Annual Report
and Accounts
2020

a deeper
understanding
of respiratory
biology

synairgen plc

Stock symbol: LSE:SNG
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Contents

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Highlights

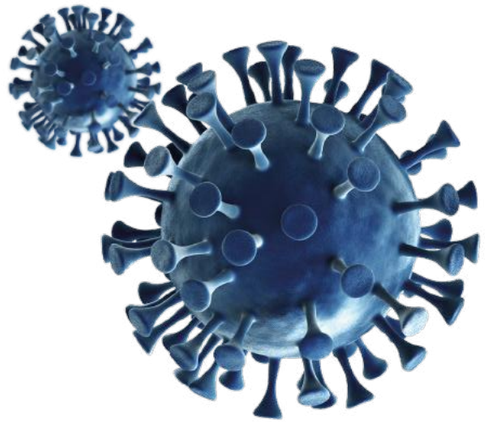
(including post period-end)

Operational highlights

- Positive results from Synairgen's Phase II trial (SG016) of inhaled interferon beta-1a (SNG001) in 101 hospitalised COVID-19 patients reported in July 2020
  - Further analyses announced in September 2020 and trial data published in The Lancet Respiratory Medicine in November 2020
- SG016 trial expanded to include a further 120 COVID-19 patients in the home environment
  - Analysis of combined data from Hospital and Home Cohorts in April 2021 showed that patients with significant breathlessness are three times more likely to recover to "no limitation of activities" on the OSCI scale when receiving SNG001 compared to placebo (p=0.004)
- SNG001 awarded Fast Track designation with IND cleared by the US FDA in December 2020
- International Phase III trial (SG018) of SNG001 in hospitalised COVID-19 patients initiated in December 2020
  - First patient dosed in January 2021, initial trial results expected in H2 2021
- SNG001 included in US NIH government-funded ACTIV-2 Phase II/III trial in COVID-19 outpatients in January 2021 and commenced patient dosing in February 2021
  - Phase II evaluation will see the recruitment of up to 220 participants
- Investment in supply chain activities for SNG001 and the Aerogen aerosol delivery system have been made in preparation for launch
- Agreements signed with Akron Biotechnology for drug substance manufacture and Catalent Biologics for fill/finish
- Positive data from interim analysis of SNG001 trial in COPD patients supporting future progression of SNG001 for exacerbating COPD patients
- Patent applications made for use of inhaled interferon beta-1a to treat:
  - COVID-19 patients
  - Virus-induced exacerbations of COPD patients undergoing treatment with systemic corticosteroids

Financial highlights

- In October 2020, Synairgen raised £87.1 million (before expenses) in an equity issue to fund SG018 Phase III trial, SNG001 manufacturing, regulatory activities, and to strengthen balance sheet
- In March 2020, Synairgen raised £14.0 million (before expenses) in an equity issue to fund initial COVID-19 clinical trial activity
- The loss from operations for the year ended 31 December 2020 was £17.7 million (2019: £4.8 million), with research and development expenditure amounting to £15.5 million (2019: £3.5 million)
  - £12.0 million year-on-year increase on research and development expenditure attributable to COVID-19 activities
- Cash balances of £75.0 million at 31 December 2020 (31 December 2019: £2.5 million)



Chairman's Statement

Synairgen has made significant progress during 2020, from being one of the first movers in the UK to begin clinical trials to combat COVID-19, to ending the year with compelling clinical data and late-stage clinical trials underway both in the UK and internationally to investigate our inhaled interferon beta candidate (SNG001) in patients with COVID-19. The year has been unprecedented globally for all sectors, and the healthcare industry, and in particular biotechnology, has played a central role. Synairgen's expanded team and speed to action has enabled the Company to make significant strides in the fight against COVID-19. Synairgen has a potential role to play in the provision of a life-saving treatment against COVID-19 and other viruses, and in situations where the various vaccines may not prove effective or suitable.

In July 2020, we received landmark positive results in the Phase II study SG016 in hospitalised COVID-19 patients. This paved the way for our follow-on trial in the home setting and, ultimately, our larger multinational Phase III study SG018, which has been approved to commence by regulators in 12 countries. The importance of progress being made in trials of COVID-19 treatments cannot be understated. While vaccination efforts are crucial to defeating the pandemic, we also need therapeutics to save lives and to help those who become infected despite vaccination. Based on the compelling data published in November 2020 in the Lancet Respiratory Medicine journal supported by evidence from the recently announced home-based trial results, we believe Synairgen's inhaled interferon beta candidate could play a critical role in addressing the impact of COVID-19 and similar viruses by reducing the severity of the disease and accelerating patient recovery.

The inclusion of SNG001 in the US government-funded ACTIV-2 trial is a further indication of international interest in our inhaled interferon beta treatment. Unlike many other treatments, inhaled interferon beta, as a drug taken through a nebuliser, can be self-administered at home under virtual supervision, making it a key part of reducing strain on healthcare systems, both through preventing severe disease and through lowering the number of necessary hospital visits for patients suffering respiratory symptoms.

These successes reflect the scientific research supporting the role of interferons in orchestrating antiviral responses undertaken by our scientific founders, Prof. Donna Davies, Prof. Ratko Djukanovic, and Prof. Sir Stephen Holgate, who continue to play an active role in Synairgen. 2021 is set to be an even more impactful year for Synairgen pending the clinical results from our late-stage trials evaluating SNG001. We are optimistic about the potential for inhaled interferon beta as a potentially effective treatment for COVID-19 and future viral outbreaks.

It has been a very challenging year for Synairgen's staff, combining the significant additional workload of our COVID-19 programmes and an escalation of our manufacturing and commercialisation strategies with the logistical limitations of lockdown and travel restrictions. On behalf of the Board, I wholeheartedly thank our staff and outsourced contractors for their hard work, perseverance and resilience.

Thanks to the support of our shareholders, Synairgen is in a robust financial position following two oversubscribed fundraises during the year. We continue to scale up operations and prepare for commercialisation of the product and look forward to reporting further progress in the coming months.

Simon Shaw
Chairman
11 May 2021

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Strategic Report

The directors present their Strategic Report for the year ended 31 December 2020.

Principal Activities and Strategy

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

Synairgen is developing a broad-spectrum inhaled antiviral for the treatment of severe viral lung infections and is currently conducting a Phase III clinical trial for COVID-19. Launch preparations are underway, which may involve licensing or partnership. A glossary on pages 58 to 61 provides additional explanation of some of the more detailed scientific and clinical terminology.

Operating Review

Summary

2020 was an unprecedented year for Synairgen. We were able to respond rapidly to the COVID-19 crisis and continue on our mission to bring our inhaled interferon beta-1a drug product to patients for the treatment of COVID-19.

SNG001 has potential value in three settings:

1. The near term business objective is to gain registrations as soon as possible to treat patients with COVID-19:
   (i) in the hospital setting, to prevent further deterioration and death, and to accelerate discharge from hospital and rate of recovery;
   (ii) in non-hospitalised patients with significant breathlessness, to prevent hospitalisation and accelerate recovery; and
   (iii) to reduce the number of patients who develop Long COVID
2. The medium term business objective is to work with governments to prepare for the next pandemic. The SARS-CoV-2 pandemic has demonstrated the value of being prepared. Providing SNG001 trials continue to produce positive data, SNG001, as a broad-spectrum antiviral, could be stockpiled for future pandemics. It can be stored in concentrated form in freezers for over six years, and in ready to use format for three years.
3. The long term business model envisages applying SNG001's broad-spectrum antiviral activity to treat patients hospitalised on account of a severe viral lung infection. Chest infections are the fifth largest cause of death globally[1] and approximately half of chest infections have a viral component.[2]

Progress in 2020

During the year Synairgen made significant clinical progress with its inhaled formulation of interferon beta, SNG001. Results from the SG016 Phase II trial of SNG001 in 101 hospitalised COVID-19 patients support its use as a valuable treatment option to prevent development of severe disease and to expedite patient recovery. Further safety, efficacy and other supporting data were provided from the interim analysis of Synairgen's SG015 Phase II COPD trial in September 2020. Expansion of the SG016 trial to include an additional 120 patients treated in the home environment was completed post period-end in January 2021, with analysis of the combined data from the Hospital and Home Cohorts announced in April 2021 showing that the more breathless patients are significantly more likely to recover to "no limitation of activities" on SNG001 than placebo.

Based on the positive outcome of these Phase II results, SNG001 is being trialled in COVID-19 patients around the world. Synairgen has initiated an international Phase III trial (SG018), which will involve a total of 610 hospitalised COVID-19 patients who require supplemental oxygen. Our inhaled interferon beta has also been included in the US government-funded ACTIV-2 Phase II/III trial in COVID-19 outpatients. Dosing began in both trials post period-end in Q1 2021.

The Company is currently focused on progressing these trials to produce the data for accelerated regulatory approvals of SNG001 as a COVID-19 treatment. We are also working on the supply chain in preparation for launch.

COVID-19

COVID-19, caused by the SARS-CoV-2 virus, is a global pandemic and there has been, and continues to be, an urgent need to assess new treatments to prevent and effectively treat the severe lower respiratory tract illness that can occur with this disease. Older people and those with co-morbidities such as obesity, heart and lung complications or diabetes are at greatest risk of developing severe or fatal disease.

The SARS-CoV-2 knowledge base is continually expanding with respect to transmissibility and pathogenicity of the virus and its variants, and the effectiveness of the interventions, which include social distancing, vaccines and therapeutics. The need for a therapeutic persists to cover the possibility that vaccine effectiveness wanes, or that vaccine rollout and uptake is sub-optimal.

Rationale for the use of inhaled interferon beta to treat COVID-19

Interferon beta ('IFN-beta') is a naturally-occurring protein, orchestrating the body's antiviral responses. There is growing evidence that deficiency in IFN-beta production by the lung could explain the enhanced susceptibility in 'at-risk' patient groups to developing severe lower respiratory tract (lung) disease during respiratory viral infections. Furthermore, viruses, including coronaviruses such as SARS-CoV-2, have evolved mechanisms to suppress endogenous IFN-beta production, helping the virus to evade the innate immune system. The addition of exogenous IFN-beta before or during viral infection of lung cells *in vitro* either prevents or greatly reduces viral replication. The Company is currently conducting further *in vitro* testing of SNG001 against two SARS-CoV-2 variants. Synairgen's SNG001 is a formulation containing the fully glycosylated form of IFN-beta (IFN-beta-1a) for direct delivery to the lungs via specific nebulisers. It is near to pH neutral, and is free of mannitol, arginine and human serum albumin, which may be pharmacologically active in the airways, making it suitable for inhaled delivery direct to the site of infection, where the aim is to halt progression of disease, reduce duration of stay in hospital and prevent further deterioration and death.

The inhaled route of delivery is necessary if levels of IFN-beta are to be attained in the lungs at the concentration needed to drive antiviral activity. We believe these concentrations could not be accomplished at the lining of the lungs via the injected route.

COVID-19 Phase II trial – SG016

Synairgen's Phase II clinical trial in COVID-19 patients, SG016, was a double-blind, placebo-controlled trial. The two cohort 221 patient trial comprised 101 patients randomised in the hospital setting (initial results reported 20 July with further analyses announced in September 2020), and a further 120 patients randomised in the home setting (trial recruitment completed, with initial data announced in April 2021).

SG016: Hospital Cohort

Synairgen's Phase II trial of SNG001 in hospitalised COVID-19 patients was conducted across nine NHS trusts in the UK and was adopted by the NIHR Respiratory Translational Research Collaboration, who gave it Urgent Public Health status.

The design of this trial, which began dosing patients in March 2020, was based on the recommendations contained within the World Health Organization (WHO) R&D Blueprint Novel Coronavirus COVID-19 Therapeutic Trial Synopsis issued in February 2020.

On 20 July 2020, the Company announced positive top-line results from the trial with further analyses announced in September 2020. The primary endpoint was the change in condition assessed using the WHO Ordinal Scale for Clinical Improvement (OSCI) during the dosing period.

In November, these results were published in the peer-reviewed Lancet Respiratory Medicine journal. The full title of the publication is: *"Safety and efficacy of inhaled nebulised interferon beta-1a (SNG001) for treatment of SARS-CoV-2 infection: a randomised, double-blind, placebo-controlled, phase 2 trial"*.

Key findings included:

- The odds of improvement across the entire OSCI scale were more than two-fold greater in the SNG001 group than the placebo group at the end of the treatment period in both the ITT (Intention-To-Treat) population (OR 2.32; p=0.033) and the PP (Per Protocol) population (OR 2.80; p=0.017).
- There was a trend towards reduced odds of progression to severe disease (requiring non-invasive ventilation, high-flow oxygen, intubation and mechanical ventilation) or death in the ITT population (72% reduction; p=0.064) that became significant in the PP population (82% reduction; p=0.041).
- Patients who received SNG001 were more than twice as likely to recover (defined as "no limitation of activities" or "no clinical or virological evidence of infection") over the course of the treatment period compared to those receiving placebo in both the ITT population (HR 2.19; p=0.043) and the PP population (HR 2.29; p=0.033).
- Over the treatment period, patient-reported Breathlessness Cough and Sputum Scale (BCSS) and in particular breathlessness scores were markedly reduced in patients who received SNG001 compared to those receiving placebo (p=0.026 for BCSS and p=0.007 for breathlessness).
- Three subjects (6%) died after being randomised to placebo. There were no deaths among subjects treated with SNG001.

Other findings included:

- The median duration of COVID-19 symptoms at the point dosing commenced was 10 days. This goes against conventional wisdom with IFN-beta usage, where efficacy is expected based on early use. If treatment is administered to hospitalised patients after 10 days of illness, then this is late in terms of time (because the patient has been ill for 10 days) and late in terms of illness severity.
- Odds ratios for improvement, recovery and hospital discharge were in favour of SNG001 at day 28 suggesting that the treatment effect extends beyond the end of the dosing period. A treatment that accelerates full recovery may be especially relevant to patients with COVID-19 who experience wide-ranging long-term symptoms for at least a month and sometimes longer (known as Long COVID or Long-haul COVID).
- SNG001 was well tolerated.

SG016: Home Cohort

In April 2020, Synairgen received approvals to extend the SG016 trial into the home environment, with the objective of initiating dosing earlier in the infection cycle of COVID-19 to prevent severe lower respiratory tract symptoms. The trial recruited patients who were either aged over 65, or over 50 with a high-risk comorbidity. Patients must have had symptoms for less than eight days. The trial was fully recruited in January 2021.

The Home Cohort trial involved SNG001 (or placebo) being delivered to eligible participants by couriers observing appropriate social distancing measures. In order to minimise risks to patients and healthcare workers in this setting, all visits were conducted remotely by video link. If positive for SARS-CoV-2, the drug (placebo or SNG001), aerosol delivery device, and other trial equipment were despatched to the patient. Each dose was taken under video supervision. Safety and efficacy endpoints were also assessed during the video calls.

The study confirmed the feasibility of rapid roll-out of antiviral treatment in the context of a pandemic, where there is a need to limit the movement of people to minimise risks to patients, the public and healthcare providers.

The top-line results from the Home Cohort and combined data for the whole SG016 trial were announced in April 2021 and the key findings were:

- The vast majority of Home Cohort patients experienced mild disease – only two patients were hospitalised due to worsening of COVID-19 during the treatment period, both on placebo.
- Home Cohort patients successfully self-administered SNG001.
- Encouraging pattern of recovery and reduction in breathlessness in SNG001-treated patients compared to placebo in those with marked or severe breathlessness at the start of treatment.
- A combined analysis of the Hospital and Home Cohorts data was conducted to explore the impact of the different levels of breathlessness, which is one of the most prominent symptoms of COVID-19, on time to recovery.
- An assessment of only those patients on placebo indicated that those with marked or severe breathlessness at time of treatment initiation had slower recovery to "no limitation of activities" than those patients who were not as breathless. This is a strong indicator of those patients who should be selected for treatment with SNG001.
- In the Hospital Cohort (reported in July 2020) patients were 2.19 times more likely to recover to level 1 on the Ordinal Scale compared to placebo, HR 2.19; p=0.043. The addition of the 12 markedly and severely breathless Home Cohort patients further improves the Hazard Ratio to 2.49; p=0.009.
- Interestingly, not all hospitalised patients were markedly or severely breathless at time of treatment initiation. An analysis including only patients who were markedly or severely breathless at the time of treatment initiation, irrespective of whether they were in hospital or at home, showed that those treated with SNG001 (n=33) were 3.41 times more likely to recover than those on placebo (n=36) (HR 3.41; p=0.004). This further underlines the potential benefit of SNG001 for patients identified as breathless.

The data from the Home Cohort and the combined data analysis showing the potential importance of breathlessness as a stratification tool to identify patients most likely to benefit from SNG001 is invaluable. We now know better who not to treat and who to treat. Fortunately, when we designed the Phase III clinical trial, we selected patients most likely to be breathless and these data make us feel more confident of a positive outcome.

COVID-19 Phase III trial – SG018

Synairgen's global Phase III "SPRINTER" clinical trial in hospitalised COVID-19 patients, SG018, is a randomised, placebo-controlled study being conducted in 17 countries enrolling a total of 610 COVID-19 patients who require supplemental oxygen (i.e. they are by definition more likely to have marked or severe breathlessness). After reporting the results for the primary and secondary endpoints of the study, enrolled patients will continue to be assessed for Long COVID symptoms.

In October 2020, Synairgen appointed Parexel Biotech, a division of the leading global clinical research organisation, Parexel, to help conduct the Phase III trial. The trial is deemed an Urgent Public Health study by the UK's National Institute for Health Research (NIHR). In the US, SNG001 has been granted Fast Track status from the US Food and Drug Administration (FDA).

There are two primary endpoints: 'time to recovery to "no limitation of activities" up to Day 28'; and 'time to hospital discharge'. In addition, there are secondary endpoints relating to changes in OSCI score and symptoms, especially breathlessness, and Long COVID. There will also be a safety assessment.

First patient dosing commenced in the UK in January 2021, where the regulators were familiar with SNG001. The trial is now approved by regulators in 11 additional countries, with further approvals expected in five more countries in the coming weeks. Initial trial results are expected in H2 2021.

US NIH ACTIV-2 trial

In January 2021, Synairgen announced signature of a clinical trial agreement to include SNG001 in the ACTIV-2/A5401 Phase II/III trial in patients with COVID-19 not yet requiring hospitalisation. This is a government-funded trial sponsored by the US National Institute of Allergy and Infectious Diseases (NIAID), part of the US National Institutes of Health (NIH). NIH's ACTIV (Accelerating COVID-19 Therapeutic Inventions and Vaccines) is a public-private partnership to develop a coordinated research strategy to speed up the development of the most promising treatments and vaccine candidates for COVID-19. ACTIV-2 is a master protocol designed for evaluating multiple investigational agents compared to placebo in adults with mild-to-moderate COVID-19, not requiring hospitalisation.

The Phase II/III study is an adaptive, randomised, blinded, placebo-controlled trial which commenced patient dosing in February 2021. The Phase II evaluation of inhaled interferon beta will see the recruitment of up to a maximum of 220 participants across US sites in home-based settings. A positive result enables progression into the Phase III stage of the study.

As in the case with the Home Cohort of Synairgen's Phase II study, the inclusion in another home-based trial reflects the ease of use that inhaled treatments offer, making it possible for patients to self-administer treatment at home with professional supervision, reducing the risk of virus transmission during hospital visits and reducing pressure on healthcare systems. At-home treatments also have the potential to be taken earlier in the course of the illness, preventing the progression of the virus in the lower respiratory tract and the concomitant risk of hospitalisation, which could be of very significant benefit if hospitals are overstretched.

Manufacturing and Delivery of SNG001

In preparation for gaining approval for inhaled interferon beta, the Company announced deals in October with Akron Biotechnology and Catalent Biologics.

Akron Biotechnology is manufacturing inhaled interferon beta drug substance to meet clinical and commercial demand.

Catalent Biologics is a leading global provider of advanced development and manufacturing solutions for drugs and biologics, and is supporting the inhaled interferon beta fill/finish at its Brussels, Belgium facility, where it is conducting manufacturing scale-up of the drug candidate into pre-filled syringes. The Company is also evaluating blow fill seal technology as an alternative to glass syringes.

Synairgen is collaborating with Aerogen, a leader in high-performance aerosol drug delivery in the acute care setting. Aerogen is providing the Aerogen Solo/Ultra aerosol delivery system, which is already widely used in hospitals in the EU and US, for delivery of SNG001 directly into the lungs of patients.

Managed Access Program

In September 2020, Synairgen put in place a Managed Access Program facility with Clinigen to enable physicians in the UK and EU to access SNG001 for hospitalised patients.

Chronic Obstructive Pulmonary Disease (COPD)

COPD is a progressive lung disease, punctuated by periods of exacerbation characterised by acute worsening of symptoms which require treatment with oral corticosteroids and/or antibiotics, which have major implications for both the patient and the healthcare system. Worldwide, COPD affects approximately 384 million people[3] and is the third leading cause of death according to the World Health Organisation.[4] COPD exacerbations are the second most common cause of unplanned hospitalisation in England.[5]

COPD trial – SG015

In 2018, Synairgen commenced a two-part COPD trial (SG015) to assess the safety and lung antiviral biomarker and efficacy responses to SNG001 in the absence of viral infection. In the first part of the trial, SNG001 was well tolerated in patients with moderate to severe COPD. We also observed a strong antiviral biomarker signal, which was comparable to the response previously observed in asthma. This paved the way to proceed into the second part of the trial, which was designed to dose 120 patients with confirmed, naturally-occurring, respiratory virus infections and in addition to look at lung function. Recruitment into the trial commenced in earnest in January 2019 and was progressing well until the emergence of COVID-19.

Impact of COVID-19 on SG015 programme

COVID-19 made it difficult to dose COPD patients in trial units without potentially exposing vulnerable patients and research staff to SARS-CoV-2. Hence in March 2020 the trial was paused (now stopped), with 109 out of the targeted 120 patients recruited. MHRA approval was then received to run an interim analysis on the grounds that the data from COPD patients with confirmed viral infection could generate useful safety, biomarker and efficacy data to support ongoing trials of SNG001 in COVID-19 patients.

Results of interim analysis of SG015 trial in COPD patients

On 8 September 2020, Synairgen announced a positive interim analysis of SNG001 in COPD patients, supporting progression of SNG001 in COVID-19. Key findings included:

- SNG001 was well tolerated during the treatment period in a study population that was elderly (mean age 66 years) and suffering from reduced respiratory function, as measured by forced expiratory volume in one second (FEV1) (59% of predicted value).
- The percentage of on-treatment adverse events was similar in the placebo and SNG001 treatment groups (48.1% versus 45.6%, respectively), with treatment-related adverse events being more frequent in the placebo group (25%) compared to the SNG001 group (15.8%).
- Over the treatment period, lung antiviral responses to viral infection were significantly enhanced in patients receiving SNG001 compared to those on placebo, as assessed by measuring increases in the gene expression of interferon beta-dependent antiviral biomarkers MX1 (p=<0.001) and OAS1 (p=<0.001) in lung (sputum) cells.
- The impact of viral infection on COPD patients in the trial was most evident on peak expiratory flow rate (PEFR), a measure of lung function, and patient-reported symptoms assessed using the Breathlessness Cough and Sputum Score (BCSS), and was particularly apparent in exacerbating patients (i.e. patients already requiring treatment with oral corticosteroids and/or antibiotics at the time of randomisation, who represented one third of patients enrolled).
- Exacerbating patients who received SNG001 had significantly better lung function during the treatment period (difference in change from baseline morning PEFR between patients receiving SNG001 and placebo over days 2-15 was 25.5L/min; p=0.041).
- Although there was no significant difference in total BCSS in this group over the treatment period, there was a trend for the breathlessness component of the score in exacerbating patients, suggesting that these patients may have recovered more rapidly if they received SNG001 rather than placebo.
- Viral infections had less impact on non-exacerbating patients and there were no significant treatment effects.

The trial data is supportive of not only the near term COVID-19 development activity, but also the longer term aim to use SNG001 to treat patients admitted to hospital with severe viral lung infections. COPD patients represent one of the largest groups of patients in this setting.

LOXL2

Pharmaxis, the Company's Australian-based partner for the antifibrotic LOXL2 inhibitor programme, updated the market post period-end on 30 April 2021[6] to state it is currently pursuing a number of different options to enable PXS-5382 to enter the clinic in Phase II trials in a chronic kidney disease. Pharmaxis also states that it continues to have discussions with potential partners and independent investigators in relation to study protocol design and funding options including grants. In the event of a qualifying licensing agreement or other commercialisation of the product, Synairgen is entitled to receive circa 17% of Pharmaxis' licence receipts/royalties, net of allowable expenses and we have no ongoing financial obligations to the programme.

Intellectual Property

Patent filings

Adding to the Company's IP portfolio, patent applications were filed following (i) the results from the study for the use of inhaled IFN-beta in COVID-19 patients and (ii) the interim analysis of the data from the trial that used inhaled IFN-beta to treat virus-induced exacerbations in COPD patients undergoing treatment with systemic corticosteroids. Further updates regarding pending patents will be provided in due course.

Addition to the management team

Richard Hennings joined Synairgen as Chief Commercial Officer in March 2021. Between 1999 and 2017 he held Commercial leadership roles at Gilead Sciences, Novartis and AstraZeneca. During his eight-year Gilead tenure, Richard led the expansion of respiratory and anti-viral portfolios in the EU and US markets, launching inhaled Cayston® for Cystic Fibrosis and HIV treatment Stribild®. During his subsequent AstraZeneca assignment, Richard led Antibiotic Zavicefta® EU/ LATAM launch readiness and divestment of the antibiotics business unit to Pfizer. Between 2017 and 2020 Richard was VP & Commercial Head of Verona Pharma.

Key Performance Indicators (KPIs)

The Board considers that the most important KPIs are non-financial and relate to the progress of the clinical programmes and the scale up of SNG001 manufacturing, which are discussed in the preceding sections of this report.

The most important financial KPIs are the planned expenditure on COVID-19 related clinical trials and manufacturing scale-up and the cash position of the Group. The actual expenditure on the COVID-19 activities was below budget and the closing cash position was ahead of budget. These are further described in the financial review below.

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 37 to 52. The consolidated financial statements are prepared in accordance with international accounting standards in conformity with the requirements of the Companies Act 2006.

The financial statements of the Company, set out on pages 53 to 57, 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 2020 was £17.74 million (2019: £4.82 million) with research and development expenditure amounting to £15.50 million (2019: £3.46 million) and other administrative expenses £2.25 million (2019: £1.36 million).

During 2019 our research and development activities were solely focussed on the Phase II trial in COPD patients. During 2020 we continued to work on the COPD trial until it was halted on account of COVID-19. However, the majority of the £12.0 million year-on-year increase in research and development expenditure is attributable to our COVID-19 clinical trials and manufacturing scale-up activities.

Clinical trial expenditure was initially focussed on the SG016 hospital and home Phase II trial activities. This was followed by preparatory activities for the international SG018 Phase III trial in hospitalised patients and finally for participation in the ACTIV-2 study, where we have provided study product for the trial. The clinical trial preparatory and execution activities necessitated a very significant scale up of our clinical trial infrastructure and this resulted in a much greater use of outsourced experts.

Significant investment was made into manufacturing scale-up. Two batches of active and placebo pre-filled syringes were manufactured to meet clinical trial requirements. Process Performance Qualification (PPQ) preparation activities (in advance of commercialisation) were commenced at both a new drug substance manufacturer and at a new drug product manufacturer, with the latter involving both pre-filled syringes and blow-fill-seal ampoules. The Company's advisory base in both regulatory and CMC activities was also significantly expanded.

Other administrative expenses increased from £1.36 million to £2.25 million. The increase was attributable to higher personnel costs, as we scaled up to handle greater volumes of transactions, higher investor relations activity costs, and the costs of hedging an element of our future foreign exchange exposures on manufacturing costs denominated in US dollars and Euros.

Despite the significant increases in cash on hand after the two fundraisings during the year, finance income reduced on account of the reduction in interest rates during the period. Finance expense relates to interest expense on lease liabilities and the increase reflects the first full year of interest expense, due to the lease signed in mid-2019 being the first to be accounted under IFRS 16.

The research and development tax credit increased from £0.91 million to £3.82 million on account of the increased qualifying expenditure. The credit equates to 25% of our 2020 research and development expenditure (2019: 26%).

The loss after tax for 2020 was £13.92 million (2019: £3.89 million) and the basic loss per share was 9.46p (2019: basic loss per share of 3.55p).

Fundraisings

During 2020, two fundraisings were conducted to fund our ongoing COVID-19 clinical and manufacturing activities.

The first of these, conducted in March 2020, raised £14 million (before expenses) by the issue of 40 million ordinary shares at a price of 35p per share to fund: COVID-19 clinical trial activity; manufacturing of SNG001 drug product and other supply chain considerations; and strengthen the balance sheet.

The second fundraising took place in October 2020 and raised £87.07 million (before expenses) by the issue of 49.75 million ordinary shares at a price of 175p per share. 45.71 million shares were issued pursuant to an institutional placing and 4.04 million shares on account of a fully subscribed Open Offer. The proceeds were raised to fund: the Phase III trial in COVID-19 patients; SNG001 manufacturing and device scale-up activities; the generation of further data to support SNG001 clinical development, manufacturing processes and regulatory activities; strengthening the balance sheet; and the net settlement of option costs.

Statement of Changes in Equity

In addition to the net proceeds from the share issues, the recognition of share-based payments and the loss after taxation, a charge of £1.29 million was taken to reserves in respect of net settled options for the year ended 31 December 2020 (2019: £nil). At the time of the second fundraising, two of the executive directors exercised options over some 1,176,334 ordinary shares. The Company net settled by paying the income tax and NICs on the option holders' behalf and issuing 534,172 new ordinary shares. The cost of the income tax and NICs paid by the Company amounted to £1.29 million and, in accordance with IFRS 2, was charged directly to reserves as it equated to the fair value of the number of shares withheld by the Company.

Statement of Financial Position and Cash Flows

At 31 December 2020, net assets amounted to £85.14 million (2019: £2.25 million), including cash balances of £74.98 million (2019: £2.45 million).

The principal elements of the £72.53 million increase during the year ended 31 December 2020 (2019: £2.88 million decrease) in cash balances were:

- Cash used in operations: £24.73 million (2019: £3.73 million);
- Research and development tax credits received: £0.91 million (2019: £0.84 million);
- Share issue proceeds (net of costs): £97.89 million (2019: £nil);
- Net settlement of options £1.29 million (2019: £nil); and
- Lease payments: £0.21 million (2019: £nil).

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

- Current tax receivable increased from £0.87 million to £3.77 million on account of the higher research and development tax credit;
- Trade and other receivables increased from £0.14 million to £9.37 million. Prepayments and accrued income increased from £0.10 million to £8.82 million on account of manufacturing and clinical trial prepayments. VAT recoverable increased from £0.04 million to £0.55 million on account of higher transactional values; and
- Trade and other payables increased from £1.49 million to £3.28 million, reflecting the increased level of activity.

Section 172 statement

In accordance with section 172(1) ((a) through (f)) of the Companies Act 2006, the directors have acted, both individually and collectively, in a way that would be most likely to promote the success of the Company for the benefit of its members as a whole. The directors have regard (amongst other matters) to the:

a) likely consequences of any decision in the long-term;

b) interests of the Company's employees;

c) need to foster the Company's business relationships with suppliers, customers and others;

d) impact of the Company's operations on the community and the environment;

e) desirability of the Company maintaining a reputation for high standards of business conduct; and

f) need to act fairly between members of the Company.

The following table, in combination with the Corporate Governance Statement set out on pages 19 to 22 and the Company's website (www.synairgen.com), sets out the framework of our engagement with key stakeholder groups.

Our stakeholders	Material topics	How we engage
Investors The Group continues to consume cash resources and remains dependent upon securing funding through share issues. It is therefore critical that we have shareholders who will continue to invest in the Company over the longer term.	• Business strategy • Operational performance • Financial performance and cash requirements • Corporate Governance	• RNS announcements • Website updates • Meetings after preliminary statement release and interims for institutional investors • AGM • Proactive investor interview
Employees Synairgen has 22 employees (including executive directors) who are multi-skilled and many of them have worked for the Group for many years. They all play a key role in the business and it is vital that they all understand and support the key decisions taken in the running of the business.	• Operational targets and progress • Opportunities to share ideas • Financial resources of the Group • Share price • Working time flexibility	• Regular full company meetings and a policy of open disclosure • Team meetings • Open door policy to executive directors • Structured appraisal process • Use of share-based incentives for employees
University of Southampton Synairgen is a spin-out company from the University and still maintains many links with it, which benefit both parties. The University is Synairgen's landlord and certain intellectual property is licensed from it.	• Operating facilities • Intellectual property • Joint projects • Published papers	• Meetings with Founders • Interaction on projects with scientists and clinicians
Suppliers We have a number of key long-term suppliers who play an important part in our development programmes and it is important that we understand their product/service development plans and they understand our needs.	• Supplier product development plans • Our clinical trial and longer-term development needs	• Regular project meetings
Customers (licensees) Our customers are the large pharmaceutical and biotech companies who have the resources and infrastructure to take our products to market. It is therefore critical that we continue to interact with these companies at an early stage to make sure we are developing a product which they may wish to license.	• Programme development plans, including clinical trial designs • Clinical trial read-outs • In-house and external competing products	• Regular meetings at key respiratory conferences (ATS, ERS)
Community We aim to develop therapeutics which pharmaceutical companies can sell to the community and which governments will buy for stockpiling and it is therefore critical that there is an identified market need in the community.	• New therapeutics development • Involvement in clinical trials	• Interactions with clinicians • Patient data from clinical trials
Regulators We work in a highly regulated sector and it is critical that we maintain full compliance with all appropriate regulations.	• Clinical trial approvals • Regulatory compliance	• Use of external consultants to make sure we are complying with regulations • Interactions with Ethics Committees, MHRA, FDA, EMA and other regulatory agencies

Principal decisions in 2020

We have considered the decisions taken by the Board which will have an impact on the longer-term performance and prospects for the Company. The Board believes that five key decisions taken during the year fall into this category and were made with full consideration of both internal and external stakeholders.

- The decision to undertake the SG016 clinical trial in hospitalised and home-based COVID-19 patients and raise £14 million (before expenses).
- The decision to raise £87 million (before expenses) to undertake a Phase III trial in hospitalised COVID-19 patients and to scale up manufacturing capacity.
- The decision to source a new drug substance manufacturer for SNG001 and to scale up manufacture of drug substance and drug product prior to any marketing authorisation being received.
- The decision in respect of primary and secondary endpoints to be measured in the Phase III clinical trial.
- The decision to proceed with a twin track strategy of progressing both pre-filled glass syringe and blow fill seal technologies for the 'Fill and Finish' element of drug product manufacturing.

Principal risks and uncertainties

In addition to the fact that the Group has one lead candidate (SNG001), albeit with a number of indications, and is therefore dependent on there being a successful outcome to its development, the Board considers that the principal risks and uncertainties facing the Group may be summarised as follows:

- *Pre-clinical testing and/or clinical trials fail to generate positive data*

  There is a high failure rate in the development of pharmaceuticals and there is a substantial risk of adverse, undesirable, unintended or inconclusive results from pre-clinical testing or clinical trials, which may substantially delay, halt entirely or make uneconomic any further development of SNG001 (whether in the indication of COVID-19 or in others) and may prevent or limit its commercial use.

- *Clinical trials overrun*

  There are a number of factors which may lead to delays, including but not limited to: (i) delays to regulatory approvals; (ii) variations in labelling and other regulatory requirements between countries; (iii) dealing with protocol changes; (iv) difficulty in finding suitable sites and patients; and (v) incidence of COVID-19 declining or resolving.

  If any of the above circumstances or events occur, then delays may impact the Phase III timetable, which in turn may also have cost and/or ultimately commercial implications.

  To mitigate this risk, the Group monitors the prevalence of COVID-19 on a country-by-country basis and has regular meetings with its outsourced Clinical Research Organisation (CRO) to expedite the set up and execution of the trial on a local level.

- *The regulatory approval processes of the MHRA, EMA, FDA and other comparable regulatory agencies may be lengthy, time-consuming and unpredictable*

  The Group's future success is dependent upon its ability to develop successfully, obtain regulatory approval for and then successfully commercialise SNG001. Even if SNG001 is successful in clinical trials, there can be no assurance it will receive regulatory approval at all or in a timely manner. A drug which has received approval in one territory may not succeed in getting approval in other territories and regulators in different jurisdictions may seek different criteria and endpoints in order for regulatory approval and marketing authorisations to be granted. In the event of COVID-19 resolving, regulators may take a different approach to regulatory approval for any new therapeutics, which may increase the regulatory burden on the Group and have both time and cost implications.

  The Group takes the advice of specialist regulatory advisers and maintains an on-going dialogue with regulators.

- *Coverage and reimbursement*

  Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical or biological products for which the Group may obtain regulatory approval. In the United States and other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use the Group's products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Sales of any products for which the Group receives regulatory approval for commercial sale will therefore depend, in part, on the availability of coverage and adequate reimbursement from third-party payors. Third-party payors include government authorities, managed care plans, private health insurers and other organisations.

- *There are a number of competing COVID-19 therapeutics at different stages of regulatory approval*

  There are a number of competing therapeutics for COVID-19 at varying stages of regulatory approval, which may be brought to market more quickly than SNG001 or prove to be more effective, desirable or cheaper. Many of the Group's competitors have substantially greater financial and other resources. There can therefore be no assurance that competitors will not succeed in developing products which would render SNG001 non-competitive or obsolete.

- *Synairgen is dependent on a small team of key personnel and scientific and clinical collaborators*

  The Group's success is highly dependent on the expertise and experience of a small team of key personnel and scientific and clinical advisers/contractors. Whilst the Group has entered into employment and other agreements with each of these key personnel, the retention of such personnel cannot be guaranteed. Should key personnel leave or no longer be party to agreements or collaborations with the Group, the Group's business prospects, financial condition and/or results of operations could be adversely affected.

  To mitigate this risk, the Group has contracted with certain key partners to provide services to the Group, including CRO services, regulatory affairs consultants, CMC consultants and clinical management services. In the event of positive Phase III trial results, it is likely that the Group will have to consider partnering with other organisations in order to scale up its operations particularly in respect of marketing and distribution activities. There can be no guarantee that the Group will find suitable partners or on commercially advantageous terms.

- *Manufacturing complexity*

  SNG001 is a biological product with inherent batch to batch variation. Manufacturing issues could substantially increase our costs and limit supply of SNG001 for clinical trials and commercial sales.

- *The Group is dependent on third party supply, manufacturing and clinical service relationships*

  In common with other drug developers of similar size, the Group engages the expertise and resources of third parties in a number of key areas including: (i) the conduct of clinical trials (Parexel); (ii) the manufacture, scale-up, fill/finish and supply of SNG001 (Rentschler, Akron Biotechnology and Catalent); and (iii) the manufacture and supply of the nebuliser (Aerogen). Critical and complex aspects of the Group's business, some of which are being scaled up for the first time and progressed to meet accelerated timelines as a result of COVID-19, are therefore in the hands of third parties over whom the Group has limited control. The Group cannot guarantee that those third parties or their suppliers (including suppliers of raw materials and components necessary for manufacturing activities) will be able to perform their contractual and regulatory obligations satisfactorily or on time.

  Default, delay, non-compliance with law and regulation or other sub-optimal performance by a third party may adversely affect the Company's ability to carry out the Phase III trial and/or deliver production in a timely and cost-effective manner, which would adversely affect the Group's business plans and prospects.

  Regulatory requirements for pharmaceutical products tend to make the substitution of counterparties costly and time-consuming. Alternative suppliers may not be able to manufacture products effectively, on time or obtain the necessary manufacturing licences from applicable regulatory authorities.

  The Group seeks to minimise risk by holding regular meetings with key suppliers and the use of project managers and other consultants to manage the relationships. Where possible the Group tries to have more than one supply route – for example it is pursuing both pre-filled syringes and blow fill seal technology for the finished dosage form.

- *Intellectual property*

  The commercial success of the Group depends on its ability to obtain patent and other protection for its pharmaceutical discoveries in the US, Europe and elsewhere 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 products. 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.

- *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 funding through the injection of equity capital. The Group may not be able to generate positive net cash flows in the future or attract such additional funding required on suitable terms, or at the time it is needed. In such circumstances, the Group's 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.

- *Cyber attack or IT systems failure*
  The Group is at risk of cyber attack or IT systems failure to it or its key suppliers, which would cause operational harm, including potential theft or loss of data.

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

Outlook

Trial readouts are due over the coming months which we anticipate will add to the growing body of evidence supporting the use of inhaled interferon beta as a potential treatment for patients with COVID-19. These include data from our international SG018 Phase III trial and the US ACTIV-2 Phase II trial in COVID-19 outpatients, with initial data for SG018 expected in H2 2021. Beyond these trials Synairgen is in regular dialogue with government bodies and companies regarding the progress of inhaled interferon beta and its application as an effective treatment in both hospitalised and home-based patients.

In the second half of 2021 Synairgen will continue its commercialisation and manufacturing plans in order to scale up manufacturing and supply capacity, with the aim of making the drug readily available internationally and to meet potential commercial demand in the event of a regulatory approval.

On behalf of the Board.

Richard Marsden
Chief Executive Officer
11 May 2021

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Synairgen's Founders

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

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

Prof. Ratko Djukanovic
is Professor of Medicine 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.

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'). 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.

Iain Buchanan
Non-executive Director

Iain 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, Iain managed the international licensee business of Cilag AG - a subsidiary of Johnson and Johnson - based in Switzerland. Iain serves as a non-executive director for Allecra Therapeutics GmbH and for Aurealis Pharma AG.

Prof. Sir 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 1,300 papers in peer-reviewed literature. He is Member of the Horizon 2020 Science Panel for Health; Board Chair of the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs); Trustee and Chair of the Research Strategy Committee of Cancer Research UK; Trustee and Chair of the Grants Panel of the Great Ormond Street Hospital Children's Charity; Trustee and Chair of The Kennedy Trust for Rheumatology Research; Member of the Governing Body of the Nuffield Council for Bioethics; and Member of the Natural Environment Research Council. He serves on a number of Advisory Committees in industry, including scientific board member or advisor to a number of companies involved in developing new treatments for airways diseases.

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 was 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.

John Ward
Chief Financial Officer

John Ward joined Synairgen in October 2004 as Finance Director and was appointed Chief Financial Officer in March 2021. 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.

Dr Bruce Campbell
Non-executive Director

Bruce Campbell joined Synairgen as a non-executive director in April 2006. He has 50 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 BenevolentAI and Syncona. 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.

Simon Shaw

Richard Marsden

Dr Phillip Monk

John Ward

Iain Buchanan

Dr Bruce Campbell

Prof. Sir Stephen Holgate CBE

Corporate Governance Statement

The Board of directors of the Company (the "Board") is accountable to the Company's shareholders for good corporate governance and it is the objective of the Board to attain and maintain a high standard of corporate governance. As Chairman, it is my primary responsibility to lead the Board effectively and to oversee the adoption, delivery and communication of the Company's corporate governance model.

In September 2018, the Board adopted the Quoted Companies Alliance Corporate Governance Code ("QCA Code"). On our website (www.synairgen.com/investors/corporate-governance-statement/) we set out how we seek to comply with the 10 principles of the QCA Code. The following sections of the Corporate Governance Statement explain how the QCA Code is applied by the Company.

During 2021 we undertook a formal Board performance review, building on the initial formal review conducted in 2019.

Board of Directors

On 31 December 2020, the Board consisted of myself, as the non-executive Chairman, three executive directors (Richard Marsden, Dr Phillip Monk and John Ward), and three non-executive directors (Iain Buchanan, Dr Bruce Campbell and Prof. Sir Stephen Holgate).

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.

Brief *curriculum vitae* details about the directors are given on pages 17 and 18. The key experience, skills, qualities and capabilities that each director brings to the Board are summarised below:

Simon Shaw
Simon is an experienced public company director, having fulfilled both the roles of Chief Financial Officer and Chief Operating Officer for listed companies. He has life science company experience and in addition to his skills as a Chairman contributes strong financial and corporate finance skills. As an executive director of a FTSE 250 company he keeps his skill set in these areas up to date.

Richard Marsden
Richard has worked in several roles within the life sciences sector and has experience of sales and marketing, clinical trials, project management, business development and general management. He is actively involved in the design and management of clinical trials and leads the Company's business development activities. He maintains and develops his skill set in these areas by regular interaction with the Company's expert advisers and key opinion leaders (KoLs).

Dr Phillip Monk
Phillip is a leading scientist in respiratory biology, with experience of managing teams of scientists and taking drugs through pre-clinical and early clinical trials. His particular contribution to the Board is championing the identification and management of new opportunities up to the clinical stage, and maximising value from clinical trials, particularly with reference to biomarker and statistical analysis. Phillip regularly interacts with expert advisers/KoLs and attends key relevant medical conferences.

John Ward
John is a Chartered Accountant who has worked for more than 20 years as Finance Director and Company Secretary in the life sciences sector, with experience gained in private and quoted companies. From his time at Price Waterhouse he also has corporate finance experience. He keeps his skill set up to date by attending appropriate courses run by accountancy firms and the ICAEW.

Iain Buchanan
Iain has 40 years' management experience in the pharmaceutical and biotech sector. Iain keeps his skill set up to date through his involvement with several other life sciences boards.

Dr Bruce Campbell
Bruce has 50 years' drug development experience. He has particular expertise in pre-clinical development. Bruce keeps his skill set up to date through his involvement with several other life sciences companies either as a director or consultant.

Prof. Sir Stephen Holgate
Stephen is a leading academic in respiratory medicine, combining an outstanding knowledge of base and clinical science. He has experience of working with many pharmaceutical companies and guides the Board on developments in the respiratory sector. Stephen keeps up to date through his ongoing involvement with many industry and government-related organisations as an advisor.

All seven members of the Board bring relevant sector experience in life sciences. Four members of the Board have capital markets experience from other companies. The Board has expertise in the following key areas: capital markets; discovery and pre-clinical respiratory projects; clinical development; business development/licensing and finance. The Board believes that its blend of relevant experience, skills and personal qualities and capabilities is sufficient to enable it to successfully execute the current phase of its strategy. However, in due course as the business evolves, the Board would seek to further enhance its experience in certain areas. The Board is still composed solely of males and recognises this gender imbalance. Over ensuing periods, the Board will look to enhance its composition appropriately.

On 18 January 2021, Simon Holden was appointed as Company Secretary, fulfilling the role previously carried out by John Ward. Simon is a corporate lawyer by background and fulfils the role of secretary for several other quoted companies, on both the Main Market and AIM. The Company Secretary reports directly to the Chairman on governance matters.

Non-executive directors are required to attend six scheduled bi-monthly Board meetings (Scheduled Board meetings) and committee or Scientific Advisory Board meetings. Non-executive directors are required to be available at other times as required for face-to-face and telephone meetings with the executive team. All members of the executive team work for the Company on a full-time basis and have no non-executive directorships with other companies.

The Board notes that its directors have been in post for more than nine years but considers that they remain functionally independent, in that they remain fully committed to promoting the success of the Company for the benefit of shareholders as a whole. It is anticipated that enhancements to Board composition over the coming periods will result in greater QCA Code compliance in respect of director independence.

The Board also notes that one of its non-executive directors was granted options in 2010, which lapsed in 2020. The practice of granting non-executive directors options has now ceased.

With effect from the 2019 AGM and on an on-going basis, the Board puts all directors up for re-election on an annual basis to enable shareholders to confirm their support for the directors and that, in the case of the non-executives, they are considered by shareholders as remaining functionally independent.

The Company does not have a Senior Independent Director and we believe that this is appropriate at this stage of the Company's development.

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. Scheduled Board meetings take place throughout the year and the Board also meets on any other occasions it considers necessary. During the year ended 31 December 2020, the Board met six times for Scheduled Board meetings, with all members in attendance. At each meeting there was an opportunity for non-executive directors to discuss matters without executive directors present.

In addition, there were 13 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.

Board performance

A Board evaluation process led by the Chairman took place in March 2021. All of the directors completed a questionnaire about the effectiveness of the Board and the results were compiled on an anonymous basis by the Company Secretary. The Board reviewed the outcome of the questionnaire and noted that some of the areas identified, such as succession planning, had not been feasible to date. However, it was agreed to review Board composition over the coming period including from the perspective of Diversity and Inclusion. It was also agreed that given the significant developments of the previous year and the speed with which the approach to COVID-19 had to operate, there had been little time for the Board's annual strategy review. This too, will be held in the coming period.

Also, during March 2021, a review of the Chairman's performance over the last year was carried out by the completion of a questionnaire by other Board members. It is intended that this internal review will be carried out on an annual basis.

Corporate Governance Statement

(continued)

Board committees

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

Audit Committee

The Audit Committee currently comprises Simon Shaw (Chairman), Iain 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, without affecting their Audit Independence).

During 2020, the committee met three times with all members in attendance. The Audit Committee Report is detailed on page 28.

Remuneration and Nomination Committee

The Remuneration and Nomination Committee currently comprises Iain Buchanan (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. 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 2020, the committee met six times with all members attending. The Directors' Remuneration Report is detailed on pages 23 to 27.

Scientific Advisory Board

The Company established a Scientific Advisory Board ("SAB") in 2016. The purpose of the SAB is to provide strategic advice and input on scientific aspects of Synairgen's research and development projects.

The SAB currently comprises Dr Phillip Monk (Chairman), Iain Buchanan, Dr Bruce Campbell, and Synairgen's three academic founders (Professors Sir Stephen Holgate, Donna Davies and Ratko Djukanovic). Other external experts and Synairgen employees attend meetings as required. Dr Bruce Campbell is responsible for feeding back the outputs from the SAB to the Board.

Business model and strategy

As detailed in the Strategic Report on page 5, Synairgen's strategy is to develop SNG001 as a broad-spectrum antiviral by conducting a Phase III study and preparing for launch. The key challenges in execution are set out in the section of the Strategic Report entitled Principal risks and uncertainties.

Corporate culture

Synairgen is a biotechnology company focussed on developing new respiratory therapies which will make a difference to people's lives. Our core values to achieve this are:

- **Passion** – to demonstrate a passion for delivering high quality service
- **Professionalism** – to demonstrate courtesy, honesty and responsibility when dealing with individuals or others in the business environment
- **Collaboration** – to work effectively and inclusively with individuals, institutions, or other companies in the business environment
- **Experience** – to demonstrate knowledge and skills in the business environment
- **Approachability** – to be accommodating, friendly and transparent when working with others

These matters are reviewed annually during staff appraisals.

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 question 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 indicates the level of proxies lodged on each resolution, after it has been dealt with by a show of hands. Details of the proxies lodged are also published on the Company's website. Details of the resolutions and explanations thereto are included with the notice, including any special arrangements necessitated by COVID-19.

Internal control and risk management

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 mitigate, rather than eliminate, the risk of failure to achieve business objectives and can only provide reasonable but not absolute assurance against material misstatement or loss.

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;
- regular financial reforecasts;
- 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.

The Company maintains a summary risk register which is reviewed by the Board on an annual basis. The principal risks and uncertainties facing the Group, with mitigation strategies, are set out in the Strategic Report on pages 13 to 15. Project risk management is continually evaluated by weekly project meetings and other management tools. IT risk is covered at bi-annual meetings with external IT advisers. A Health and Safety report is reviewed by the Board.

Simon Shaw
Chairman

11 May 2021

Directors' Remuneration Report

In September 2018, the Company adopted the QCA Corporate Governance Code which includes the requirement to prepare a remuneration committee report. This report includes and complies with the disclosure obligations of the AIM Rules.

2020 was a transformative year for the Group with considerable progress on its drug pipeline including its SNG001 treatment for COVID-19. The Group also raised some £101 million of new capital and its share price rose over the year from 6p to 153p. Both the executives and the wider workforce were critical to the delivery of these exceptional results and, after many years of providing modest fixed pay due to affordability constraints, the Remuneration Committee reviewed pay both for the executives and the wider workforce. For completeness, no staff were made redundant or placed on furlough.

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 pages 21. The members of the Committee are Iain Buchanan (Chairman), Dr Bruce Campbell and Simon Shaw.

The Committee, which is required to meet at least twice a year, met six times during the year ended 31 December 2020 and considered the pay of the executive directors and ensured it understood pay arrangements more broadly across the Group. 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 9% pension contribution (which has been frozen as explained in this report) either to the executive director's individual money purchase scheme or, as a salary supplement after deducting an amount to reflect employer's NICs to ensure that the overall cost to the employer is not increased and typical benefits including family private health cover, permanent health and life assurance.

The previous salary and benefit review took effect from 1 January 2020, at which point the executive directors' salaries were increased by 2% (in line with or below the level awarded to staff generally).

During the year, a benchmarking exercise was undertaken across the workforce. Salaries and benefits have therefore been reviewed with effect from 1 January 2021, taking into account Group and individual performance, external benchmark information and internal relativities. As a consequence of the 2021 review, executive director salaries were increased by 12%, which was consistent with the level awarded to staff generally. Given the significant accomplishments made in 2020, this award is considered merit-based and modest when benchmarked against equivalently sized companies, demonstrating that the Committee is being conscious of the need to both show restraint and ensure that colleagues are appropriately but not excessively paid in a sector currently subject to intense skills shortages. It, therefore, plans to keep all salaries and packages under review and may make an interim award if it considers that to be necessary or appropriate.

	1 January 2020 to 31 December 2020		From 1 January 2021	
	Salary per annum (£000)	Maximum bonus as a % of salary	Salary per annum (£000)	Maximum bonus as a % of salary
Richard Marsden	194	100%	217	100%
Dr Phillip Monk	140	100%	157	100%
John Ward	151	100%	169	100%

Recognising the increased focus on pension provision, the Committee decided that the level of pension provision should be frozen with the current 9% contribution level only applying to the pre-2021 salary levels. This will be reconsidered as part of subsequent reviews. If the recipient takes cash in lieu of a contribution to a registered pension, the amount payable is reduced to ensure that the total cost to the employer (inclusive of employers' NICs) is not increased.

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

Directors' remuneration for the year ended 31 December 2020 is set out on page 27 of this document.

(ii) Chairman and non-executive director remuneration

No changes have been made to the fees set out in last year's report which remain a fee payable to the Chairman of £45,000 per annum, a fee for the non-executive directors of £25,000 and a fee of £5,000 will continue to be paid to non-executive directors who chair either the Audit or Remuneration and Nomination committees. The Chairman continues to waive his entitlement to the fee for chairing the Audit Committee.

(iii) Annual bonus plan

The Company operates a discretionary bonus scheme for executive directors for delivery of exceptional performance against pre-set relevant corporate objectives, which are subject to malus and clawback provisions within an overall cap of 100% of salary. Given the exceptional achievements including the conducting of the COVID-19 clinical trial, manufacturing scale up activities and significant fundraisings, as reflected by the share price increasing some twenty-five fold, the Committee awarded the maximum opportunity of 100% of salary.

Bonuses in respect of 2020 will be paid in H1 2021.

(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 LTIP, 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) is the sole long-term incentive vehicle for executive directors.

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

As indicated in last year's report, an LTIP award was made in June 2020 during the six week period following the preliminary announcement of the results for the year ended 31 December 2019, with each of Richard Marsden, Phillip Monk and John Ward being granted awards over shares worth 100% of salary with performance conditions as set out below.

The Committee intends to make a similar LTIP award (the 2021 award) during the six week period following the preliminary announcement of the results for the year ended 31 December 2020, with each of Richard Marsden, Phillip Monk and John Ward being granted awards over shares worth up to 100% of salary with vesting and performance conditions similar to the 2020 LTIP award.

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. Each of the executive directors has achieved this level.

All awards will lapse at the end of the applicable performance period to the extent that the applicable performance 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.

Directors' Remuneration Report

(continued)

Performance conditions for the 2018, 2019 and 2020 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:

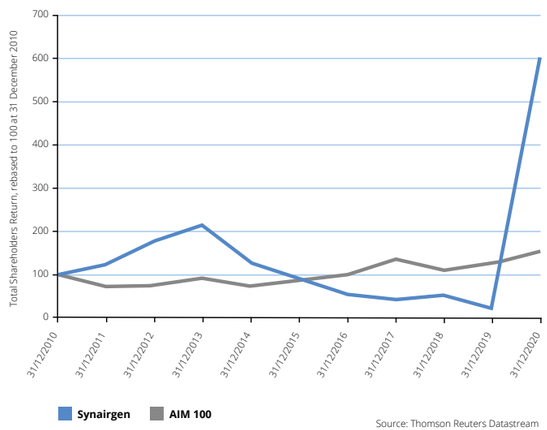
TSR growth over the performance period less percentage increase in the techMARK mediscience™ index over the same period	Vesting percentage of total number of shares subject to award
Less than 10%	0%
10%	25%
20%	50%
30%	100%
Performance between the steps	Pro-rata on a straight-line basis

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%.

Post period-end, the 2018 LTIP award vested in full.

TSR Performance

The latest guidelines from the QCA encourage companies to include a chart showing its TSR performance over the preceding 10 years relative to a recognised index. While the Company has principally focused on the techMARK mediscience™ index, it does not formally publish a TSR based index, so the AIM100 has been used below.



Source: Thomson Reuters Datastream

(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. In February 2021, Richard Marsden's notice period was amended from six months to twelve months from either party.

During the year ended 31 December 2020, 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 2020	Granted during the year	Exercised during the year	At 31 December 2020	Exercise price	Earliest exercise date	Expiry date
Richard Marsden							
7 September 2009	605,000	–	(605,000)	–	1p	7 Sept 2012	31 Dec 2020[1]
8 September 2010	246,889	–	(246,889)	–	1p	8 Sept 2013	31 Dec 2020[1]
21 September 2011	538,063	–	–	538,063	1p	21 Sept 2014	20 Sept 2021
5 April 2018	880,903	–	–	880,903	1p	5 April 2021	4 April 2028
4 April 2019	772,167	–	–	772,167	1p	4 April 2022	3 April 2029
18 June 2020	–	490,817	–	490,817	1p	18 June 2023	17 June 2030
Dr Phillip Monk							
21 September 2011	400,212	–	–	400,212	1p	21 Sept 2014	20 Sept 2021
5 April 2018	636,208	–	–	636,208	1p	5 April 2021	4 April 2028
4 April 2019	557,679	–	–	557,679	1p	4 April 2022	3 April 2029
18 June 2020	–	354,483	–	354,483	1p	18 June 2023	17 June 2030
John Ward							
7 September 2009	100,000	–	(100,000)	–	1p	7 Sept 2012	31 Dec 2020[1]
8 September 2010	224,445	–	(224,445)	–	1p	8 Sept 2013	31 Dec 2020[1]
21 September 2011	489,148	–	–	489,148	1p	21 Sept 2014	20 Sept 2021
5 April 2018	685,147	–	–	685,147	1p	5 April 2021	4 April 2028
4 April 2019	600,575	–	–	600,575	1p	4 April 2022	3 April 2029
18 June 2020	–	381,749	–	381,749	1p	18 June 2023	17 June 2030

Note 1. Awards normally lapse on the tenth anniversary of grant. Due to close period constraints, it was not feasible for the executives to exercise their 2009 and 2010 awards and the Committee agreed to extend the exercise window until the end of 2020.

Note 2. The Company issued (i) 40,000,000 new shares pursuant to a placing on 30 March 2020 and 15 April 2020 and (ii) 49,753,026 new shares pursuant to a further placing on 19 October 2020 and 4 November 2020. While this would have permitted the Committee to adjust the shares subject to awards using the HMRC established Theoretical Ex-Rights Price (TERPS) formulae (which would have increased the shares subject to awards by approximately a further one-third), the Committee felt that this was not appropriate as the placing was offered on a non-pre-emptive basis.

Options over 1,176,334 shares granted under the LTIP were exercised during the year by Richard Marsden and John Ward. The Company agreed to net-settle these options on behalf of Richard Marsden and John Ward. Under this process, the Company settled the relevant options by delivering 534,172 ordinary shares (386,842 to Richard Marsden and 147,330 to John Ward), which represented the notional gain on exercise with the income tax and National Insurance Contributions (NICs) due on such gain paid by the Company to HMRC on behalf of Richard Marsden and John Ward. Richard Marsden and John Ward did not receive any cash proceeds from the exercise of these options.

Synairgen Qualifying Non-Employee Option Scheme

Date of grant	At 1 January 2020	Lapsed during the year	At 31 December 2020	Exercise price	Earliest exercise date	Expiry date
Iain Buchanan						
28 June 2010	212,765	(212,765)	–	23.5p	28 June 2013	27 June 2020

These awards were granted under a legacy plan. The exercise of the options awarded in June 2010 (which vested in 2013) is subject to the rules of the scheme. The option granted to Mr Buchanan lapsed without being exercised on its 10th anniversary.

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 2020 was 153.0p. During the year then ended, the mid-market price ranged from 5.875p to 247.52p. On 11 May 2021 the closing price was 102.2p.

Directors' Remuneration Report

(continued)

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 2020 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 2020 and 2019 was as follows:

		Year ended 31 December 2020						Year ended 31 December 2019		
£000	Notes	Salary/ fee	Bonus	Benefits (iii)	Total (excl. pension)	Pension (iv)	Total (incl. pension)	Total (excl. pension)	Pension	Total (incl. pension)
Executive Directors										
Richard Marsden	(i)	194	194	10	398	17	415	272	17	289
Dr Phillip Monk		140	140	9	289	13	302	196	12	208
John Ward		151	151	9	311	13	324	213	13	226
Non-executive Directors										
Simon Shaw		45	–	–	45	–	45	30	–	30
Iain Buchanan		30	–	–	30	–	30	28	–	28
Dr Bruce Campbell		25	–	–	25	–	25	26	–	26
Paul Clegg	(ii)	–	–	–	–	–	–	13	–	13
Prof. Sir Stephen Holgate		25	–	–	25	–	25	25	–	25
Total		610	485	28	1,123	43	1,166	803	42	845

(i) Richard Marsden was the highest paid director during the year ended 31 December 2020, earning a total of £415,000 as set out above. In addition, he made a gain (before tax and NICs) on the exercise of 851,889 options amounting to £1,712,000 and Mr Ward made a gain of £652,000 on the exercise of 324,445 options. Richard Marsden was the highest paid director during the year ended 31 December 2019 and did not exercise any options during that year.

(ii) Paul Clegg retired as a non-executive director on 3 June 2019. He received no payment for loss of office.

(iii) The Committee approved that executive directors could carry forward a maximum of 10 days' holiday pay into 2021 and that, owing to the exceptional nature of 2020, the remaining element of unused holiday entitlement could be paid. The amounts payable in respect of Mr Marsden, Dr Monk and Mr Ward amounted to £8,000, £8,000 and £6,000 and were paid in Q1 2021. These sums are included under Benefits in the table above.

(iv) The Company permits employees, including executive directors, to change their pension provision through an election under a flexible benefits arrangement. The reported numbers are before any personal elections.

In respect of key management personnel (the three executive directors), for the year ended 31 December 2020, the total share-based payment amounted to £152,000 (2019: £85,000) and total social security costs were £134,000 (2019: £126,000).

On behalf of the Board

Iain Buchanan

Chairman of the Remuneration and Nomination Committee

11 May 2021

Report of the Audit Committee

for the year ended 31 December 2020

Constitution and membership

The Audit Committee (the 'Committee') has primary responsibility for ensuring that the financial performance of the Group is properly measured and reported on. It was established in October 2004 and its terms of reference are outlined in the Corporate Governance Statement on page 21.

The members of the Committee during the year under review and at the date of this report are Simon Shaw (Chairman), Iain 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.

Matters covered by the Committee

The Committee, which is required to meet at least twice a year, met three times during the year ended 31 December 2020, with all members attending all meetings, and covered the following matters:

- May 2020: audit completion meeting for the 2019 year-end audit including reviews of: the valuation model to support Synairgen plc's investment in Synairgen Research Limited; the financial forecast to support the Group's ability to account on a going concern basis, including the potential impact of COVID-19; the implementation of IFRS 16 accounting, the auditor's report on the audit; and the annual report.
- September 2020: interim report completion meeting for 2020, including agreement of scope and materiality and reviews of: the financial forecast to support the Group's ability to account on a going concern basis; the report from the Company's auditors; and the interim statement.
- December 2020: planning meeting for the 2020 year-end audit, including agreement of audit scope, materiality, areas of audit focus, audit fees and auditor independence.

The Committee also met in March 2021 for the audit completion meeting for the 2020 year-end audit including reviews of: the support for Synairgen plc's investment in Synairgen Research Limited; the financial forecast to support the Group's ability to account on a going concern basis, the auditor's report on the audit; and the annual report.

BDO, the Company's auditors, were present at all meetings. John Ward, the Group's Chief Financial Officer, was present at all meetings except for when his performance was being discussed by the Committee.

Auditor independence

As set out in the Corporate Governance Statement on page 21, 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 for tax advice during the year (as detailed in note 4 to the Financial Statements) amounted to £46,000. £9,000 of these fees relate to tax compliance services. The majority of the remaining tax advice was for indirect tax advisory services in relation to the Group's overseas manufacturing and clinical trial activities. Whilst the Committee notes that the non-audit fees are in excess of the audit fees, it has confirmed that the amount of the audit fees are not material to BDO or the audit partner concerned. The Committee therefore considers that the amount of non-audit fees does not impair the independence of BDO as auditor.

Internal audit function

The Group does not have an internal audit function, but the Committee considers that this is appropriate, given the size and relative lack of complexity of the Group at this stage in its development. The Committee keeps this matter under review annually.

Simon Shaw

Chairman of the Audit Committee

11 May 2021

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 2020.

The review of future developments is covered in the Outlook section of 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 2020, the Group has invested £15,495,000 (2019: £3,460,000) in research and development activities and a review of this expenditure is included in the Strategic Report.

Going concern

The directors have prepared financial forecasts to estimate the likely cash requirements of the Group over the next twelve months, given its stage of development and lack of recurring revenues. In preparing these financial forecasts, the directors have made certain assumptions with regards to the timing and amount of future expenditure over which they have control. The directors have attempted to take a prudent view in preparing these forecasts, recognising the inherent variability in costs of the ongoing Phase III clinical trial of SNG001 in COVID-19 patients and the manufacturing scale-up activities.

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.

Treasury policy and financial risk management

The Group's treasury policy and financial risk management is set out in note 16 to the financial statements on pages 49 and 50.

Dividends

The directors do not propose the payment of a dividend.

Substantial shareholdings

As at 11 May 2021, the Company had been advised of the following shareholders with an interest of 3% or more in its ordinary share capital:

Name of shareholder	Number of ordinary shares	% of share capital
Polar Capital LLP	17,740,403	8.9%
Polygon Global Partners LLP	9,996,978	5.0%

Directors

The directors of the Company during the year ended 31 December 2020 were:

Executive directors:	*Non-executive directors:*
Richard Marsden (Chief Executive Officer)	Simon Shaw (Chairman)
Dr Phillip Monk (Chief Scientific Officer)	Iain Buchanan
John Ward (Finance Director)	Dr Bruce Campbell
	Prof. Sir Stephen Holgate CBE

Directors' interests in ordinary shares

The directors, who held office at 31 December 2020, had the following interests in the ordinary shares of the Company:

	At 31 December 2020 Number of shares	At 1 January 2020 Number of shares
Richard Marsden (i)	754,667	310,682
Dr Phillip Monk	244,600	230,314
John Ward	514,907	339,006
Simon Shaw (ii)	1,531,239	1,474,096
Iain Buchanan	112,741	112,741
Dr Bruce Campbell (iii)	322,830	294,259
Prof. Sir Stephen Holgate	886,931	858,360

(i) Richard Marsden's shareholding includes 184,821 shares held in his pension plan.

(ii) Simon Shaw's shareholding includes 105,516 shares held in his pension plan.

(iii) Dr Bruce Campbell's shareholding includes 40,299 owned by his wife, Susan Campbell.

(iv) Prof. Sir Stephen Holgate's shareholding includes 1,923 shares owned by his wife, Elizabeth Holgate.

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 to 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

Simon Holden

Company Secretary

11 May 2021

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 year. Under that law the directors have elected to prepare the Group financial statements in accordance with international accounting standards in conformity with the requirements of the Companies Act 2006 and the Company financial statements in accordance with United Kingdom Generally Accepted Accounting Practice (United Kingdom Accounting Standards 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 AIM.

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 the Group financial statements have been prepared in accordance with international accounting standards in conformity with the requirements of the Companies Act 2006 and the Company financial statements in accordance with United Kingdom Generally Accepted Accounting Practice (United Kingdom Accounting Standards and applicable law), 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 Group's and Company's transactions and disclose with reasonable accuracy at any time the financial position of the Group and 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 Group and 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 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.

By order of the Board

Simon Holden

Company Secretary

11 May 2021

Independent Auditor's Report to the members of Synairgen plc

Opinion on the financial statements

In our opinion:

- the financial statements give a true and fair view of the state of the Group's and of the Parent Company's affairs as at 31 December 2020 and of the Group's loss for the year then ended;
- the Group financial statements have been properly prepared in accordance with international accounting standards in conformity with the requirements of the Companies Act 2006;
- the Parent Company 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.

We have audited the financial statements of Synairgen plc (the 'Parent Company') and its subsidiary (the 'Group') for the year ended 31 December 2020 which comprise the Consolidated Statement of Comprehensive Income, Consolidated Statement of Changes in Equity, Consolidated Statement of Financial Position, Consolidated Statement of Cash Flows, Parent Company Balance Sheet, Parent Company Statement of Changes in Equity and notes to the Consolidated and Parent Company financial statements, including a summary of significant accounting policies.

The financial reporting framework that has been applied in the preparation of the Group financial statements is applicable law and international accounting standards in conformity with the requirements of the Companies Act 2006. The financial reporting framework that has been applied in the preparation of the Parent Company financial statements is applicable law and United Kingdom Accounting Standards, including Financial Reporting Standard 101 Reduced Disclosure Framework (United Kingdom Generally Accepted Accounting Practice).

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 believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Independence

We remain independent of the Group and the Parent 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 as applied to listed entities, and we have fulfilled our other ethical responsibilities in accordance with these requirements.

Conclusions relating to going concern

In auditing the financial statements, we have concluded that the Directors' use of the going concern basis of accounting in the preparation of the financial statements is appropriate. Our evaluation of the Directors' assessment of the Group and the Parent Company's ability to continue to adopt the going concern basis of accounting included evaluating the following:

- The Directors' method for assessing going concern including the relevance and reliability of underlying data used to make the assessment, and whether assumptions and changes to assumptions from prior years are appropriate and where relevant consistent with each other. The assumptions were assessed against the Group's development plans and committed expenditure.
- The Directors' plans for future actions in relation to the going concern assessment including whether such plans are feasible in the circumstances.
- The Directors' stress-testing of the forecasts to the extent of reasonable worst-case scenarios, solely in relation to their estimates of planned operational costs.
- The adequacy and appropriateness of disclosures in the financial statements regarding the going concern assessment.

We carried out the above procedures through using our understanding of the business model, objectives, strategies and related business risk, the measurement and review of the entity's financial performance, forecasting and budgeting processes and the entity's risk assessment process.

Based on the work we have performed, we have not identified any material uncertainties relating to events or conditions that, individually or collectively, may cast significant doubt on the entity's ability to continue as a going concern for a period of at least twelve months from when the financial statements are authorised for issue.

Our responsibilities and the responsibilities of the Directors with respect to going concern are described in the relevant sections of this report.

Overview

Coverage	100% (2019: 100%) of Group loss before tax 100% (2019: 100%) of Group total assets		
Key audit matters		2020	2019
	Clinical trial accounting	✓	✗
	Investment in subsidiary: impairment review	✗	✓
	Investment in subsidiary: impairment review is no longer considered to be a key audit matter because of the extent of headroom in recoverable amount over carrying value, represented by the Group's AIM market capitalisation at the reporting date, as all of the Group's intellectual property is held in this subsidiary		
Materiality	Group financial statements as a whole £900,000 (2019: £200,000) based on 5% (2019: 5%) of the loss before tax		

An overview of the scope of our audit

Our Group audit was scoped by obtaining an understanding of the Group and its environment, including the Group's system of internal control, and assessing the risks of material misstatement in the financial statements. We also addressed the risk of management override of internal controls, including assessing whether there was evidence of bias by the Directors that may have represented a risk of material misstatement.

The Group's operations are based solely in Southampton, United Kingdom.

Both components, Synairgen plc and Synairgen Research Limited, are considered significant components and were subject to full-scope audits by the group audit team.

Independent Auditor's Report to the members of Synairgen plc

(continued)

Key audit matters

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the financial statements of the current period and include the most significant assessed risks of material misstatement (whether or not due to fraud) that we identified, including those which had the greatest effect on: the overall audit strategy, the allocation of resources in the audit, and directing the efforts of the engagement team. These matters were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

Key audit matter		How the scope of our audit addressed the key audit matter
Clinical trial accounting The accounting policy in respect of the accounting for manufacturing activities is included within the Inventories accounting policy on page 41; the accounting policy in respect of research and development activities is included within the "Research and development" accounting policy on page 40; significant balance sheet items in relation to clinical trial activities are included in notes 13 and 15.	Due to the nature of clinical trials, drug manufacturing processes and general research, it is often difficult to estimate the length of time a particular research process is going to take. This is reinforced by the fact that such activities are often contracted to third parties. As a result, it can be challenging for the entity to measure what costs have been incurred in relation to outsourced research and manufacturing at a particular point in time and as such, based on billings received, whether project accruals and prepayments recorded are reasonably estimated. Our audit risk is focused on whether the relevant expenditure has been appropriately included in the income statement and whether prepayments and accruals are appropriately calculated and recognised.	We have assessed the key terms of all material ongoing third party research and drug manufacturing agreements to ensure that we understood the nature of the goods or services to be provided, the total contracted costs and, where relevant, milestone payments. We then reviewed a sample of invoices raised in accordance with the research and drug manufacturing agreements and reviewed their content to determine the correct accounting treatment and if the expenditure was appropriately classified within the financial statements. Where relevant, we have obtained third party confirmation of stages of completion of a project and compared the progress against both the contract and the value of expenditure billed to date. We have then verified this to the year-end cost position to determine whether related prepayments or accruals are accurately recognised. We verified the completeness of management's calculation of the accruals and prepayments position by selecting a sample of significant purchase orders raised in the final quarter of the year and checking that, based on evidence such as invoices received and third party confirmations, the associated costs had been recognised in the appropriate accounting period. We also considered completeness of related accruals through testing a sample of invoices recorded post year end checking that, based on the terms of the service, they had been accounted for correctly. In addition, we inspected board meeting minutes for evidence of any significant contracts entered that might require cost accruals that had not been recognised. **Key observations:** We consider the Group's related accounting policies have been appropriately applied, in the recording of research and development expenditure, related prepayments and accruals in the financial statements.

Our application of materiality

We apply the concept of materiality both in planning and performing our audit, and in evaluating the effect of misstatements. We consider materiality to be the magnitude by which misstatements, including omissions, could influence the economic decisions of users that are reasonably taken on the basis of the financial statements.

In order to reduce to an appropriately low level the probability that any misstatements exceed materiality, we use a lower materiality level, performance materiality, to determine the extent of testing needed. Importantly, misstatements below these levels will not necessarily be evaluated as immaterial as we also take account of the nature of identified misstatements, and the particular circumstances of their occurrence, when evaluating their effect on the financial statements as a whole.

Based on our professional judgement, we determined materiality for the financial statements as a whole and performance materiality as follows:

	Group financial statements		Parent company financial statements	
	2020 £'000	2019 £'000	2020 £'000	2019 £'000
Materiality	900	200	550	180
Basis for determining materiality	5% of the loss before tax		60% of Group materiality	90% of Group materiality
Rationale for the benchmark applied	Loss before tax is considered to be one of the principal considerations for the users of the financial statements in assessing the financial performance of the Group.		Capped 60% (2019: 90%) of Group materiality given the assessment of the components aggregation risk.	
Performance materiality	675	150	415	135
Basis for determining performance materiality	75% of materiality based on a low expected total value of known and likely misstatements.			

Component materiality

Aside from the Parent company, there is only one additional component – being the trading subsidiary Synairgen Research Limited. The materiality for this component was set at £800,000 (2019: £180,000), based on 90% (2019: 90%) of Group materiality. In the audit of this component, we further applied a performance materiality level of 75% of the component materiality to our testing to ensure that the risk of errors exceeding component materiality was appropriately mitigated.

Reporting threshold

We agreed with the Audit Committee that we would report to them all individual audit differences in excess of £18,000 (2019: £4,000). We also agreed to report differences below this threshold that, in our view, warranted reporting on qualitative grounds.

Other information

The directors are responsible for the other information. The other information comprises the information included in the Annual Report and Accounts 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 to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon. 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 course of 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 this gives rise to a material misstatement in the financial statements themselves. 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.

Independent Auditor's Report to the members of Synairgen plc

(continued)

Other Companies Act 2006 reporting

Based on the responsibilities described below and our work performed during the course of the audit, we are required by the Companies Act 2006 and ISAs (UK) to report on certain opinions and matters as described below.

Strategic Report and Directors' Report	In our opinion, based on the work undertaken in the course of the audit: • the information given in the Strategic Report and the Directors' Report for the financial year for which the financial statements are prepared is consistent with the financial statements; and • the Strategic Report and the Directors' Report have been prepared in accordance with applicable legal requirements. In the light of the knowledge and understanding of the Group and Parent Company and its environment obtained in the course of the audit, we have not identified material misstatements in the Strategic Report or the Directors' Report.
Matters on which we are required to report by exception	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 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.

Responsibilities of Directors

As explained more fully in the Statement of 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 Group's and the Parent Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the Directors either intend to liquidate the Group or the Parent Company or to cease operations, or have no realistic alternative but to do so.

Auditor's responsibilities for the audit of the financial statements

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.

Extent to which the audit was capable of detecting irregularities, including fraud

Irregularities, including fraud, are instances of non-compliance with laws and regulations. We design procedures in line with our responsibilities, outlined above, to detect material misstatements in respect of irregularities, including fraud. The extent to which our procedures are capable of detecting irregularities, including fraud, is detailed below.

We focused on laws and regulations that could give rise to a material misstatement in the Group financial statements and the susceptibility of the entity's financial statements to material misstatement including fraud. Our procedures included, but were not limited to:

- Evaluation of management incentives and opportunities for fraudulent manipulation of the financial statements including management override;
- This evaluation involved a particular focus on the judgements and estimates inherent in the key audit matter and exercising professional scepticism in considering the impact of those estimates and judgements on the reported results and key performance measures such as the loss before tax;
- The evaluation also involved gaining an understanding of management remuneration schemes and the extent to which remuneration is influenced by reported results;
- Discussions with Management and the Audit Committee regarding known or suspected instances of non-compliance with laws and regulations;
- Obtaining and understanding of controls designed to prevent and detect irregularities;
- Review of board meeting minutes for any evidence of fraud or non-compliance with laws and regulations including health and safety; taxation regulations; and drug development regulatory authorities and
- Assessment of journal entries to accounts that are considered to carry a greater risk of fraud as part of our planned audit approach.

We also communicated relevant identified laws and regulations and potential fraud risks to all engagement team members and remained alert to any indications of fraud or non-compliance with laws and regulations throughout the audit.

Our audit procedures were designed to respond to risks of material misstatement in the financial statements, recognising that the risk of not detecting a material misstatement due to fraud is higher than the risk of not detecting one resulting from error, as fraud may involve deliberate concealment by, for example, forgery, misrepresentations or through collusion. There are inherent limitations in the audit procedures performed and the further removed non-compliance with laws and regulations is from the events and transactions reflected in the financial statements, the less likely we are to become aware of it.

A further description of our responsibilities is available on the Financial Reporting Council's website at: www.frc.org.uk/auditorsresponsibilities. This description forms part of our auditor's report.

Use of our report

This report is made solely to the Parent 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 Parent 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 Parent Company and the Parent Company's members as a body, for our audit work, for this report, or for the opinions we have formed.

Ian Oliver (Senior Statutory Auditor)

For and on behalf of

BDO LLP, Statutory Auditor

Reading, United Kingdom

11 May 2021

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 2020

	Notes	Year ended 31 December 2020 £000	Year ended 31 December 2019 £000
Research and development expenditure		**(15,495)**	(3,460)
Other administrative expenses		**(2,246)**	(1,357)
Total administrative expenses and loss from operations		**(17,741)**	(4,817)
Finance income	6	**19**	30
Finance expense	6	**(10)**	(6)
Loss before tax		**(17,732)**	(4,793)
Tax	7	**3,816**	908
Loss and total comprehensive loss for the period attributable to equity holders of the parent		**(13,916)**	(3,885)
Loss per ordinary share			
Basic and diluted loss per share (pence)	8	**(9.46)p**	(3.55)p

Consolidated Statement of Changes in Equity

for the year ended 31 December 2020

	Share capital £000	Share premium £000	Merger reserve £000	Retained deficit £000	Total £000
Note	18a	18b	18c	18d	
At 1 January 2019	1,094	28,262	483	(23,812)	6,027
Recognition of share-based payments	–	–	–	111	111
Loss and total comprehensive loss for the year	–	–	–	(3,885)	(3,885)
At 31 December 2019	1,094	28,262	483	(27,586)	2,253
Issue of ordinary shares	905	100,170	–	–	101,075
Transaction costs in respect of share issues	–	(3,187)	–	–	(3,187)
Recognition of share-based payments	–	–	–	207	207
Net settlement of share options	–	–	–	(1,291)	(1,291)
Loss and total comprehensive loss for the year	–	–	–	(13,916)	(13,916)
At 31 December 2020	**1,999**	**125,245**	**483**	**(42,586)**	**85,141**

Consolidated Statement of Financial Position

as at 31 December 2020

	Notes	31 December 2020 £000	31 December 2019 £000
Assets			
Non-current assets			
Intangible assets	9	**44**	16
Property, plant and equipment	10	**250**	301
Right-of-use assets	11	**94**	255
		388	572
Current assets			
Inventories	12	**41**	41
Current tax receivable		**3,771**	865
Trade and other receivables	13	**9,372**	139
Cash and cash equivalents	14	**74,976**	2,454
		88,160	3,499
Total assets		**88,548**	4,071
Liabilities			
Non-current liabilities			
Lease liabilities	11	**–**	(127)
Current liabilities			
Trade and other payables	15	**(3,279)**	(1,490)
Lease Liabilities	11	**(128)**	(201)
		(3,407)	(1,691)
Total liabilities		**(3,407)**	(1,818)
Total net assets		**85,141**	2,253
Equity			
Capital and reserves attributable to equity holders of the parent			
Share capital	17	**1,999**	1,094
Share premium	17	**125,245**	28,262
Merger reserve	18	**483**	483
Retained deficit	18	**(42,586)**	(27,586)
Total equity		**85,141**	2,253

The financial statements on pages 37 to 52 were approved and authorised for issue by the Board of directors on 11 May 2021 and signed on its behalf by:

Richard Marsden
Chief Executive Officer

John Ward
Chief Financial Officer

Consolidated Statement of Cash Flows

for the year ended 31 December 2020

	Notes	Year ended 31 December 2020 £000	Year ended 31 December 2019 £000
Cash flows from operating activities			
Loss before tax		**(17,732)**	(4,793)
Adjustments for:			
Finance income		**(19)**	(30)
Finance expense		**10**	6
Depreciation of property, plant and equipment		**90**	83
Depreciation of right-of-use assets		**161**	67
Amortisation of intangible fixed assets		**9**	13
Share-based payment charge		**207**	111
Cash flows from operations before changes in working capital		**(17,274)**	(4,543)
Decrease in inventories		**–**	15
(Increase)/Decrease in trade and other receivables		**(9,244)**	81
Increase in trade and other payables		**1,789**	713
Cash used in operations		**(24,729)**	(3,734)
Tax credit received		**910**	838
Net cash used in operating activities		**(23,819)**	(2,896)
Cash flows from investing activities			
Interest received		**31**	26
Purchase of intangible assets		**(37)**	–
Purchase of property, plant and equipment		**(39)**	(10)
Decrease in other financial assets		**–**	50
Net cash (used in)/generated from investing activities		**(45)**	66
Cash flows from financing activities			
Proceeds from issuance of ordinary shares		**101,075**	–
Transaction costs in respect of share issues		**(3,187)**	–
Net settlement of share options		**(1,291)**	–
Principal paid on lease liabilities		**(196)**	–
Interest paid on lease liabilities		**(15)**	–
Net cash generated from financing activities		**96,386**	–
Increase/(Decrease) in cash and cash equivalents		**72,522**	(2,830)
Cash and cash equivalents at beginning of the year		**2,454**	5,284
Cash and cash equivalents at end of the year	14	**74,976**	2,454

Notes to the Consolidated Financial Statements

for the year ended 31 December 2020

1. Accounting policies

Basis of preparation

The Group financial statements have been prepared in accordance with international accounting standards in conformity with the requirements of the Companies Act 2006.

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

Amendments to Existing Standards

With effect from 1 January 2020, the Group adopted two amendments to existing standards:

(i) Amendments to References to the Conceptual Framework in IFRS Standards

The revised Conceptual Framework introduces a number of new aspects including: concepts on measurement, including factors to be considered when selecting a measurement basis; concepts on presentation and disclosure, including when to classify income and expenses in other comprehensive income; and guidance on when assets and liabilities are removed from financial statements. It also updates the definitions of asset and liability and the criteria for recognising assets and liabilities in financial statements. Finally, it has clarified the guidance on prudence, stewardship, measurement uncertainty, and substance over form.

(ii) Amendments to IAS 1 and IAS 8 – Definition of Material

The amendments clarify the definition of 'material' and align the definition used in the Conceptual Framework and the standards themselves.

The adoption of these amendments has not had a material impact on the Group's financial statements.

The Group financial statements are presented in Sterling.

Going concern

The directors have prepared financial forecasts to estimate the likely cash requirements of the Group over the next twelve months, given its stage of development and lack of recurring revenues. In preparing these financial forecasts, the directors have made certain assumptions with regards to the timing and amount of future expenditure over which they have control. The directors have attempted to take a prudent view in preparing these forecasts, recognising the inherent variability in costs of the ongoing Phase III clinical trial of SNG001 in COVID-19 patients and the manufacturing scale up activities.

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.

Basis of consolidation

The consolidated financial statements incorporate the financial statements of the Company and entities controlled by the Company (as detailed in note 4 to the Parent Company Financial Statements on page 57) made up to the reporting date. All intra-group transactions, balances, income and expenses are eliminated on consolidation. The formation of the Group arose from merger accounting and as the business combination took place prior to 1 July 2006, the date of transition to IFRS, the transaction has not been restated as permitted by IFRS 1 "First-time Adoption of International Financial Reporting".

Revenue

Revenue is stated net of value added tax.

The Group's licensing and collaboration agreement with Pharmaxis in respect of the jointly developed LOXL2 inhibitors was renegotiated in December 2017. No substantive performance obligations on the Group remained at 1 January 2019. 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 Group'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 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.

1. Accounting policies (continued)

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

Share-based payments
Where equity-settled share options are awarded to employees, the fair value of the options at the date of grant is charged to the consolidated statement of comprehensive income over the vesting period. 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 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.

Where vested share options are exercised by the participants but settled by the Company net of shares withheld to meet the participant's tax and NIC liabilities ('net settlement'), the payment to meet such tax and NIC liabilities is treated as a deduction to equity to the extent that the payment equates to the settlement date fair value of the shares withheld, and in the consolidated statement of cash flows is included within cash flows from financing activities.

Intangible 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 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 of products approved for sale are stated at the lower of cost and net realisable value.

Raw materials inventory purchased and associated processing/manufacturing costs, related to therapeutics produced for clinical trial purposes or commercial use ahead of regulatory approval, are expensed as incurred through research and development expenditure.

Where inventory manufacturers invoice in advance of the manufacturing activities, the invoice is recorded as a prepayment within trade and other receivables.

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 financial assets held at amortised cost.

These assets arise principally from the provision of goods and services to customers (e.g. 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 Group's financial assets measured at amortised cost 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, other short term highly liquid investments with original maturities of three months or less.

Notes to the Consolidated Financial Statements
for the year ended 31 December 2020 (continued)

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.

Leases
All leases are accounted for by recognising a right-of-use asset and a lease liability except for leases of low value assets and leases with a duration of twelve months or less.

Lease liabilities are measured at the present value of the contractual payments due to the lessor over the lease term, with the discount rate determined by reference to the rate inherent in the lease unless (as is typically the case) this is not readily determinable, in which case the Group's incremental borrowing rate on commencement of the lease is used. Variable lease payments are only included in the measurement of the lease liability if they depend on an index or rate. In such cases, the initial measurement of the lease liability assumes the variable element will remain unchanged throughout the lease term. Other variable lease payments are expensed in the period to which they relate.

On initial recognition, the carrying value of the lease liability also includes: amounts expected to be payable under any residual value guarantee; the exercise price of any purchase option granted in favour of the Group if it is reasonably certain to exercise that option; and any penalties payable for terminating the lease, if the term of the lease has been estimated on the basis of termination option being exercised.

Right-of-use assets are initially measured at the amount of the lease liability, reduced for any lease incentives received, and increased for: lease payments made at or before commencement of the lease; initial direct costs incurred; and the amount of any provision recognised where the Group is contractually required to dismantle, remove or restore the leased asset.

Subsequent to initial measurement, lease liabilities increase as a result of interest charged at a constant rate on the balance outstanding and are reduced for lease payments made. Right-of-use assets are amortised on a straight-line basis over the remaining term of the lease or over the remaining economic life of the asset if, rarely, this is judged to be shorter than the lease term.

For contracts that both convey a right to the Group to use an identified asset and require services to be provided to the Group by the lessor, the Group has elected to account for the entire contract as a lease, i.e. it does not allocate any amount of the contractual payments to, and account separately for, any services provided by the supplier as part of the contract.

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 nor 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.

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.

The directors consider that the research and development tax credit recognised in respect of 2020, which amounts to £3.8 million (2019: £0.9 million), is a critical accounting estimate on account of its size.

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, with the exception of some manufacturing work in progress assets. All losses were generated in the United Kingdom.

4. Loss from operations

The loss from operations has been arrived at after charging:

	2020 £000	2019 £000
Depreciation of property, plant and equipment	**90**	83
Depreciation of right-of-use assets	**161**	67
Amortisation of intangible assets	**9**	13
Operating lease rentals payable (out of IFRS 16 scope):		
Land and buildings	**–**	42
Other operating lease rentals	**–**	54

The fees of the Group's auditor, BDO LLP, for services provided are analysed below:

	2020 £000	2019 £000
Fees payable to the Company's auditor for the audit of the Group and Company financial statements	**25**	21
Fees payable to the Company's auditor for other services:		
The audit of the Company's subsidiary, pursuant to legislation	**16**	14
Audit-related assurance services	**7**	6
Tax compliance services	**9**	7
Tax advisory services	**37**	–
Total fees	**94**	48

5. Employee benefit expense

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

	2020	2019
Research	**14**	11
Administration	**4**	3
	18	14

Their aggregate remuneration comprised:	2020 £000	2019 £000
Wages and salaries	**1,530**	1,293
Social security costs	**291**	164
Pension costs – defined contribution plans	**124**	105
Total cash-settled remuneration	**1,945**	1,562
Accrued holiday pay	**59**	(6)
Share-based payment	**207**	111
Total remuneration	**2,211**	1,667

For the purpose of presentation in the consolidated statement of comprehensive income, remuneration costs of £1,116,000 (2019: £788,000) are included in research and development expenditure and £1,095,000 (2019: £879,000) are included in other administrative expenses.

Notes to the Consolidated Financial Statements
for the year ended 31 December 2020 (continued)

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 Directors' Remuneration Report on page 27, which are ascribed as forming part of these financial statements.

6. Finance income and expense

Finance income represents bank interest receivable.

Finance expense represents interest expense on lease liabilities.

7. Taxation

Current tax

	2020 £000	2019 £000
UK corporation tax credit on loss for the year	**(3,771)**	(865)
Adjustment in respect of prior years	**(45)**	(43)
Total income tax credit	**(3,816)**	(908)

The tax assessed on the loss on ordinary activities for the year is different to the standard rate of corporation tax in the UK of 19% (2019: 19%). The differences are reconciled below:

	2020 £000	2019 £000
Loss on ordinary activities before tax	**(17,732)**	(4,793)
Loss on ordinary activities before tax multiplied by the standard rate of corporation tax in the UK	**(3,369)**	(911)
Effects of:		
Tax relief on share option exercises	**(277)**	–
Expenses not deductible for tax purposes	**39**	21
Enhanced research and development relief	**(2,940)**	(674)
Variable rates on tax losses surrendered for research and development tax credit	**1,170**	269
Movement in unrecognised losses and temporary differences	**1,606**	430
Adjustment in respect of previous years	**(45)**	(43)
Total tax credit for the current year	**(3,816)**	(908)

Deferred taxation

Changes in tax rates and factors affecting the future tax charge

The expected reduction in main UK corporation tax rate to 17% from 1 April 2020 enacted by the Finance Act 2016 was reversed in the Finance Act 2020. Therefore, the UK statutory tax rate remains at 19% and the rate used to calculate any deferred tax balances at 31 December 2020 has increased from 17% to 19%.

7. Taxation (continued)

Recognised deferred taxation

	2020 £000	2019 £000
Accelerated capital allowances	**(3)**	(12)
Other temporary differences	**(18)**	(2)
Trading losses	**21**	14
Charge for the year	**–**	–

Unrecognised deferred taxation

At 31 December 2020 the Group has trading losses carried forward which are available for offset against future profits of the Group amounting to £24,254,000 (2019: £16,653,000) and non-trading losses of £2,847,000 (2019: £2,444,000). At 31 December 2020 the Group has an unrecognised deferred tax asset in respect of these losses of £5,149,000 (2019: £3,247,000). 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 £8,921,000 (2019: £248,000) and a deferred tax asset of £1,695,000 (2019: £42,000) 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:

	2020 £000	2019 £000
Unrecognised deferred tax asset at the start of the year	**(3,289)**	(2,995)
Change in tax rate	**(387)**	–
Movement in the year	**(3,168)**	(294)
Unrecognised deferred tax asset at the year-end	**(6,844)**	(3,289)

8. Loss per ordinary share

	2020 £000	2019 £000
Loss attributable to ordinary equity holders of the parent company (£000)	**(13,916)**	(3,885)
Weighted average number of ordinary shares in issue (000)	**147,120**	109,433
Basic and diluted loss per share (pence)	**(9.46)**	(3.55)

Basic loss per share is calculated by dividing the loss attributable to ordinary equity holders of the parent company by the weighted average number of ordinary shares in issue during the year.

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 of IAS 33.

Notes to the Consolidated Financial Statements
for the year ended 31 December 2020 (continued)

9. Intangible assets

	Patent costs £000
Cost	
At 1 January 2019 and 31 December 2019	212
Additions	37
At 31 December 2020	**249**
Amortisation	
At 1 January 2019	183
Charge for the year	13
At 31 December 2019	196
Charge for the year	9
At 31 December 2020	**205**
Net book amount	
At 31 December 2020	**44**
At 31 December 2019	16
At 1 January 2019	29

At 31 December 2020 £44,000 (31 December 2019: £16,000) of the net book amount relates to interferon beta patent costs.

10. Property, plant and equipment

	Computer equipment £000	Laboratory and clinical equipment £000	Total £000
Cost			
At 1 January 2019	44	520	564
Additions	7	3	10
At 31 December 2019	51	523	574
Additions	8	31	39
At 31 December 2020	**59**	**554**	**613**
Depreciation			
At 1 January 2019	39	151	190
Charge for the year	3	80	83
At 31 December 2019	42	231	273
Charge for the year	5	85	90
At 31 December 2020	**47**	**316**	**363**
Net book value			
At 31 December 2020	**12**	**238**	**250**
At 31 December 2019	9	292	301
At 1 January 2019	5	369	374

11. Leases

The Group has one lease with its landlord, the University of Southampton, which provides the Group with office space and access to laboratory equipment. A new two-year lease was entered into with effect from 1 August 2019.

The lease liability has been measured at the present value of the contractual payments due to the lessor over the lease term using a discount rate of 5%, which is an estimate of the discount rate applicable to a property lease.

	Land and buildings £000	Plant and machinery £000	Total £000
Right-of-use assets			
At 1 January 2019	–	–	–
Additions	161	161	322
Depreciation	(34)	(33)	(67)
At 31 December 2019	127	128	255
Depreciation	(80)	(81)	(161)
At 31 December 2020	**47**	**47**	**94**

	Land and buildings £000	Plant and machinery £000	Total £000
Lease liabilities			
At 1 January 2019	–	–	–
Additions	161	161	322
Interest expense related to lease liabilities	3	3	6
At 31 December 2019	164	164	328
Interest expense related to lease liabilities	5	5	10
Lease payments	(105)	(105)	(210)
At 31 December 2020	**64**	**64**	**128**

Lease liabilities	Up to 3 months £000	Between 3 and 12 months £000	Between 1 and 2 years £000
At 31 December 2020	**42**	**86**	**–**
At 31 December 2019	81	120	127

	2020 £000	2019 £000
Analysis of lease expense		
Depreciation of right-of-use assets		
Land and buildings	**80**	34
Plant and machinery	**81**	33
Short term lease expense	**–**	96
Charge to operating loss	**161**	163
Interest expense related to lease liabilities	**10**	6
Charge to loss before taxation for leases	**171**	169

Notes to the Consolidated Financial Statements
for the year ended 31 December 2020 (continued)

12. Inventories

	2020 £000	2019 £000
Raw materials and consumables	**41**	41

Raw materials comprises the Group's BioBank.

13. Trade and other receivables

Amounts receivable within one year:	2020 £000	2019 £000
Other tax and social security	**551**	43
Prepayments and accrued income	**8,821**	96
	9,372	139

14. Cash and cash equivalents

	2020 £000	2019 £000
Cash available on demand	**74,976**	2,454

At 31 December 2020, £5,000,000 was on 35 days' notice (2019: £750,000 on 32 days' notice).

15. Trade and other payables

	2020 £000	2019 £000
Trade payables	**1,541**	161
Social security and other taxes	**224**	114
Accrued expenses and deferred income	**1,514**	1,215
	3,279	1,490

16. Financial instruments

	Notes	2020 Book and fair value £000	2019 Book and fair value £000
Financial assets			
Amortised cost			
Trade and other receivables	(i)	**1**	44
Cash and cash equivalents (less than one year)		**74,976**	2,454
Total		**74,977**	2,498

	Notes	2020 Book and fair value £000	2019 Book and fair value £000
Financial liabilities			
Other financial liabilities			
Trade and other payables (less than one year)	(ii)	**3,055**	1,376
Lease liabilities (less than one year)		**128**	201
Lease liabilities (greater than one year)		**–**	127
Total		**3,183**	1,704

(i) Trade and other receivables shown above excludes prepayments and other taxes, which are not a contractual right to receive cash, amounting to £9,371,000 (2019: £95,000).

(ii) Trade and other payables shown above excludes amounts due in respect of social security and other taxes, which are not a contractual obligation to pay cash, amounting to £224,000 (2019: £114,000).

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, credit risk and currency risk.

Interest rate risk

The Group's deposit balances are subject to the risk of fluctuating base rates.
Interest rate risk profile of financial assets, excluding short-term debtors:

	2020 Floating rate financial assets £000	2019 Floating rate financial assets £000
Euro	**2,297**	5
Sterling	**67,216**	2,449
US Dollar	**5,463**	–
	74,976	2,454

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 £46,000 (2019: £9,000).

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 2020 and 31 December 2019 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 follows a risk-averse policy of treasury management. Sterling deposits are held with one or more approved UK-based financial institutions (HSBC UK Bank plc and National Westminster Bank Plc, which at 31 December 2020 had good short term credit ratings, being at least F1 for Fitch, P-1 for Moody's and A-1 for Standard and Poor's) and in the Institutional Cash Series plc Institutional Sterling Liquidity Fund managed by BlackRock Investment Management (UK) Limited (rated at 31 December 2020 as AAAmmf by Fitch, Aaa-mf by Moody's and AAAm by Standard and Poor's). The Group's primary treasury objective is to minimise exposure to potential capital losses whilst at the same time securing prevailing market rates. The Group seeks to lessen risk by placing its cash deposits with the three above institutions.

Currency risk

During the year under review, the Group was exposed to Euro and US Dollar currency movement as some of the manufacturing costs and clinical trial costs are denominated in these currencies. To naturally hedge against currency movement, the Group purchases these currencies in advance of payment due dates.

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 2020 amounted to £85.14 million (2019: £2.25 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.

Cash and cash equivalents held by the Group at 31 December 2020 amounted to £74.98 million and comprised short-term deposits (with original maturities of greater than three months and less than one year) and cash and cash equivalents as shown below:

	2020 £m	2019 £m	2018 £m	2017 £m	31 Dec 2016 £m
Short-term deposits	–	–	0.05	2.00	1.66
Cash and cash equivalents	74.98	2.45	5.28	4.85	3.11
Net funds	**74.98**	**2.45**	**5.33**	**6.85**	**4.77**

The Group did not have any bank borrowings as at 31 December 2020 (2019: £nil).

There have been ten significant issues of shares raising a total (net of costs) of £127.61 million, with the most recent two raising £97.89 million in March and October 2020. The other major sources of funding received by the Group from the formation of the business until 31 December 2020 have been: revenues from licensing transactions of £9.25 million, research and development tax credits of £5.49 million, bank interest of £1.81 million, and revenues from collaborative work of £0.79 million.

17. Share capital, share premium and share-based payment

	Notes	Number of shares	Ordinary shares of 1p each £000	Share premium £000	Total £000
At 1 January 2019 and 2020		109,433,442	1,094	28,262	29,356
Issue of ordinary shares	(i) - (v)	90,480,960	905	100,170	101,075
Costs of issue of shares		–	–	(3,187)	(3,187)
At 31 December 2020		**199,914,402**	**1,999**	**125,245**	**127,244**

(i) A total of 40,000,000 ordinary shares of 1p were issued on 30 March 2020 (10,943,295 ordinary shares) and 15 April 2020 (29,056,705 ordinary shares) at a premium of 34p to fund COVID-19 clinical trial activity and drug manufacturing and other supply chain considerations, and also to strengthen the Company's balance sheet.

(ii) A total of 49,753,026 ordinary shares of 1p were issued on 19 October 2020 (14,943,300 ordinary shares) and 4 November 2020 (34,809,726 ordinary shares) at a premium of 174p to fund: a Phase III clinical trial in COVID-19 patients; the scale up of SNG001 manufacturing and devices; the generation of additional data to support SNG001 clinical development, manufacturing processes and regulatory activities; the strengthening of the Company's balance sheet; and the net settlement of options.

(iii) 534,172 ordinary shares of 1p were issued on 19 October 2020 at par following the exercise and net settlement of share options under the Company's LTIP.

(iv) 177,300 ordinary shares of 1p were issued on 21 October 2020 at par following the exercise of share options under the Company's LTIP.

(v) 16,462 ordinary shares of 1p were issued on 22 October 2020 at par following the exercise of share options under the Company's LTIP.

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.

Options

At 31 December 2020 there were options outstanding over 8,671,279 un-issued ordinary shares, equivalent to 4.3% of the issued share capital, as follows:

Date of grant	Note	Number of shares	Exercise price	Earliest exercise date	Latest exercise date
21 September 2011 (LTIP)	(i)	1,431,282	1p	21 September 2014	20 September 2021
5 April 2018 (LTIP)	(ii)	2,822,316	1p	5 April 2021	4 April 2028
4 April 2019 (LTIP)	(ii)	2,649,696	1p	4 April 2022	3 April 2029
18 June 2020 (LTIP)	(ii)	1,767,985	1p	18 June 2023	17 June 2030
		8,671,279			

Notes

(i) These options are vested in full.
(ii) The vesting performance conditions for these options are detailed in the Directors' Remuneration Report on page 25.

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:

	2020 Number	2020 Weighted average exercise price	2019 Number	2019 Weighted average exercise price
Outstanding at start of the year	**8,487,515**	**1.6p**	6,087,819	2.6p
Granted during the year	**1,767,985**	**1.0p**	2,649,696	1.0p
Exercised during the year	**(1,371,456)**	**1.0p**	–	n/a
Lapsed during the year	**(212,765)**	**23.5p**	(250,000)	20.0p
Number of outstanding options at year-end	**8,671,279**	**1.0p**	8,487,515	1.6p

At 31 December 2020, 1,431,282 share options were capable of being exercised, with an exercise price of 1p (2019: 3,015,503, with exercise prices ranging from 1p to 23.5p). The options outstanding at 31 December 2020 had a weighted average remaining contractual life of 6.9 years (2019: 6.1 years). Vesting conditions are disclosed in the Directors' Remuneration Report.

The Group uses a number of share-based incentive schemes as detailed above and in the Directors' Remuneration Report on pages 24 and 25. 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
21 Sept 2011	LTIP	1,431,282	1p	22.5p	13.4p	3	0.79%	56%	Market
5 Apr 2018	LTIP	2,822,316	1p	13.0p	7.5p	3	0.90%	56%	Market
4 Apr 2019	LTIP	2,649,696	1p	12.5p	6.2p	3	0.70%	59%	Market
18 Jun 2020	LTIP	1,767,985	1p	39.5p	25.8p	3	0.00%	80%	Market
		8,671,279							

The Company has applied IFRS 2 to all the above share-based payments and the following comments apply to these options:

(i) Stochastic valuation methodology was used for all awards.

(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) Volatility for the grants made in 2018 and 2019 was calculated by reviewing share price movement over the period of three years prior to grant, excluding any large share price movements (as these were not considered to be representative of future expectations of volatility). Volatility for the grant made in 2020 was calculated by reviewing share price movement over the period of three years prior to grant with no adjustments.

(vi) The charge for the year ended 31 December 2020 for share-based payment amounted to £207,000 (2019: £111,000). An amount of £1,291,000 (2019: £nil) was debited directly to reserves following the net settlement of share options in order to satisfy scheme participants' tax and NI liabilities on options exercised.

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. Related party transactions and balances

Details of key management personnel and their compensation are given in note 5 and on page 27 of the Directors' Remuneration Report.

20. Other commitments

At 31 December 2020 the Group had entered into non-cancellable purchase commitments amounting to £9.7 million (2019: £nil) in respect of manufacturing-related activities.

Parent Company Balance Sheet

as at 31 December 2020

Company number: 5233429

	Notes	31 December 2020 £000	31 December 2019 £000
Fixed assets			
Investments	4	**51,059**	26,893
Current assets			
Debtors	5	**143**	109
Cash at bank and in hand		**74,694**	2,445
		74,837	2,554
Creditors: amounts falling due within one year	6	**(93)**	(44)
Net current assets		**74,744**	2,510
Total assets less current liabilities		**125,803**	29,403
Capital and reserves			
Called up share capital		**1,999**	1,094
Share premium account		**125,245**	28,262
Retained earnings		**(1,441)**	47
Shareholders' funds		**125,803**	29,403

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 Company's loss for the year ended 31 December 2020 was £404,000 (2019: loss of £221,000).

The financial statements on pages 53 to 57 were approved and authorised for issue by the Board of directors on 11 May 2021 and signed on its behalf by:

Richard Marsden
Chief Executive Officer

John Ward
Chief Financial Officer

Parent Company Statement of Changes in Equity

for the year ended 31 December 2020

	Share capital £000	Share premium account £000	Retained earnings £000	Shareholders' funds £000
At 1 January 2019	1,094	28,262	157	29,513
Loss for the year and total comprehensive loss	–	–	(221)	(221)
Share-based payment credit	–	–	111	111
At 31 December 2019	1,094	28,262	47	29,403
Loss for the year and total comprehensive loss	–	–	(404)	(404)
Issue of ordinary shares	905	100,170	–	101,075
Transaction costs in respect of share issues	–	(3,187)	–	(3,187)
Share-based payment credit	–	–	207	207
Net settlement of share options	–	–	(1,291)	(1,291)
At 31 December 2020	**1,999**	**125,245**	**(1,441)**	**125,803**

1. Accounting policies

Basis of preparation

The financial statements have been prepared in accordance with 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.

Going Concern

The directors have prepared financial forecasts for the next twelve months to estimate the likely cash requirements of the Company and its subsidiary Synairgen Research Limited, to which the Company has confirmed its intention to provide financial support for a period of not less than twelve months from the date that its financial statements for the year ended 31 December 2020 are signed, given its stage of development and lack of recurring revenues. In preparing these financial forecasts, the directors have made certain assumptions with regards to the timing and amount of future expenditure over which they have control. The directors have attempted to take a prudent view in preparing these forecasts, recognising the inherent variability in costs of the ongoing Phase III clinical trial of SNG001 in COVID-19 patients and the manufacturing scale up activities being conducted by Synairgen Research Limited.

After due consideration of these forecasts and current cash resources, 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 financial statements have been prepared on a going concern basis.

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.

Investments 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.

Financial assets

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

These assets incorporate 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 debtors, investments: short-term deposits and cash and cash equivalents in the balance sheet. Investments: short-term deposits 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 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 creditors are initially recognised at fair value and subsequently carried at amortised cost using the effective interest rate method.

Share-based payments

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.

Taxation

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. 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.

The Company holds a significant investment in its subsidiary, Synairgen Research Limited, of £51.1 million (2019: £26.9 million).

At 31 December 2020, the Directors assessed recoverable amount by reference to Synairgen Research Limited's fair value less costs to sell, estimated by reference to the AIM market capitalisation of the Group (since all group intellectual property is owned by the subsidiary) at that date, £306 million. No impairment was identified.

3. Profit and loss account

The only employees of the Company during 2020 and 2019 were the three executive directors. Their aggregate remuneration, which is borne by the Company's subsidiary undertaking, comprised:

	2020 £000	2019 £000
Wages and salaries	**956**	921
Social security costs	**130**	126
Pension costs – defined contribution plans	**59**	54
Total cash-settled remuneration	**1,145**	1,101
Accrued holiday pay	**43**	(5)
Share-based payment	**152**	85
Total remuneration	**1,340**	1,181

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 27, which are ascribed as forming part of these financial statements.

Auditor's remuneration is disclosed in note 4 to the Group accounts on page 43.

Notes to the Parent Company Financial Statements

for the year ended 31 December 2020 (continued)

4. Investments

	Investment in subsidiary undertaking £000	Capital contribution £000	Total £000
At 1 January 2020	140	26,753	26,893
Capital contribution for the year	–	25,250	25,250
Subsidiary share-based payment	–	207	207
Net settlement of share options	–	(1,291)	(1,291)
At 31 December 2020	**140**	**50,919**	**51,059**

At 31 December 2020, the Company has an investment in the following subsidiary undertaking:

Name of company	Registered address	Proportion of voting rights and ordinary share capital held	Nature of business
Synairgen Research Limited	Mailpoint 810, Southampton General Hospital, Tremona Road, Southampton SO16 6YD	100%	Drug discovery and development

5. Debtors

	2020 £000	2019 £000
Other tax and social security	**29**	3
Prepayments and accrued income	**97**	103
Amounts due from subsidiary undertaking	**17**	3
	143	109

All amounts fall due for payment within one year.

6. Creditors: amounts falling due within one year

	2020 £000	2019 £000
Trade creditors	**33**	3
Accruals and deferred income	**60**	41
	93	44

7. 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 51 and 52.

Corporate Directory

Company number
5233429

Directors
Executive: Richard Marsden, Dr Phillip Monk, John Ward

Non-executive: Simon Shaw (Chairman), Iain Buchanan, Dr Bruce Campbell, Prof. Sir Stephen Holgate CBE

Secretary
Simon Holden

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Bankers
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Joint broker
Numis Securities Limited
The London Stock Exchange Building, 10 Paternoster Square, London EC4M 7LT

Registrars
Link Group
10th Floor, Central Square, 29 Wellington Street, Leeds LS1 4DL

Solicitors
Fieldfisher LLP
Riverbank House, 2 Swan Lane, London EC4R 3TT

Glossary

Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) programme
NIH's ACTIV programme is a public-private partnership to develop a coordinated research strategy to speed up the development of the most promising treatments and vaccine candidates for COVID-19

ACTIV-2
A master protocol designed for evaluating multiple investigational agents compared to placebo in adults with mild to-moderate COVID-19, not requiring hospitalisation

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

Aerogen-Ultra
A portable mesh nebuliser manufactured by Aerogen that allows for continuous delivery of inhaled drugs to the airways

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-1a formulation (aka SNG001) used for the AstraZeneca INEXAS study. See INEXAS

Bacteria
Single-cell organisms that are found everywhere and are the cause of many diseases

BCSS
The breathlessness, cough and sputum scale (BCSS) is a three-item questionnaire, rating breathlessness, cough and sputum on a 5-point scale from 0 (no symptoms) to 4 (severe symptoms)

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

Biologics License Application (BLA)
A request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce. Regulated by the FDA

Breathlessness, Cough and Sputum Scale (BCSS)
A three-item questionnaire rating breathlessness, cough and sputum on a 5-point Likert scale from 0 (no symptoms) to 4 (severe symptoms)

Brief Pain Inventory - Short Form
A 9 item self-administered questionnaire used to evaluate the severity of a patient's pain and the impact of this pain on the patient's daily functioning

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 short-acting beta-agonist drugs are the most commonly used

Glossary

(continued)

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

CAT
The COPD Assessment Test (CAT) is a patient-completed questionnaire, which assists patients and their physicians in quantifying the impact of COPD on the patient's health and quality of life

CellScale MicroSquisher
A machine for measuring the stiffness of tissue

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

Collagen
The main structural protein found in skin and other connective tissues

Community Acquired Pneumonia (CAP)
Pneumonia that is acquired outside of the hospital setting

Contract Research Organisation (CRO)
A company that provides support to the pharmaceutical industries in the form of research services out sourced on a contract basis

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

COVID-19
Coronavirus disease 2019 is a respiratory illness caused by SARS-CoV-2

COVID-19 symptom assessment
A self-reported assessment of the presence of COVID-19 symptoms

Cross-link
A chemical bond that acts like a glue, holding collagen fibres together. Lysyl oxidase (LOX) enzymes catalyse this process

DNA
Nucleic acid that carries genetic information in the cell

Double-blind
A double-blind study is one in which neither the patients nor the clinical staff know who is receiving a particular treatment

Drug Product
The formulated drug substance with excipients. These excipients do not have a therapeutic effect but can influence the delivery of the drug substance. The drug product is typically the final marketed dosage form of the drug substance for example a tablet or capsule

Drug Substance
The unformulated active pharmaceutical ingredient

DSMC
A Data Safety Monitoring Committee (DSMC) reviews and assesses safety information from a clinical trial

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

Emergency Use Authorisation (EUA)
Authorisation by the FDA of unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases

European Medicines Agency (EMA)
The EMA evaluate and supervise medicines for the benefit of public and animal health in the European Union (EU)

EuroQuol 5 Dimension 5 Level (Eq-5D-5L)
A self-assessed, health related, quality of life questionnaire. The scale measures quality of life on a 5-component scale including mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The responses record 5 levels of severity

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

Fast Track Designation
A designation by the United States Food and Drug Administration (FDA) of an investigational drug for expedited review to facilitate development of drugs to treat a serious or life-threatening condition to fill an unmet medical need

FDA
USA Food and Drug Administration. An American body that is responsible for protecting public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation

FEV_1
Forced Expiratory Volume in the first second. The volume of air that can be forced out in one second after taking a deep breath, an important measure of pulmonary function

Fibroblast
A fibroblast is a type of cell that synthesizes the extracellular matrix and collagen, the structural framework for animal tissues, and plays a critical role in wound healing

Fibrosis
The thickening and scarring of connective tissue, usually as a result of injury

BIOFIRE® FILMARRAY®
A system which enables rapid simultaneous testing for a panel of viruses and bacteria in patient samples and was used by Synairgen in SG015

Functional Assessment of Chronic Illness Therapy – Fatigue (FACIT-F)
A 13-item tool that measures an individual's level of fatigue during their usual daily activities over the past week. The level of fatigue is measured on a four-point Likert scale (4 = not at all fatigued to 0 = very much fatigued)

Generalised Anxiety Disorder Assessment (GAD-7)
A seven-item instrument that is used to measure or assess the severity of generalised anxiety disorder (GAD)

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

I-neb
A nebuliser manufactured by Philips that delivers inhaled drugs to the airway

INEXAS
AstraZeneca's Phase IIa study entitled 'A Study in Asthma Patients to Evaluate Efficacy, Safety and Tolerability of 14 Days Once Daily Inhaled Interferon Beta-1a After the Onset of Symptoms of an Upper Respiratory Tract Infection'

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

Intention to Treat (ITT)
All patients that were enrolled and randomly assigned to a treatment arm

Investigational New Drug (IND)
A drug developed by the sponsor that is ready for clinical trials in humans

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

Long COVID
Long COVID (Post-COVID-19 syndrome) is defined as "signs and symptoms that develop during or following an infection consistent with COVID-19, that continue for more than 12 weeks and are not explained by an alternative diagnosis"

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), 3 (LOXL3), 4 (LOXL4)
Each is a member of a family of enzymes which catalyses cross-linking of collagen and elastin

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

Managed Access Programme
A programme through which physicians can prescribe, within their professional responsibility, a yet unapproved treatment for patients with serious or life-threatening diseases or conditions

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

National Early Warning Score (NEWS2)
A system for scoring the physiological measurements that are routinely recorded at the patient's bedside; respiration rate, oxygen saturation, systolic blood pressure, pulse rate, level of consciousness or new confusion and temperature

National Institute of Health and Research (NIHR)
UK funding body for health and care research

Operation Warp Speed (OWS)
A public–private partnership initiated by the U.S. government to facilitate and accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics

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

Patient Health Questionnaire (PHQ-9)
PHQ-9 is a self-assessed nine question form used to screen depression and monitor changes in signs/symptoms of depression

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

Pharmaxis or Pharmaxis Limited
An established pharmaceutical research company based in Australia with whom Synairgen collaborated on the LOXL2 programme. Pharmaxis is quoted on the Australian Securities Exchange (ASX) under the code PXS. Its website address is www.pharmaxis.com.au

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

Pre-clinical
A stage of drug development preceding human clinical trials

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

Glossary

(continued)

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

Randomisation
The random assignment of patients in a clinical trial to different treatment groups (e.g. active drug or placebo)

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

Safety study
See Phase I Clinical Trial

SARS-CoV-2
Severe Acute Respiratory Syndrome-Coronavirus 2 is the virus strain that causes COVID-19

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

SG005
A randomised, double-blind, 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

SG015
A randomised, double-blind, placebo-controlled phase II study in COPD patients without (Part 1) and with (Part 2) a confirmed respiratory virus infection, assessing antiviral biomarker responses and clinical effects of inhaled SNG001 compared to placebo

SG016 Home Study
Synairgen's randomised, double-blind, placebo-controlled trial to determine the safety and efficacy of inhaled SNG001 (IFN-β1a for nebulisation) for the treatment of patients with confirmed SARS-CoV-2 infection in the home environment

SG016 Hospital Study
Synairgen's randomised, double-blind, placebo-controlled trial to determine the safety and efficacy of inhaled SNG001 (IFN-β1a for nebulisation) for the treatment of patients with confirmed SARS-CoV-2 infection in the hospital setting

SG018
Synairgen's Phase III Trial evaluating inhaled interferon beta in hospitalised COVID-19 patients. A randomised double-blind placebo-controlled study being conducted in approximately 20 countries enrolling a total of 610 COVID-19 patients

SNG001
A formulation of Interferon Beta-1a delivered to the lung using a nebuliser

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-β

United States National Institute of Health (US NIH)
The medical research agency of the USA

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

Virus
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

World Health Organisation (WHO)
A United Nations body responsible for international public health

World Health Organisation (WHO) Ordinal Scale for Clinical Improvement (OSCI)
A scale used to measure clinical improvement in patients from a score of 0; uninfected to 8; death

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

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