 10. Property, plant and equipment

	Computer equipment	Laboratory and clinical equipment	Total
Cook	£000	£000	£000
Cost At 1 January 2014	44	133	177
Additions	12	2	14
Derecognised assets	(25)	(9)	(34)
At 31 December 2014	31	126	157
Additions	5	5	10
At 31 December 2015	36	131	167
Depreciation			
At 1 January 2014	36	126	162
Derecognised assets	(25)	(9)	(34)
Charge for the year	7	5	12
At 31 December 2014	18	122	140
Charge for the year	8	2	10
At 31 December 2015	26	124	150
Net book value			
At 31 December 2015	10	7	17
At 31 December 2014	13	4	17
At 1 January 2014	8	7	15
11. Inventories		2015 £000	2014 £000
Raw materials		56	56
Raw materials comprises the Group's BioBank.			
12. Trade and other receivables			
Amounts receivable within one year:		2015 £000	2014 £000
Other tax and social security		17	18
Prepayments and accrued income		95	84
rrepayments and accided income		112	102
		112	102
13. Other financial assets – bank deposits			
Amounts receivable within one year:		2015 £000	2014 £000
Sterling fixed rate deposits of greater than three months' maturity at inception		3,722	6,752
Sterning fixed rate deposits of greater than three months maturity at inception		3,722	0,732
14. Cash and cash equivalents			
		2015	2014
Cash available on demand		£000	£000
Cash available on demand		3,992	2,847

for the year ended 31 December 2015 (continued)

### 15. Trade and other payables

	2015 £000	2014 £000
Trade payables	281	78
Social security and other taxes	61	33
Accrued expenses and deferred income	594	384
	936	495

#### 16. Financial instruments

An explanation of the Group's objectives, policies and strategies for financial instruments and analysis of the capital structure and capital funding of the Group can be found on page 13 in the Financial Review.

Notes	2015 Book and fair value £000	2014 Book and fair value £000
Financial assets		
Loans and receivables		
Trade and other receivables (i)	29	51
Other financial assets (less than one year)	3,722	6,752
Cash and cash equivalents (less than one year)	3,992	2,847
Total	7,743	9,650
Financial liabilities		
Other financial liabilities		
Trade and other payables (less than one year) (ii)	866	450

<sup>(</sup>i) Trade and other receivables shown above excludes prepayments, which are not a contractual obligation to receive cash, amounting to £83,000 (2014: £51,000).

The objective of holding financial instruments is to have access to finance for the Group's operations and to manage related risks. The main risks arising from holding these instruments are interest rate risk, liquidity risk, and credit risk.

Interest rate risk profile of financial assets, excluding short-term debtors:

	2015 Floating rate	2014 Floating rate
	financial assets £000	financial assets £000
Australian Dollar	45	-
Euro	72	93
Sterling	7,556	9,491
US Dollar	41	15
	7,714	9,599

Short-term deposits are placed with banks for periods of up to twelve months and are categorised as floating-rate financial assets. Contracts in place at 31 December 2015 had a weighted average period to maturity of 38 days and a weighted average annualised rate of interest of 0.70% (2014: 33 days, 0.65%).

Trade and other payables shown above excludes amounts due in respect of social security and other taxes and deferred income, which are not a contractual obligation to pay cash, amounting to £70,000 (2014: £45,000).

for the year ended 31 December 2015 (continued)

#### **16. Financial instruments** (continued)

#### Sensitivity analysis

It is estimated that an increase of quarter of one percentage point in interest rates would have decreased the Group's loss before taxation by approximately £22,000 (2014: £15,000).

#### Liquidity risk

The Group's policy is to maintain adequate cash resources to meet liabilities as they fall due. All Group payable balances as at 31 December 2015 and 31 December 2014 fall due for payment within one year. Cash balances are placed on deposit for varying periods with reputable banking institutions to ensure there is limited risk of capital loss. The Group does not maintain an overdraft facility.

#### Credit risk

The Group's credit risk is attributable to its banking deposits. The Group places its deposits with reputable financial institutions to minimise credit risk.

### 17. Share capital and premium

	Notes	Number of shares	Ordinary shares of 1p each £000	Share premium £000	Total £000
At 1 January 2014		75,195,891	752	19,422	20,174
Issuance of ordinary shares	(i) - (v)	16,120,780	161	6,761	6,922
Costs of issuance of shares		_	-	(412)	(412)
At 31 December 2014 and 2015		91,316,671	913	25,771	26,684

<sup>(</sup>i) 3,125,000 ordinary shares of 1p were issued on 10 March 2014 at a premium of 47p to provide working capital to progress the out-licensing of SNG001 through to a conclusion.

At 31 December 2014, the total authorised number of ordinary shares was 125 million shares with a par value of 1p per share. At the Company's 2015 Annual General Meeting held on 22 June 2015 shareholders passed a special resolution removing the restriction on the Company's share capital and amending the articles of association of the Company so that the number of shares the Company can allot and issue became unlimited.

All issued shares are fully paid.

<sup>(</sup>ii) 266,363 ordinary shares of 1p were issued on 18 June 2014 at par following the exercise of share options under the Company's long term incentive plan (LTIP).

<sup>(</sup>iii) 10,627,299 ordinary shares of 1p were issued on 11 July 2014 at a premium of 49p to enable the progression of new development opportunities. On the same day the following ordinary shares of 1p were issued following the exercise of share options: 1,285,819 at par (LTIP); 420,000 at a premium of 9p (options granted on 11 October 2004); and 250,000 at a premium of 19p (QNEOS).

<sup>(</sup>iv) 4,712 ordinary shares of 1p were issued on 13 October 2014 at par following the exercise of share options under the 'LTIP'.

<sup>(</sup>v) 141,587 ordinary shares of 1p were issued on 17 November 2014 at par following the exercise of share options under under the 'LTIP'.

for the year ended 31 December 2015 (continued)

#### 17. Share capital and premium (continued)

#### **Options**

At 31 December 2015 there were options outstanding over 6,587,094 un-issued ordinary shares, equivalent to 7.2% of the issued share capital,

Date of grant	Number of shares	Exercise price	Earliest exercise date	Latest exercise date
Approved EMI scheme				
2 October 2006	90,115	85.5p	2 October 2009	1 October 2016
29 October 2007	17,792	61.5p	29 October 2010	28 October 2017
Unapproved schemes				
7 September 2009 (LTIP)	705,000	1p	7 September 2012	6 September 2019
7 September 2009 (QNEOS)	250,000	20p	7 September 2012	6 September 2019
28 June 2010 (QNEOS)	212,765	23.5p	28 June 2013	27 June 2020
8 September 2010 (LTIP)	471,334	1p	8 September 2013	7 September 2020
21 September 2011 (LTIP)	1,742,550	1p	21 September 2014	20 September 2021
11 March 2013 (LTIP)	821,391	1p	11 March 2016	10 March 2023
3 November 2014 (LTIP)	1,054,106	1p	3 November 2017	2 November 2024
27 October 2015 (LTIP)	1,222,041	1p	27 October 2018	26 October 2025
	6,587,094			

The Group has no legal or constructive obligation to repurchase or settle the options in cash. The movement in the number of share options is set out below:

	Number	2015 Weighted average exercise price	Number	2014 Weighted average exercise price
Outstanding at start of year	5,467,644	5.0p	7,393,272	15.6p
Granted during the year	1,222,041	1.0p	1,086,997	1.0p
Exercised during the year	-	n/a	(2,368,481)	4.6p
Lapsed during the year	(102,591)	35.1p	(644,144)	121.6p
Number of outstanding options at year-end	6,587,094	3.8p	5,467,644	5.0p

At 31 December 2015, 3,489,556 share options were capable of being exercised, with exercise prices ranging from 1p to 85.5p (2014: 3,522,464, with exercise prices ranging from 1p to 136.5p). The options outstanding at 31 December 2015 had a weighted average remaining contractual life of 6.7 years (2014: 7.0 years). Vesting conditions are disclosed in the Directors' Remuneration Report.

for the year ended 31 December 2015 (continued)

#### 17. Share capital and premium (continued)

The Group uses a number of share-based incentive schemes as detailed above and in the Directors' Remuneration Report on pages 23 and 24. The fair value per award granted and the assumptions are as follows:

Date of grant	Type of award	Number of shares	Exercise price (p)	Share price at date of grant (p)	Fair value per option (p)	Award life (years)	Risk free rate	Expected volatility rate	Performance conditions
2 Oct 2006	EMI	90,115	85.5p	85.5p	24.4p	5	4.75%	20%	None
29 Oct 2007	EMI	17,792	61.5p	61.5p	17.8p	5	4.95%	20%	None
7 Sept 2009	LTIP	705,000	1p	18.5p	7.1p	3	2.09%	30%	Market
7 Sept 2009	QNEOS	250,000	20p	18.5p	4.0p	5	2.67%	30%	Market
28 Jun 2010	QNEOS	212,765	23.5p	23.5p	5.6p	5	2.09%	30%	Market
8 Sept 2010	LTIP	471,334	1р	24.25p	12.1p	3	0.92%	40%	Market
21 Sept 2011	LTIP	1,742,550	1р	22.5p	13.4p	3	0.79%	56%	Market
11 Mar 2013	LTIP	821,391	1р	53p	30.9p	3	0.36%	44%	Market
3 Nov 2014	LTIP	1,054,106	1p	41.5p	22.4p	3	1.11%	46%	Market
27 Oct 2015	LTIP	1,222,041	1p	29p	14.2p	3	0.71%	38%	Market
		6,587,094							

In accordance with IFRS 2, the Company has applied IFRS 2 to all share-based payments granted after 7 November 2002 which had not vested by 1 July 2006. The following comments apply to those options which have been fair valued in accordance with IFRS 2.

- (i) Stochastic valuation methodology was used for the LTIP awards and the QNEOS awards with market performance conditions and Black-Scholes methodology for the
- (ii) Expected dividend yield is nil, consistent with the Directors' view that the Group's model is to generate value through capital growth rather than payment of dividends.
- (iii) The risk free rate is equal to the prevailing UK Gilts rate at grant date that most closely matches the expected term of the grant.
- (iv) The fair value charge is spread evenly over the expected vesting period.
- (v) The charge for the year ended 31 December 2015 for share-based payment amounted to £166,000 (2014: £159,000).

#### 18. Capital and reserves

#### 18a Share capital

Share capital represents the nominal value of shares issued.

#### 18b Share premium

Share premium represents amounts subscribed for share capital in excess of nominal value less the related costs of share issues.

#### 18c Merger reserve

The merger reserve represents the reserve arising on the acquisition of Synairgen Research Limited on 11 October 2004 via a share for share exchange accounted for as a Group reconstruction using merger accounting under UK GAAP.

#### 18d Retained deficit

The retained deficit represents cumulative net gains and losses recognised in the consolidated statement of comprehensive income, adjusted for cumulative recognised share-based payments.

#### 19. Commitments under operating leases

The total future value of minimum lease payments committed at the balance sheet date under non-cancellable operating leases is due as follows:

	2015 £000	2014 £000
Not later than one year	163	-
Later than one year and not later than five years	95	-
Total	258	-

#### 20. Related party transactions and balances

Details of key management personnel and their compensation are given in note 5 and on page 26 of the Directors' Remuneration Report.

# Parent Company Balance Sheet

as at 31 December 2015

### Company number: 5233429

	Notes	31 December 2015 £000	31 December 2014 £000
Fixed assets	11000	2000	2000
Investments	3	19,510	17,763
			,
Current assets			
Debtors	4	15	39
Investments: short-term deposits		3,722	6,752
Cash at bank and in hand		3,879	2,709
		7,616	9,500
Creditors: amounts falling due within one year	5	(34)	(69)
Net current assets		7,582	9,431
Total assets less current liabilities		27,092	27,194
Capital and reserves			
Called up share capital		913	913
Share premium account		25,771	25,771
Retained earnings		408	510
Shareholders' funds		27,092	27,194

# Parent Company Statement of Changes in Equity

for the year ended 31 December 2015

	Share capital £000	Share premium account £000	Retained earnings £000	Shareholders' funds £000
At 1 January 2014	752	19,422	605	20,779
Loss for the year and total comprehensive loss	_	-	(254)	(254)
Issuance of ordinary shares	161	6,761	_	6,922
Transaction costs in respect of share issues	-	(412)	-	(412)
Share-based payment credit	_	-	159	159
At 31 December 2014	913	25,771	510	27,194
Loss for the year and total comprehensive loss	_	-	(268)	(268)
Share-based payment credit	_	-	166	166
At 31 December 2015	913	25,771	408	27,092

The financial statements on pages 43 to 46 were approved and authorised for issue by the Board of directors on 21 March 2016 and signed on its behalf by:

#### **Richard Marsden**

Chief Executive Officer

#### John Ward

Finance Director

### Notes to the Parent Company Financial Statements

for the year ended 31 December 2015

#### 1. Accounting policies

#### Basis of preparation

The financial statements have been prepared in accordance with Financial Reporting Standard 100 Application of Financial Reporting Requirements ('FRS 100') and Financial Reporting Standard 101 Reduced Disclosure Framework ('FRS 101').

#### Disclosure exemptions adopted

In preparing these financial statements the Company has taken advantage of all disclosure exemptions conferred by FRS 101. Therefore these financial statements do not include:

- · certain comparative information as otherwise required by EU-endorsed IFRS;
- · certain disclosures regarding the Company's capital;
- · a statement of cash flows;
- · the effect of future accounting standards not yet adopted;
- the disclosure of the remuneration of key management personnel; and
- · disclosures of related party transactions with other wholly-owned members of Synairgen plc group of companies.

In addition, and in accordance with FRS 101, further disclosure exemptions have been adopted because equivalent disclosures are included in the Company's consolidated financial statements. These financial statements do not include certain disclosures in respect of:

- · share-based payments; or
- · financial instruments.

#### Principal accounting policies

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

#### Basis of accounting

The financial statements have been prepared under the historical cost convention. The presentation currency used is sterling and amounts have been presented in round thousands (£000s).

#### First time application of FRS 100 and 101

In the current year the Company has adopted FRS 100 and FRS 101. In previous years the financial statements were prepared in accordance with applicable UK accounting standards. This change in the basis of preparation has not materially altered the recognition and measurement requirements previously applied in accordance with applicable UK accounting standards. Consequently the principal accounting policies are unchanged from the prior year. The change in the basis of preparation has enabled the Company to take advantage of all of the available disclosure exemptions permitted by FRS 101 in the financial statements, the most significant of which are summarised above. There have been no other material amendments to the disclosure requirements previously applied in accordance with applicable UK accounting standards.

#### **Foreign currency**

The financial statements are presented in UK pounds sterling, which is the Company's functional currency.

Transactions entered into by the Company in a currency other than the currency of the primary economic environment in which it operates (its 'functional currency') are recorded at the rates ruling when the transactions occur. Foreign currency monetary assets and liabilities are translated at the rates ruling at the reporting date. Exchange differences arising on the retranslation of unsettled monetary assets and liabilities are recognised immediately in profit or loss.

#### Investment in subsidiary undertakings

Investments in subsidiary undertakings where the Company has control are stated at cost less any provision for impairment.

#### **Financial instruments**

Financial assets and financial liabilities are recognised on the Company's balance sheet when the Company becomes a party to the contractual provisions of the instrument.

The Company classifies its financial assets as loans and receivables. These assets are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. They are initially recognised at fair value plus transaction costs that are directly attributable to their acquisition or issue, and are subsequently carried at amortised cost using the effective interest rate method, less provision for impairment. Impairment provisions are recognised when there is objective evidence (such as significant financial difficulties on the part of the counterparty or default or significant delay in payment) that the Company will be unable to collect all of the amounts due under the terms receivable; the amount of such a provision being the difference between the net carrying amount and the present value of the future expected cash flows associated with the impaired receivable.

## Notes to the Parent Company Financial Statements

for the year ended 31 December 2015 (continued)

#### 1. Accounting policies (continued)

The Company's loans and receivables comprise debtors, investments; short-term deposits and cash and cash equivalents in the balance sheet. Other financial assets comprise short-term deposits not meeting the definition of a cash equivalent. Cash and cash equivalents includes cash in hand, deposits held at call with banks and other short-term bank deposits with a maturity period of three months or less from the date of initial deposit.

#### Financial liabilities

The Company classifies its financial liabilities as financial liabilities held at amortised cost. Trade creditors are initially recognised at fair value and subsequently carried at amortised cost using the effective interest rate method.

When the Company grants options over equity instruments directly to the employees of a subsidiary undertaking, the effect of the share-based payment is capitalised as part of the investment in the subsidiary as a capital contribution, with a corresponding increase in equity.

The charge for taxation is based on the loss for the period and takes into account taxation deferred.

Current tax is measured at amounts expected to be paid using the tax rates and laws that have been enacted or substantively enacted by the balance sheet date. Deferred tax balances are recognised in respect of all timing differences that have originated but not reversed by the balance sheet date, except that the recognition of deferred tax assets is limited to the extent that the Company anticipates making sufficient taxable profits in the future to absorb the reversal of the underlying timing differences.

Deferred tax balances are not discounted.

#### Share capital

The Group's ordinary shares are classified as equity instruments. Financial instruments issued by the Company are classified as equity only to the extent that they do not meet the definition of a financial liability or financial asset.

#### 2. Profit and loss account

As permitted by Section 408 of the Companies Act 2006, the Company's profit and loss account has not been included in these financial statements. The loss for the year dealt with in the consolidated financial statements of the Company the £268,000 (2014: loss of £254,000).

The only employees of the Company are the executive directors and all their costs are borne by its subsidiary undertaking.

In respect of directors' remuneration, the disclosures required by Schedule 5 to the Large and Medium-sized Companies and Groups (Accounts and Reports) Regulations 2008 are included in the detailed disclosures in the audited section of the Directors' Remuneration Report on page 26, which are ascribed as forming part of these financial statements.

Auditor's remuneration is disclosed in note 4 to the Group accounts on page 35.

#### 3. Investments

	Investment in subsidiary undertaking £000	Loan to subsidiary undertaking £000	Capital contribution £000	Total £000
At 1 January 2015	140	16,343	1,280	17,763
Additions	-	1,581	166	1,747
At 31 December 2015	140	17,924	1,446	19,510

At 31 December 2015, the Company had an investment in the following subsidiary undertaking:

Name of company	Country of incorporation	Proportion of voting rights and ordinary share capital held	Nature of business
Synairgen Research Limited	England	100%	Drug discovery and development

# Notes to the Parent Company Financial Statements

for the year ended 31 December 2015 (continued)

#### 4. Debtors

	2015 £000	2014 £000
Other tax and social security	2	7
Prepayments and accrued income	13	32
	15	39

All amounts fall due for payment within one year.

#### 5. Creditors: amounts falling due within one year

	2015 £000	2014 £000
Trade creditors	4	27
Accruals and deferred income	30	42
	34	69

#### 6. Share capital and share premium

Details of the Company's share capital, share premium, share option schemes and LTIP can be found in note 17 to the Group accounts on pages 40 to 42.

#### 7. First time adoption of FRS 101 Reduced Disclosure Framework

This is the first time that the Company has adopted FRS 101, having previously applied applicable UK accounting standards. The date of transition to FRS 101 was 1 January 2014. In applying FRS 101 for the first time, the Company has made the following election:

· To retain the cost of investment in subsidiary undertakings at their carrying amount under applicable UK accounting standards.

Other than the adoption of the reduced disclosures, there was no material impact of applying FRS 101 for the first time. The disclosure exemptions are included in note 1 to the financial statements.

# Corporate Directory

### **Company number**

#### **Directors**

#### Secretary

#### Head office and Registered office

#### Website

#### E-mail

#### **Advisers**

#### **Independent auditor** BDO LLP

#### **Bankers**

#### **HSBC** Bank plc

#### Financial public relations

Consilium Strategic Communications

#### Nominated adviser and broker FinnCap Limited

#### **Registrars**

#### **Capita Asset Services**

#### **Solicitors**

#### Fladgate LLP

### Glossary

#### Acute

An acute disease is a disease with a rapid onset and/or a short course

#### **Adenovirus**

A virus that can cause respiratory disease (e.g. the common cold), conjunctivitis and gastroenteritis

#### Airways (or bronchial tubes)

The tubes that carry air in and out of the lungs

#### Allergen

A usually harmless substance capable of triggering a response that starts in the immune system and results in an allergic reaction

#### Antibiotic

A drug that inhibits bacterial growth or kills bacteria

#### **Antiviral**

Any substance that can either destroy viruses or suppress their growth

#### **Apoptosis**

A naturally-occurring form of programmed cell death

#### Assay

A laboratory test to determine parameters such as the strength of a solution, the proportion of a compound in a mixture, the potency of a drug or the purity of a preparation

#### **Asthma**

A disorder in which the airways become episodically narrowed, leading to wheeze, shortness of breath, cough and chest tightness

#### AZD-9412

Inhaled interferon beta formulation

#### **BioBank**

A collection of samples from clinically-characterised volunteers, comprising blood, induced sputum, bronchial biopsies and epithelial cells. These samples are used to develop the complex in vitro human disease models

#### **Biomarker**

A biochemical feature or facet that can be used to measure the progress of disease or the effects of treatment

#### **British Thoracic Society (BTS) Step** classification system

A stepwise treatment regime (from steps 1 to 5, with 5 being the most severe) for treating asthma in Britain aiming to achieve optimum control without excessive medication

#### **Broad spectrum antibiotic**

An antibiotic that acts against a wide range of disease-causing bacteria

#### **Bronchodilators**

Medicines which relax the muscles around the airways, helping the airways to open up, so making it easier to breathe. There are several types of bronchodilators, of which shortacting beta-agonist drugs are the most commonly used

#### **Bronchospasm**

A sudden contraction of airway smooth muscle resulting in a narrowing of the airways

#### Candidate

A candidate drug is a compound (e.g. small molecule, antibody, etc.) with strong therapeutic potential and whose activity and specificity have been optimised

#### **Chronic bronchitis**

An inflammation of the airways accompanied by coughing and production of phlegm. The symptoms are present for at least three months in each of two consecutive years. See COPD

#### Chronic disease

A persistent or long-lasting condition

#### **Clinical Trial Authorisation or CTA**

An authorisation from the MHRA (see below) to conduct a clinical trial

#### COPD

Chronic Obstructive Pulmonary Disease covers two conditions: chronic bronchitis and emphysema. COPD usually results from long-term exposure of irritants to the lungs, of which the most prevalent is tobacco smoke. Unlike asthma, where airflow obstruction varies, in COPD airflow obstruction is usually irreversible

#### Coronavirus

A virus that can cause respiratory disease such as the common cold or SARS (depending on the type of coronavirus) and gastroenteritis

#### DNA

Nucleic acid that carries genetic information in the cell

#### **Emphysema**

A destructive process involving the air spaces (alveoli) of the lungs, which leads to over-inflation of the lung and, when sufficiently advanced, causes breathlessness and lack of oxygenation of blood. See COPD

#### Eosinophil

A type of white blood cell that has a role in allergy and asthma

#### **Epithelium**

In the lung, the epithelium is a thin layer of cells which lines airway tubes in order to protect and regulate the tissue underneath

#### **Exacerbation**

A rapid deterioration of a chronic disease that makes the symptoms worse

#### **Fibroplastic focus**

A hallmark of IPF lung tissue characterised by dense collections of fibroblasts (the cells that secrete scar tissue)

#### Gene

A hereditary unit consisting of a sequence of DNA that determines a particular characteristic of a living organism

#### **Idiopathic Pulmonary Fibrosis** (IPF)

A disease in which tissue deep in the lungs becomes thick and stiff, or scarred, over time by unknown cause. The formation of scar tissue is called fibrosis. It usually affects middle-aged and older people

#### Interferon beta (IFN-β)

Interferon beta is a natural protein found in the body which helps to regulate the immune system and fight off viruses. IFN-β is currently marketed by a number of companies as an injectable therapy for the treatment of multiple sclerosis

#### Influenza

A contagious viral infection of the respiratory tract, leading to fever, headaches, sore throat, congestion of the nose and body aches

#### In vitro

Carried out in the laboratory, e.g. in a test tube or culture plate

#### In vitro model (complex)

A research model which contains more than one cell type and allows the study of interactions between different cell types and 'test' agents relevant to the disease or a therapy

#### Long acting beta agonist

An asthma drug that acts to relax (open) the airways for 12 or more hours

#### Lower airway

The airway tubes in the lung running from the throat down, ending in the air spaces (alveoli) where gas exchange occurs

#### Lysyl oxidase (LOX)

An enzyme responsible for the maintenance of collagen and elastin in tissues

#### Lysyl oxidase-like protein 2 (LOXL2)

An enzyme released from fibroblasts that links collagen fibres together to stiffen scar tissue

#### Macrophages

Phagocytic (i.e. cells that can engulf other cells and cell components) white blood cells involved in cellular clearance and inflammation

#### **MHRA**

The Medicines and Healthcare Products Regulatory Agency; a UK government body tasked with ensuring that medicines and medical devices work and are safe

#### Morbidity

Incidence or prevalence of a disease

#### Mucus

A gelatinous substance normally produced by the airway cells to protect and hydrate the airway surface from harmful agents

#### Multiple sclerosis (MS)

A disease affecting nerves in the brain and spinal cord, causing problems with muscle movement, balance and vision

#### Non-alcoholic steatohepatitis (NASH)

A form of chronic liver disease in adults and children

#### Pandemic influenza

An influenza pandemic occurs when a new influenza virus appears against which the human population has no immunity, resulting in epidemics worldwide with enormous number of deaths and illness

#### **Parainfluenza**

A virus that can cause the common cold. Parainfluenza is also responsible for 75% of croup cases in children

#### **Patent Cooperation Treaty** or PCT

A system by which a patent application can be filed in many different countries at once. A single international application is filed initially at a receiving office. After a search and publication, the application may be converted to a series of national applications in different countries

#### **Pathway**

A signalling pathway is a group of molecules that work together in a cell to control one or more cell functions

#### Peak expiratory flow

A lung function test that measures a person's ability to breathe out air

#### Personalised/P4/stratified

The customisation of healthcare to the individual patient

#### **Phase I Clinical Trial**

A study conducted in volunteers to determine the biological effects of a drug, especially safety and tolerability

#### Phase II Clinical Trial

A study in patients with the aim of making a preliminary determination of the efficacy of a drug to provide proof of concept and/or to study drug dose ranges

#### **Phase IIa Clinical Trial**

Used to describe a Phase II clinical trial evaluating efficacy, adverse effects and safety risks

#### **Phase IIb Clinical Trial**

Used to describe a subsequent Phase II clinical trial that also evaluates dosage tolerance and optimal dosage frequency in a larger number of patients than enrolled in a Phase IIa trial

#### **Phase III Clinical Trial**

A full scale clinical trial to determine drug efficacy and safety prior to seeking marketing approval

#### Phlegm

See Sputum

#### Placebo

An inactive substance or preparation used as a control/ comparator (in a clinical trial for example) to determine the effectiveness of a medicinal drug

# Glossary (continued)

#### Pre-candidate

A chemical compound that has pharmacological or biological activity likely to be therapeutically useful but which has not yet met all the criteria that are required to be a candidate drug

#### **Primary endpoint**

The most important measure (endpoint) assessed in a clinical trial

#### **Prognostic biomarker**

A biomarker that can predict the future course of a disease or response to a therapy

#### **Prophylaxis**

A measure taken for the prevention of a disease or condition

#### **Protein**

Large molecules made of smaller biological units known as 'amino acids'. Proteins are responsible for the majority of the function and much of the structure of living things, including humans

#### **Pulmonary**

Relating to, functioning like, or associated with the lungs

#### **Rhinovirus**

Rhinoviruses are the most common viral infective agents in humans. The most well-known disease caused by rhinoviruses is the common cold

#### RNA

Nucleic acid that is involved in protein synthesis and transmission of genetic information

#### Respiratory syncytial virus (RSV)

RSV can cause both mild respiratory illness (e.g. the common cold) and serious respiratory tract infections (such as bronchiolitis and pneumonia). More severe infections can occur in the very young, the very old and those with weakened immune systems

#### Safety study

See Phase I Clinical Trial

#### Seasonal Influenza

Seasonal influenza is a yearly outbreak of influenza infection, caused by influenza virus. The seasonal influenza is somewhat different every year, as influenza viruses are always changing

#### Secondary/exploratory endpoint

The second most important (or additional) measure (or endpoint) assessed in a clinical trial

#### Severe asthma

Asthma which requires treatment with high dose inhaled corticosteroids plus a second controller (and/or oral corticosteroids) to prevent it from becoming 'uncontrolled' or which remains 'uncontrolled' despite this therapy

#### SG004

A double-blinded, placebocontrolled, single and multiple dose-escalating Phase I study to assess the safety and tolerability of inhaled IFN-β in controlled asthmatic male and female subjects

#### SG005

A randomised, double-blinded, placebo-controlled Phase II study, comparing the efficacy and safety of inhaled IFN-β to placebo administered to asthmatic subjects after the onset of a respiratory viral infection for the prevention or attenuation of asthma symptoms caused by respiratory viruses

#### SOCS-1 or Suppressor of cytokine signalling-1

A protein that inhibits IFN-β signalling

#### Sputum

The thick mucus which is coughed up by a person. Sputum contains cells and soluble substances secreted into the airways (bronchi), some of which can mediate disease if present in amounts different to normal. Sputum is also commonly called phlegm

#### **Steroids**

A group of chemicals that is produced naturally in the body by the adrenal gland. In asthma, steroids are given by inhalation or by mouth to reduce the inflammation of the airways

#### Systemic absorption

The fraction of drug that reaches the systemic circulation

#### Toxicology

The study of the nature and mechanisms of deleterious effects of chemicals on humans, animals and other biological systems

#### Translational medicine

The process of converting a scientific discovery into something that aims to improve the health of individuals and the community

#### Type I IFNs

A classification of interferon that includes IFN-B

#### **Upper airway**

The tubes in the nose and neck which conduct air into the lung

A virus is a non-living small particle that infects cells in biological organisms. Viruses can reproduce only by invading and controlling other cells as they lack the cellular machinery for self-reproduction

#### Wheeze

A whistling sound made by a person who has airflow obstruction when breathing

# synairgen plc