Report and Financial Statements

Year ended

1 1

31 December 2018

Company Number 04793696

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# Report and financial statements for the year ended 31 December 2018

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### **Directors**

17

Richard Marsden
Dr Phillip Monk
John Ward
Professor Stephen Holgate CBE

# **Company number**

04793696

## Secretary and registered office

John Ward

Mailpoint 810, Level F, South Block, Southampton General Hospital, Tremona Road, Southampton SO16 6YD

## **Auditor**

BDO LLP, Level 12, Thames Tower, Station Road, Reading RG1 1LX

### **Bankers**

HSBC Bank plc, 165 High Street, Southampton SO14 2NZ

### **Solicitors**

Fladgate LLP, 16 Great Queen Street, London WC2B 5DG

# Strategic Report for the year ended 31 December 2018

The directors present their Strategic Report for Synairgen Research Limited (the 'Company' or 'Synairgen') for the year ended 31 December 2018.

## **Principal Activities and Strategy**

Synairgen Research Limited is a respiratory drug discovery and development company.

Synairgen leverages its deep understanding of respiratory biology to discover and develop novel therapies in areas of high unmet respiratory medical need, including severe asthma, chronic obstructive pulmonary disease (COPD) and idiopathic pulmonary fibrosis (IPF). Using our BioBank platform (consisting of 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 license them to partners to advance through to commercialisation.

The BioBank platform gives us competitive advantage by being able to use tissue from patients with disease to identify targets that would not reveal themselves in other discovery systems (e.g, the mouse). We also use the technology to test new compounds against these targets. The net effect is that as we progress programmes towards and in the clinic we do so with greater confidence because we know that the programme is underpinned by human sample based science.

## **Operating Review**

## Summary

2018 has been a year of excellent operational progress. We successfully advanced our inhaled interferon beta (IFN- $\beta$ ) programme, to treat or prevent COPD exacerbations, into the clinic and, in September 2018, we raised £2.7 million (net of costs) to expand the number of patients to be included in our clinical trial, to increase the power of the study and enhance our chance of partnering our inhaled IFN- $\beta$  programme for COPD. In addition, our Australian partner, Pharmaxis, has completed Phase I clinical trials for the LOXL2 inhibitor programme with positive results and we now eagerly await the next steps for this product where Synairgen has a significant financial interest in its success.

## Inhaled IFN-β programme

## Inhaled IFN-β progression in COPD to treat or prevent virus-induced exacerbations

We have progressed inhaled IFN-β into COPD, where the risk that a patient will exacerbate due to a cold infection is much higher (approximately 50%¹) compared to asthma (<10%²), with some identifiable sub-groups at higher risk than others.³ The cost to both patient and healthcare providers of virus-induced COPD exacerbations is also substantial – in England alone, COPD is the second most common cause of unplanned hospitalisations after cardiovascular disease.⁴

We have long known that COPD represents a very substantial market for inhaled IFN-β, addressing a large number of patients who are expensive to treat. The historical barrier to progressing into COPD was the complexity around identifying the virus-positive patients for treatment. COPD patients can suffer from bacterial infections as well as viral infections and, up until recently, distinguishing between viral and bacterial infections, at the point of assessment, was too great an obstacle to allow progression of inhaled IFN-β into COPD clinical trials.

Our ability to progress with COPD has been enabled by the availability of a novel point of care test launched by bioMérieux. This test confirms the presence of a respiratory virus in a patient within 45 minutes of a nasal or throat swab being taken. Utilisation of this new diagnostic test

# Strategic Report for the year ended 31 December 2018 (continued)

means that we can be sure that every patient we treat in the COPD trial is virus positive. This will eliminate the background "noise" associated with the inclusion of patients with no viral infection in the trial and thereby reduce the required trial size, and therefore cost, to obtain meaningful results.

We are starting treatment at the onset of respiratory symptoms in virus-positive patients. At the moment, COPD patients are not encouraged to visit their GP/pulmonologist if they have a cold. This is because there are no broad spectrum antiviral therapeutic options available to limit the spread of virus to the lungs. The advent of this new diagnostic technology changes this paradigm. The bioMérieux point of care test enables rapid identification of common bacterial and viral pathogens. For the virus-positive patients, the availability of an antiviral therapy with the potential to either prevent exacerbations, or to limit their severity, would be a major breakthrough.

In Q1 2018 we commenced a two-part Phase II clinical trial in COPD patients.

### Part 1 of Phase II trial

The first part of the trial was conducted to confirm the safety of inhaled IFN- $\beta$  in this patient population. Inhaled IFN- $\beta$  has been well tolerated in all of the asthma trials; COPD patients' lungs are different and it was necessary to assess safety prior to dosing patients in part two of the trial. Our target patients have typically lost approximately 40% of their lung function, their lungs are often colonised by bacteria, and their lung inflammation is driven by different factors than in asthma. During this first phase, we were pleased to ascertain that inhaled IFN- $\beta$  was well tolerated in COPD patients. We also undertook a biomarker assessment. Patients in this part of the trial were free of viral infection and inhalation of IFN- $\beta$  should activate their antiviral defences. Indeed, as reported in June 2018, the antiviral biomarkers assessed 24 hours after administration of a dose of inhaled IFN- $\beta$  were elevated. This increase in relevant biomarkers was very similar to that which we had observed in asthma. We were particularly pleased to see firstly, the robust antiviral response in these older patients' lungs that have typically been exposed to many years of cigarette smoke, and secondly, that this effect mirrored *in vitro* findings in COPD patients' lung cells from our models where IFN- $\beta$  is effective.

## Part 2 of Phase II trial

Completion of part one enabled the commencement of part two of the trial. In part two, COPD patients without infection are screened and entered into a waiting phase. We are building this pool of 'waiting patients' to approximately 200 patients. Patients then contact the trial site as soon as they develop a cold or COPD symptoms which are suspected to be caused by a virus. Upon arrival at the trial site, patients are tested to determine whether they have a respiratory virus; those that are positive are treated with either inhaled IFN- $\beta$  or placebo for 14 days.

In October 2018 Synairgen's parent company (Synairgen plc) completed a placing which raised £2.7 million (net of costs), primarily to increase the COPD trial size from 80 patients to 120 patients in order to be able to focus on clinical endpoints, to enhance the chance of obtaining a positive result, and ultimately to partner the programme when the trial is completed.

The trial is progressing well and we have now initiated 13 trial sites, all in the UK. As at 15 February 2019, 181 patients have been screened and 133 patients have been entered into the 'pool', waiting to develop virus symptoms, ahead of the confirmatory virus testing. In the first three months of the trial (up to 11 January), 22 patients developed symptoms and were tested for a respiratory virus; 3 out of the 22 tested positive and were subsequently dosed. This reflected the mild start to the respiratory virus season as reported by Public Health England (PHE). In the subsequent five weeks to 15 February, PHE reported an uplift in influenza like illness (an

# Strategic Report for the year ended 31 December 2018 (continued)

indication of the impact of respiratory viruses on healthcare system) and this has been reflected in an uplift in the number of patients dosed in our trial. Since 11 January a further 30 patients have been tested, of whom 15 were virus positive and dosed. The virus test has therefore proved its value, particularly during the late autumn and early winter, screening out patients who, historically, may have been dosed based on their symptoms, but who had no potential to gain from an antiviral. The following viruses have been detected: enterovirus/rhinovirus; RSV; coronavirus; human metapneumovirus; and influenza. The milder start to this virus season means that we now expect the trial to continue into the 2019/2020 virus season.

### Size of market opportunity

COPD is a common disease which consumes substantial healthcare resources, particularly in the non-summer months. COPD patients will typically have one to two colds per year. Each cold carries a risk of exacerbation of approximately 50%. In the USA, the average cost of a hospitalisation following a visit to the Emergency Department for a COPD patient is \$29,000.5 Pathogen testing at the onset of an exacerbation is being recommended to reduce unnecessary antibiotic prescribing for viral exacerbations. The need for a broad spectrum antiviral therapy is substantial. We expect considerable interest from potential partners for this programme and have commenced a dialogue with several large pharma companies.

## LOXL2 inhibitor programme

In collaboration with Pharmaxis we identified and progressed a LOXL2 inhibitors programme from the pre-clinical stage through to commencement of a Phase I clinical trial. Initially the collaboration was focussed on idiopathic pulmonary fibrosis (IPF), an area of expertise for Synairgen.

Over the two years of the collaboration, our interactions with potential large pharma partners led to an expansion of the programme to also embrace other fibrotic diseases, including non-alcoholic steatohepatitis (NASH, a type of liver fibrosis), heart fibrosis, and kidney fibrosis. In December 2017 we elected to pass responsibility for the further development and commercialisation of these compounds to Pharmaxis, who were better placed to conduct research in the non-lung fibrotic arena, in return for £5 million and a share of at least 17% (net of allowable expenses) of any receipts from any onward licensing by Pharmaxis of the LOXL2 inhibitors in fibrotic indications.

During 2018, Pharmaxis successfully completed Phase I trials for two compounds, and showed best in class inhibition of the LOXL2 enzyme in these clinical trials. Post period-end (17 January 2019), Pharmaxis announced that the 3 month toxicology studies had been successfully completed for both compounds, allowing them to progress the next strategic steps for the programme. We continue to track Pharmaxis' progress with great interest.

### **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 KPI is the planned R&D expenditure. This is further described in the financial review below.

# Strategic Report for the year ended 31 December 2018 (continued)

#### **Financial Review**

The Financial Review should be read in conjunction with the financial statements of the Company and the notes thereto on pages 14 to 26. The financial statements of the Company are prepared in accordance with Financial Reporting Standard 101 *Reduced Disclosure Framework*.

## Statement of Comprehensive Income

The loss from operations for the year ended 31 December 2018 was £3.89 million (2017: profit £1.83 million). Revenues for the year amounted to £0.11 million (2017: £5.03 million). 2017 included a non-recurring £5 million payable by Pharmaxis as consideration for the change in collaboration terms. The 2018 revenue comprised fee for service work in relation to the LOXL2 programme. Research and development expenditure for the year amounted to £3.29 million (2017: £2.13 million), and was focussed almost entirely on the IFN-β Phase II clinical trial in COPD and associated pharmaceutical development costs.

Other administrative costs for the year amounted to £0.70 million (2017: £1.06 million), with the decrease being attributable to lower staff bonus costs and reduced legal costs. The tax credit increased from £0.13 million in 2017 to £0.80 million in 2018. The 2017 credit was at lower levels than preceding years because the Company was in profit and this limited the amount of research and development tax credit which could be claimed. The loss after tax for 2018 was £3.09 million (2017: profit of £1.97 million).

## Statement of Financial Position, Capital structure and funding

At 31 December 2018 net assets amounted to £0.78 million (2017: net liabilities £18.54 million). At 31 December 2018 Synairgen plc made a capital contribution to the Company of £22.31 million, which was the amount of the intercompany loan at that date. Synairgen plc has confirmed to the Company that it will continue to provide such financial support as the Company requires for its continued operations for a period of not less than one year from the date of this report. The Company did not have any bank borrowings as at 31 December 2018 (2017: £nil).

The other significant changes in the statement of financial position were:

- The net book value of property, plant and equipment increased from £0.01 million to £0.37 million at 31 December 2018. This was due to the purchase of 13 bioMérieux multiplex PCR virus detection machines (one for each clinical trial site) at a total cost of £0.36 million. The remainder of the capital expenditure was for laboratory and IT equipment;
- Current tax receivable increased from £0.07 million to £0.80 million on account of the higher R&D tax credit as discussed above;
- The decrease in trade and other receivables (2018: £0.20 million, 2017: £0.63 million) is attributable to the reduction in amounts receivable from Pharmaxis;
- The decrease in creditors payable within one year (2018: £0.83 million, 2017: £19.40 million) is caused by the capital contribution referred to above and a reduction in accruals for staff bonuses; and
- The retained deficit reduced from £20.87 million to £1.66 million on account of the loss for the year of £3.09 million and the capital contribution of £22.31 million.

# Strategic Report for the year ended 31 December 2018 (continued)

## Principal risks and uncertainties

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

#### • Interferon beta Phase II trial overruns

The Company is currently running a Phase II trial in COPD, which is seeking to randomise 120 patients. The speed of the trial is dependent upon the rate of recruitment into the pre-treatment pool and the rate at which such patients contract colds. Overrunning of the trial into 2020 would result in extra costs to complete the trial, as a number of the monthly costs are fixed in nature.

The Company is continually monitoring the progress of the trial and looking to secure efficiencies and maximise the size of the pre-treatment pool as quickly as possible.

## • Interferon beta Phase II trial fails to meet endpoints

There can be no guarantee that the trial will meet its endpoints and generate good enough results to merit further development expenditure in the programme either by Synairgen or a licensee.

#### Commercial risk

There can be no guarantee that the Company, or Pharmaxis, in the case of its LOXL2 programme in which the Company has a 17% share, 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 Company 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.

## • The Company may not be able to add further programmes to its portfolio

The Company currently has two programmes – the interferon beta programme and a share of Pharmaxis' LOXL2 programme. Whilst it is seeking to add additional programmes, this may not be possible for a number of reasons, including failure to agree commercial terms, due diligence findings or inability to fund additional programmes if additional expenditure is required on the interferon beta programme.

## • Intellectual property risk

The commercial success of the Company 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 Company's intellectual property rights and exclude competitors with similar pharmaceutical products. The success of the Company 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 Company may not be able to license upon favourable terms, potentially inhibiting the Company's ability to develop and exploit its own business. Litigation may be necessary to protect the Company's intellectual property, which may result in substantial costs.

The Company 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.

# Strategic Report for the year ended 31 December 2018 (continued)

## Competition risk

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

### • Funding risk

The Company continues to consume cash resources. Until the Company generates positive net cash inflows from successful out-licensing transactions and commercialisation of its products, it remains dependent upon securing additional funding from its parent company Synairgen plc. The Company 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 Company's discovery and development programmes may be delayed or cancelled and the business operations curtailed.

The Company seeks to reduce this risk through tight financial control and prioritising programmes which will generate the best returns.

### • Dependence on Founders, senior management and key staff

The Founders and certain members of staff are highly skilled scientists and clinicians. The Company 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 Company seeks to reduce this risk by appropriate incentivisation of staff through participation in long term equity incentive schemes over the shares of Synairgen plc.

### Cyber attack or IT systems failure

The Company is at risk of cyber attack or IT systems failure, which would cause operational harm, including potential theft or loss of data.

The Company seeks to minimise this risk by retaining the services of external IT advisers, and pursuing suitable back up and security policies.

#### Brexit

Following the referendum vote in June 2016 the UK government started the withdrawal process from the European Union in March 2017, putting the UK on course to leave at the end of March 2019.

There is still substantial uncertainty as to what form Brexit will take. In the short term our exposure relates to whether the supply chain for consumables for the running of the Phase II clinical trial will be impacted. A review is being undertaken to determine what extra levels of stocks need to be purchased to manage any potential disruption. The trial is being conducted solely at UK sites and all drug supplies are located in the UK.

# Strategic Report for the year ended 31 December 2018 (continued)

#### Outlook

Operationally we are wholly focussed on our inhaled IFN- $\beta$  programme in COPD and engaging with potential partners for this programme in advance of Phase II data availability. We are pleased that Pharmaxis have announced completion of the three month toxicology studies which were necessary to progress partnering discussions in disease areas which are of great interest to large pharma. We continue to assess new opportunities to complement our existing COPD programme.

By order of the Board

John Ward

Company Secretary

8 March 2019

### References

- 1. Johnston NW, et al. Colds as predictors of the onset and severity of COPD exacerbations International Journal of COPD 2017:12: 839-848
- 2. (i) Aviragen Therapeutics presentation Directing Next Generation Direct-Acting Antivirals May 2017. (ii) Synairgen analysis of INEXAS trial results, dated 27 September 2017 (https://www.synairgen.com/wp-content/uploads/2018/06/ifnb-press-release-final-26-sept-002.pdf)
- 3. Wilkinson TMA, et al. A prospective, observational cohort study of the seasonal dynamics of airway pathogens in the aetiology of exacerbations in COPD *Thorax 2017;0:1-9.*Doi:10.1136/thoraxinl=2016-209023
- 4. Department of Health. An Outcomes Strategy for Chronic Obstructive Pulmonary Disease (COPD) and Asthma in England. Published July 2011
- Singh JA, et al. Utilization due to chronic obstructive pulmonary disease and its predictors: a study using the U.S. National Emergency Department Sample (NEDS). Respiratory Research 2016; 17:1

# Directors' report for the year ended 31 December 2018

The directors present their report together with the audited financial statements for Synairgen Research Limited (the 'Company') for the year ended 31 December 2018.

There are a number of items required to be included in the Directors' Report, which are covered in the Strategic Report:

- Principal activities
- Review of the business and future developments
- Key performance indicators
- Principal risks and uncertainties

## Research and development

During the year, the Company has invested £3,290,000 (2017: £2,128,000) in research and development activities and a review of this expenditure is included in the Strategic Report.

#### Results and dividends

The Company's loss for the year after taxation amounted to £3,094,000 (2017: profit of £1,965,000). The directors do not propose the payment of a dividend.

#### **Directors**

The directors who served during the year were:
Richard Marsden
Dr Phillip Monk
John Ward
Professor Stephen Holgate CBE

### 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 Company during the course of their service with the Company. This insurance has been in place during the year and on the date of this report.

#### **Political donations**

During the year, the Company made no political donations (2017: None).

#### Going concern

The directors have prepared and reviewed financial forecasts. After due consideration of these forecasts, current cash resources and the indicated financial support from Synairgen plc, the directors consider that the Company has 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 accounts have been prepared on a going concern basis.

## **Directors' responsibilities**

The directors are responsible for preparing the strategic report, the directors' 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 financial statements in accordance with United Kingdom Generally Accepted Accounting Practice (United Kingdom Accounting Standards), including FRS 101 "Reduced Disclosure Framework" ("FRS 101") 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 Company and of the profit or loss of the Company for that period.

# Directors' report for the year ended 31 December 2018 (continued)

## **Directors' responsibilities** (continued)

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 applicable UK Accounting Standards have been followed, 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 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.

#### **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** 

8 March 2019

### Independent auditor's report

# INDEPENDENT AUDITOR'S REPORT TO THE MEMBER OF SYNAIRGEN RESEARCH LIMITED

## **Opinion**

We have audited the financial statements of Synairgen Research Limited ("the Company") for the year ended 31 December 2018 which comprise the Statement of Comprehensive Income, the Statement of Changes in Equity, the Statement of Financial Position and notes to the financial statements, including a summary of significant accounting policies. The financial reporting framework that has been applied in their preparation is applicable law and United Kingdom Accounting Standards, including Financial Reporting Standard 101 Reduced Disclosure Framework (United Kingdom Generally Accepted Accounting Practice).

In our opinion, the financial statements:

- give a true and fair view of the state of the Company's affairs as at 31 December 2018 and of its loss for the year then ended;
- have been properly prepared in accordance with United Kingdom Generally Accepted Accounting Practice; and
- have been prepared in accordance with the requirements of the Companies Act 2006.

## **Basis for opinion**

We conducted our audit in accordance with International Standards on Auditing (UK) (ISAs (UK)) and applicable law. Our responsibilities under those standards are further described in the Auditor's responsibilities for the audit of the financial statements section of our report. We are independent of the Company in accordance with the ethical requirements that are relevant to our audit of the financial statements in the UK, including the FRC's Ethical Standard, and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

### Conclusions relating to going concern

We have nothing to report in respect of the following matters in relation to which the ISAs (UK) require us to report to you where:

- the Directors' use of the going concern basis of accounting in the preparation of the financial statements is not appropriate; or
- the Directors have not disclosed in the financial statements any identified material uncertainties that may cast significant doubt about the Company's ability to continue to adopt the going concern basis of accounting for a period of at least twelve months from the date when the financial statements are authorised for issue.

#### Other information

The Directors are responsible for the other information. The other information comprises the information included in the report, other than the financial statements and our auditor's report thereon. Our opinion on the financial statements does not cover the other information and, except

## **Independent auditor's report** (continued)

to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated. If we identify such material inconsistencies or apparent material misstatements, we are required to determine whether there is a material misstatement in the financial statements or a material misstatement of the other information. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact.

We have nothing to report in this regard.

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

In our opinion, based on the work undertaken in the course of the audit:

- 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; and
- the Strategic report and Directors' report have been prepared in accordance with applicable legal requirements.

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

In the light of the knowledge and understanding of the Company and its environment obtained in the course of the audit, we have not identified material misstatements in the Strategic report and Director's report.

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

- adequate accounting records have not been kept, or returns adequate for our audit have not been received from branches not visited by us; or
- the 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.

## **Responsibilities of Directors**

As explained more fully in the Directors' responsibilities statement, the Directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view, and for such internal control as the Directors determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the Directors are responsible for assessing the Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern

Independent auditor's report (continued)

and using the going concern basis of accounting unless the Directors either intend to liquidate the Company or to cease operations, or have no realistic alternative but to do so.

## Auditor's responsibilities for the audit of the financial statements

This report is made solely to the Company's member, 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 member those matters we are required to state to it 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 member as a body, for our audit work, for this report, or for the opinions we have formed.

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

A further description of our responsibilities for the audit of the financial statements is located at the Financial Reporting Council's website at:

https://www.frc.org.uk/auditorsresponsibilities. This description forms part of our auditor's report.

BDO LLP

Ian Oliver (Senior Statutory Auditor)
For and on behalf of BDO LLP, statutory auditor
Reading

8 March 2019

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

# Statement of comprehensive income for the year ended 31 December 2018

	Note	Year ended 31 December 2018 £'000	Year ended 31 December 2017 £'000
Revenue		105	5,025
Research and development expenditure Other administrative expenses		(3,290) (704)	(2,128) (1,064)
Total administrative expenses		(3,994)	(3,192)
(Loss)/Profit from operations and (loss)/profit on ordinary activities before taxation	3	(3,889)	1,833
Taxation on (loss)/profit on ordinary activities	7	795	132
(Loss)/Profit on ordinary activities after taxation and total comprehensive (loss)/income for the period	n	(3,094)	1,965

All amounts relate to continuing activities.

The notes on pages 17 to 26 form part of these financial statements.

# Statement of changes in equity for the year ended 31 December 2018

	Share capital £'000	Share premium account £'000	Share- based payment reserve £'000	Retained deficit £'000	Shareholder's funds/(deficit) £'000
At 1 January 2017 Share-based payments Profit for the year	1 -	622	1,600 113 -	(22,838) 1,965	(20,615) 113 1,965
At 31 December 2017 Share-based payments Loss for the year Capital contribution	1 - - -	622 - - -	1,713 98 - -	(20,873) - (3,094) 22,311	(18,537) 98 (3,094) 22,311
At 31 December 2018	1	622	1,811	(1,656)	778

The notes on pages 17 to 26 form part of these financial statements.

# Statement of financial position at 31 December 2018

Company number 04793696	Note	31 December 2018 £'000	31 December 2018 £'000	31 December 2017 £'000	31 December 2017 £'000
Fixed assets Intangible assets	8	29		45	
Property, plant and equipment	9	374		12	
			403		57
Current assets	10	56		56	
Inventories Current tax receivable	10	795		71	
Trade and other receivables	11	199		625	
Cash and cash equivalents		159 ————		53 ———	
Creditors: amounts falling due		1,209		805	
within one year	12	(834)		(19,399)	
Net current assets/(liabilities)			375		(18,594)
Net assets/(liabilities)			778		(18,537)
Capital and reserves					0.000 1010 0 1 1000
Share capital	14		1		1
Share premium account Share-based payment reserve			622 1,811		622 1,713
Retained deficit			(1,656)		(20,873)
Shareholder's funds/(deficit)	. ·		778		(18,537)

The financial statements were approved by the Board of Directors and authorised for issue on 8 March 2019 and signed on behalf of the board by:

John Ward

Director

The notes on pages 17 to 26 form part of these financial statements.

# Notes forming part of the financial statements for the year ended 31 December 2018

## 1 Accounting policies

## **Basis of preparation**

The financial statements have been prepared in accordance with Financial Reporting Standard 101 Reduced Disclosure Framework and the Companies Act 2006. The principal accounting policies adopted in the presentation of the financial statements are set out below. The policies have been applied consistently to all the years presented except for the adoption of IFRS 9 and IFRS 15.

The financial statements have been prepared on a historical cost basis. The presentation currency used is sterling and amounts have been presented in round thousands ("£000s").

### Adoption of new standards

IFRS 9

The Company adopted IFRS 9 Financial Instruments, which addresses the classification, measurement and derecognition of financial assets and financial liabilities, on 1 January 2018, considering the cumulative impact at this date in assessing whether an adjustment to opening reserves is required. This standard also had no financial impact on either the current or comparative periods.

#### **IFRS 15**

IFRS 15 Revenue from Contracts with Customers has replaced IAS 18, effective for accounting periods beginning on or after 1 January 2018. The Company has transitioned to the new standard through means of the cumulative effect method as at 1 January 2018 (the date of initial application). It has performed an impact assessment, taking advantage of the practical expedient not to apply IFRS 15 to any contracts that were completed contracts at that date and, instead, to continue to apply IAS 18 to those contracts. No material transitional entries were required on the adoption of IFRS 15 at its date of initial application. An explanation of the accounting treatment adopted for completed contracts in all periods presented, and in future accounting periods, is set out in the revenue accounting policy below.

The recognition policy for future revenues, which may arise from new collaboration or licensing agreements signed after 1 January 2018, will be considered under IFRS 15, when they arise.

#### 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
- disclosure of related party transactions with other wholly-owned members of the group headed by Synairgen plc.

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

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

The financial statements of Synairgen plc can be obtained as described in Note 17.

#### Judgements and key areas of estimation uncertainty

The preparation of financial statements in compliance with FRS 101 requires the use of certain critical accounting estimates. It also requires the Company's directors to exercise judgement in applying the Company's accounting policies.

Notes forming part of the financial statements for the year ended 31 December 2018 (continued)

### 1 Accounting policies (continued)

#### Going concern

The financial statements have been prepared on a going concern basis as the Company's parent undertaking has expressed a willingness to provide financial support to allow the Company to meet its liabilities as they fall due for a period of at least 12 months.

A summary of the material accounting policies which have been applied consistently throughout the period is set out below.

#### Revenue

Revenue is stated net of value added tax.

The Company's licensing and collaboration agreement with Pharmaxis in respect of the jointly developed LOXL2 inhibitors was renegotiated in December 2017. As no substantive performance obligations remained at 1 January 2018, it was treated as a completed contract on transition to IFRS 15 and the Company elected to account for the income related to it in the 2017 financial year, together with any future income resulting from the Company's share of its partner's future income from the collaboration, under IAS 18. Only the upfront receipt was recognised as revenue in 2017, as a reliable estimate of the other amounts which might be received could not be made at that time. Revenue from other amounts which may be received in future under this agreement, will be recognised when a reliable estimate can be made, which is likely to be when the partner's income has been earned and the Company's share is contractually due.

Revenue from the provision of services (which is not considered to be material in the current or prior year) is recognised over time, based on the estimated stage of completion of the contracted work.

#### 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 Company'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 Company. The Company currently has no such qualifying expenditure.

#### **Employee benefits**

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

#### Intangible fixed assets

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

Notes forming part of the financial statements for the year ended 31 December 2018 (continued)

### 1 Accounting policies (continued)

#### Financial instruments

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

#### Financial assets

The Company classifies its financial assets as financial assets held at amortised cost.

These assets arise principally from the provision of goods and services to customers (eg trade receivables), but also incorporate other types of financial assets where the objective is to hold these assets in order to collect contractual cash flows and the contractual cash flows are solely payments of principal and interest. 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.

The Company's financial assets measured at amortised cost comprise trade and other receivables, and cash and cash equivalents in the statement of financial position. Cash and cash equivalents includes cash in hand, deposits held at call with banks, other short term highly liquid investments with original maturities of three months or less.

#### Financial liabilities

The Company 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.

#### Share capital

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.

#### Leased assets

Where substantially all of the risks and rewards incidental to ownership are not transferred to the Company (an 'operating lease'), the total rentals payable under the lease are charged to the 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 Company 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.

Notes forming part of the financial statements for the year ended 31 December 2018 (continued)

### 1 Accounting policies (continued)

### **Share-based payments**

Where equity-settled share options are awarded by the parent company to employees of the Company the fair value of the options at the date of grant is charged to profit or loss over the vesting period with a corresponding entry in the share-based payment reserve. Non-market vesting conditions are taken into account by adjusting the number of equity instruments expected to vest at each reporting date so that, ultimately, the cumulative amount recognised over the vesting period is based on the number of options that eventually vest. Non-vesting conditions and market vesting conditions are factored into the fair value of the options granted. As long as all the other vesting conditions are satisfied, a charge is made irrespective of whether the market vesting conditions are satisfied. The cumulative expense is not adjusted for failure to achieve a market vesting condition.

### 2 Critical accounting estimates and judgements

The Company makes certain estimates and judgements regarding the future. Estimates and judgements are continually evaluated based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances. In the future, actual experience may differ from these estimates and assumptions. There are no critical accounting estimates and judgements.

3	Expenses by nature	2018 £'000	2017 £'000
	Staff costs (Note 6) Depreciation of tangible assets Amortisation of intangible assets Operating leases:	997 24 16	1,449 7 17
	- Land and buildings - Other	72 93	71 93
4	Auditor remuneration	2018 £'000	2017 £'000
	Fees for the audit of the Company	14	15

Fees paid to the Company's auditor, BDO LLP, for services other than the statutory audit of the Company are not disclosed in Synairgen Research Limited's accounts since the consolidated accounts of Synairgen plc are required to disclose non-audit fees on a consolidated basis.

#### 5 Directors' emoluments

No directors' emoluments were paid during the years ended 31 December 2018 and 2017.

Notes forming part of the financial statements for the year ended 31 December 2018 *(continued)* 

## 6 Employees

The average monthly number of persons employed by the Company, including executive directors, during the year was:

2018 Number	2017 Number
9	8
3	3
<del></del>	<del></del>
12	11
2018	2017
£'000	£'000
729	1,091
84	138
94	102
907	1,331
(8)	. 5
98	113
997	1,449
	Number  9 3  12  2018 £'000  729 84 94  907 (8) 98

The Company makes payments to personal defined contribution pension schemes. The pension charge to the statement of comprehensive income represents the amount payable by the Company is respect of the period.

#### 7 Tax credit

Analysis of tax credit in the period:	2018 £'000	2017 £'000
Current tax Current tax on (loss)/profit for the year Adjustment in respect of previous periods	(795) -	(71) (61)
Total tax credit	(795)	(132)

Notes forming part of the financial statements for the year ended 31 December 2018 *(continued)* 

# 7 Tax credit (continued)

The tax assessed on the (loss)/profit on ordinary activities for the period is different than the standard rate of corporation tax in the UK. The differences are explained below:

	2018 £'000	2017 £'000
(Loss)/Profit before income taxes	(3,889)	. 1,833
Expected tax credit based on the standard rate of United	4700	0.50
Kingdom corporation tax at the domestic rate of 19% (2017 – 19.25%) Effects of:	(739)	353
	(2)	
Tax relief on share option exercises Expenses not deductible for tax purposes	(2) 19	22
Fixed asset and other timing differences	(69)	22
		(452)
Research and development enhanced tax relief Movement on unutilised tax losses	(620) 369	• •
Variable rates on tax losses surrendered for research and	303	(17)
	247	23
development tax credits Adjustment for over provision in previous periods	-	(61)
Total tax credit	(795)	(132)
See note 13 in respect of deferred taxation.		
Intangible assets		Patent
· · · · · · · · · · · · · · · · · · ·		costs
		£'000
Cost		
At 1 January and 31 December 2018		212
Amortisation		407
At 1 January 2018		167
Provided for the year		16 
At 31 December 2018		183
Net book amount		
At 31 December 2018		
At 31 December 2017		45

Notes forming part of the financial statements for the year ended 31 December 2018 *(continued)* 

9	Property, plant and equipment			· · · · · · · · ·
		Computer equipment £'000	Laboratory and clinical equipment £'000	Total £'000
	Cost	2000		
	At 1 January 2018 Additions	40	138 382	178 386
	At 31 December 2018	44	520	564
	Depreciation			
	At 1 January 2018 Provided for the year	37 2	129 22	166 24
	At 31 December 2018	39	151	190
	Net book value At 31 December 2018	5	369	374
			-	( ,
	At 31 December 2017	3	9	12
10	Inventories		2018 £'000	2017 £'000
	Raw materials		56	56
	Raw materials at 31 December 2018 comprises the	- Company's Bio	Bank.	
11	Trade and other receivables			
••	Amounts receivable within one year:		2018 £'000	2017 £'000
	Trade receivables		-	292
	Other tax and social security		<b>79</b>	66
	Prepayments and accrued income	_	120	<u> 267</u>
		_	199	625
12	Creditors: amounts falling due within one year			
			2018 £'000	2017 £'000
	Trade payables		300	278 18 210
	Amounts due to parent undertakings Other tax and social security		44	18,219 94
	Accruals and deferred income		490	808
		_	834	19,399

Notes forming part of the financial statements for the year ended 31 December 2018 (continued)

13	Deferred taxation	2018	2017
	Recognised deferred taxation	£'000	£'000
	Accelerated capital allowances Other timing differences Trading losses	63 (3) (60)	1 (1)
		-	-

## Unrecognised deferred taxation

At 31 December 2018 the Company has trading losses carried forward which are available for offset against future profits of the Company amounting to £14,964,000 (31 December 2017: £12,978,000) and an unrecognised deferred tax asset in respect of these losses of £2,544,000 (31 December 2017: £2,206,000). 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 Company has a potential future tax deduction on share options of £429,000 (2017: £369,000) and a deferred tax asset of £73,000 (2017: £63,000) 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 Company 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 asse	et comprises the	following:	£'000		
	Unrecognised deferred tax asset at 1 January 2018  Movement in current year						
	Unrecognised deferred tax asset at 31 December 2018						
14	Share capital	2018 Number	2017 Number	2018 £'000	2017 £'000		
	Share capital - ordinary shares of 1p each						
	Authorised Allotted, called up and fully paid	200,000 140,000	200,000 140,000	2 1	2		
				······			

Notes forming part of the financial statements for the year ended 31 December 2018 (continued)

#### 15 Share options

Synairgen plc grants options to certain of its employees and those of the Company over its ordinary shares. The details of each scheme are included within Synairgen plc's group accounts. The fair value per award granted, and the assumptions used in the calculation for the 6,087,819 options held by the employees of the Company and the employees of Synairgen plc, whose costs are fully recharged to the Company, are as follows:

Date of grant	Type of award	Number of shares	Exercise price	Share price at date of grant	Fair value per option	Award life per option (years)	Risk free rate	Expected volatility rate	Performance conditions
7 Sept 09	(a)	705,000	1p	18.5p	7.1p	3	2.09%	30%	Market
7 Sept 09	(b)	250,000	20p	18.5p	4.0p	5	2.67%	30%	Market
28 Jun 10	(b)	212,765	23.5p	23.5p	5.6p	5	2.09%	30%	Market
8 Sept 10	(a)	471,334	1р	24.25p	12.1p	3	0.92%	40%	Market
21 Sept 11	(a)	1,626,404	· 1p	22.5p	13.4p	3	0.79%	56%	Market
5 Apr 18	(a)	2,822,316	1p	13p	7.5p	3	0.90%	56%	Market
		6,087,819							

Types of awards: (a) LTIP; (b) Qualifying Non-Employee Option Scheme ('QNEOS').

The Company has applied the principles of IFRS 2 to all share-based payments. The following comments apply to those options which have been fair valued in accordance with these principles.

- (i) Stochastic valuation methodology was used for the LTIP awards and the QNEOS awards.
- (ii) Expected dividend yield is nil, consistent with the Directors' view that Synairgen plc'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 2018 for share-based payments amounted to £98,000 (2017: £113,000).
- (vi) The performance criteria for the options awarded under the LTIP and the QNEOS are summarised in the Directors' Remuneration Report in the annual report of Synairgen plc.

The movement in the total number of share options is set out below:

	Number	2018 Weighted average exercise price	Number	2017 Weighted average exercise price
Outstanding at start of the year	4,529,237	3.1p	5,629,647	2.9p
Granted during the year	2,822,316	1.0p	-	n/a
Exercised during the year	(70,205)	1.0p	-	n/a
Lapsed during the year	(1,193,529)	1.0p	(1,100,410)	2.0p
Number of outstanding options at year-end	6,087,819	2.6p	4,529,237	3.1p

At 31 December 2018, 3,265,503 share options were capable of being exercised, with exercise prices ranging from 1p to 23.5p (2017: 3,335,708, with exercise prices ranging from 1p to 23.5p). The options outstanding at 31 December 2018 had a weighted average remaining contractual life of 5.3 years (2017: 4.2 years).

# Notes forming part of the financial statements for the year ended 31 December 2018 (continued)

#### 16 Reserves

The following describes the nature and purpose of each reserve within equity:

Reserve	Description and purpose
Share capital	Nominal value of share capital subscribed for.
Share premium account	Amount subscribed for share capital in excess of nominal value less the related costs of share issues.
Share-based payment reserve	Cumulative recognised share-based payments.
Retained deficit	Cumulative net gains and losses recorded in the statement of comprehensive income plus capital contributions.

### 17 Parent company and ultimate parent undertaking

The parent company and ultimate parent undertaking of the Company is Synairgen plc, which is incorporated in England and Wales. The financial statements of the Company are consolidated within Synairgen plc's group accounts. A copy of these accounts may be obtained from: The Company Secretary, Synairgen plc, Mailpoint 810, Southampton General Hospital, Tremona Road, Southampton, SO16 6YD.

## 18 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:

Not later than one year	2018 £000	2017 £000
Land and buildings	18	18
Other	23	23
	41	41