Press release

Synairgen plc

('Synairgen' or the 'Company')

Interim results for the six months ended 30 June 2020

Southampton, UK – 29 September 2020: Synairgen plc (LSE: SNG), the respiratory drug discovery and development company, today announces its unaudited interim results for the six months ended 30 June 2020.

Highlights (including post period-end)

Operational

- Positive results from SG016, its double-blind placebo-controlled Phase II trial of SNG001 in hospitalised COVID-19 patients announced in July
- The Company extended the SG016 Phase II trial to include a further 120 patients with confirmed COVID-19 to be dosed in the home environment (ongoing)
- Positive results from interim analysis of SG015, its double-blind placebo-controlled Phase II trial of SNG001 in COPD patients announced in September, supporting the COVID-19 programme
- Patent applications for SNG001 in COVID-19 patients and in exacerbating COPD patients undergoing treatment with systemic corticosteroids were submitted post period-end
- Synairgen launched a Managed Access Program with Clinigen, to provide SNG001 to hospitalised COVID-19 patients – see separate announcement issued today
- The Company is currently in discussions with regulatory agencies to establish the route to approval of SNG001 as a treatment for COVID-19
- The Company is also investing in supply chain activities to ensure that drug and aerosol delivery system availability can meet potential demand, pending approval

Financial

- In March 2020, Synairgen raised £14.0 million (before expenses) in an equity issue to fund its initial COVID-19 related activities and strengthen its balance sheet
- Research and development expenditure for the six months ended 30 June 2020 was £4.47 million (30 June 2019: £1.69 million) as the Company advanced its clinical trial of SNG001 in COVID-19 patients and scale-up activities
- The loss from operations for the six months ended 30 June 2020 was £5.08 million (30 June 2019: £2.21 million loss)
- Cash balances of £10.9 million at 30 June 2020 (30 June 2019: £3.52 million)

Richard Marsden, CEO of Synairgen, said: *"The first six months of this year have been the most significant in Synairgen's history. We were delighted to announce positive results from our hospital-based COVID-19 trial in July, and have been working tirelessly on the progression of SNG001 as a potential treatment for COVID-19 patients. With further positive results from our interim analysis of SNG001 in COPD announced in September 2020, we feel well-equipped to realise our strategy of progressing inhaled interferon beta for the treatment of respiratory viruses. I'd like to thank everyone involved in the Company and trials for all their hard work to date."*

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) No. 596/2014 ('MAR').

For further enquiries, please contact:

Synairgen plc
Richard Marsden, Chief Executive Officer
John Ward, Finance Director
Tel: + 44 (0) 23 8051 2800

finnCap
Geoff Nash, Kate Bannatyne, Charlie Beeson (Corporate Finance)
Alice Lane, Manasa Patil (ECM)
Tel: + 44 (0) 20 7220 0500

Consilium Strategic Communications (Financial Media and Investor Relations)
Mary-Jane Elliott, Sue Stuart, Olivia Manser
synairgen@consilium-comms.com
Tel: +44 (0) 20 3709 5700

Notes for Editors

About Synairgen

Synairgen is a respiratory drug discovery and development company founded by University of Southampton Professors Stephen Holgate, Donna Davies and Ratko Djukanovic. The business, focused primarily on lung viral defence in asthma, COPD, and COVID-19, uses its differentiating human biology BioBank platform and world-renowned international academic KOL network to discover and develop novel therapies for respiratory disease. Synairgen is quoted on AIM (LSE: SNG). For more information about Synairgen, please see https://www.synairgen.com

OPERATING REVIEW

Summary

During the first half of the year, Synairgen made significant clinical progress with its inhaled formulation of interferon beta, SNG001. Most importantly, Synairgen's results from its Phase II trial of SNG001 in 101 hospitalised COVID-19 patients indicated that its inhaled interferon beta could provide a valuable treatment option in the face of the global pandemic. With further safety, efficacy and other supporting data for SNG001 provided from the interim analysis of Synairgen's Phase II COPD trial in September 2020, the Company is currently wholly focused on working with governments, regulators and other key stakeholders to progress SNG001 as a treatment for COVID-19.

COVID-19

COVID-19, caused by the SARS-CoV-2 virus, is a global threat and there is 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 heart and lung complications or diabetes are at greatest risk of developing severe or fatal disease.

Interferon beta applicability to 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 which 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. Synairgen's SNG001 is a formulation of IFN-beta-1a for direct delivery to the lungs via nebulisation. It is pH neutral, and is free of mannitol, arginine and human serum albumin, making it suitable for inhaled delivery direct to the site of action.

The COVID-19 trial – SG016

Synairgen's clinical trial in COVID-19 patients, SG016, is a double-blind, placebo-controlled trial. The two-part 221 patient trial comprises 101 patients initiated in the hospital setting (results announced 20 July 2020, see below), and a further 120 patients in the home setting (currently ongoing).

Hospital trial

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. These sites are leading centres in respiratory medicine in the UK, whose internationally recognised experts are working together to accelerate development and discovery of treatments for COVID-19.

Results of SG016 trial in hospital patients

On 20 July 2020, the Company announced positive top-line results from the trial.

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.

The primary endpoint was the change in condition assessed using the WHO Ordinal Scale for Clinical Improvement (OSCI; see table below) during the dosing period in the Intention-to-Treat population (ITT).

WHO Ordinal Scale for Clinical Improvement (Feb 2020)

Patient State	Descriptor	OSCI Score
Uninfected	No clinical or virological evidence of infection	0
Ambulatory	No limitation of activities	1
	Limitation of activities	2
Hospitalised – Mild disease	Hospitalised, no oxygen therapy	3
	Oxygen by mask or nasal prongs	4
Hospitalised – Severe disease	Non-invasive ventilation or high-flow oxygen	5
	Intubation and mechanical ventilation	6
	Ventilation + additional organ support	7
Dead	Death	8

As no clinical data had been collected using the OSCI in the study population at the time, multiple pre-specified analyses were conducted at fixed time points and over the whole dosing period, with the aim of learning about SNG001 as a potential treatment for COVID-19 patients, and to inform future trial design. There was no hierarchy within the analyses or adjustments made for multiplicity. Top-line data was presented on 20 July.

101 patients were randomised; 48 received SNG001 and 50 received placebo (ITT population; patients who took at least one dose of study medication). Of these 86, 43 in each arm, met the criteria for the per-protocol population (PP population; positive PCR test, had taken at least two out of their first three scheduled doses and had no protocol deviations impacting on efficacy).

Results of primary endpoint analyses are shown in the tables below (where an Odds Ratio (OR) or Hazard Ratio (HR) of 1 would indicate no difference between SNG001 and placebo):

A ratio above 1 signifies a greater likelihood of (for HR), or odds of (for OR), the effect occurring on SNG001 compared to placebo

	ITT population (n = 98)		**PP population (n = 86)**	
Analysis	**Ratio (95% CI)**	**p-value**	**Ratio (95% CI)**	**p-value**
Odds of improvement across the OSCI (any improvement at day 15/16 compared to baseline)	OR 2·32 (1·07, 5·04)	0·033	OR 2.80 (1.21, 6.52)	0·017
Time to Recovery[a] (time from first dose to no limitation of activities without subsequent relapse)	HR 2·19 (1·03, 4·69)	0·043	HR 2.29 (1.07, 4.91)	0.033
Odds of Recovery (no limitation of activities recorded at day 15/16 without subsequent relapse)	OR 3·19 (1·24, 8·24)	0·017	OR 3.18 (1.21, 8.39)	0.019
Time to Hospital Discharge[b] (time from first dose to hospital discharge with no subsequent hospital re-admission)	HR 1·37 (0·85, 2·20)	0·196	HR 1.53 (0.96, 2.42)	0.072
Odds of Hospital Discharge (discharged from hospital at day 15/16 without subsequent hospital re-admission)	OR 1·63 (0·61, 4·35)	0·330	OR 2.14 (0.64, 7.12)	0.215

[a] Recovery was defined as a post baseline OSCI score of 0 or 1 which does not rise above 1 at any subsequent visits.
[b] Hospital Discharge was defined as a post baseline OSCI score of 2 or less which does not rise above 2 at any subsequent visits.

A ratio below 1 signifies a lower likelihood of (for HR), or odds of (for OR), the effect occurring on SNG001 compared to placebo

	ITT population (n = 98)		**PP population (n = 86)**	
Analysis	**Ratio (95% CI)**	**p-value**	**Ratio (95% CI)**	**p-value**
Time to severe disease or death (time from first dose until first incidence of OSCI≥5)	HR 0·50 (0.18, 1.38)	0·179	Not calculated as not part of statistical analysis plan	
Odds of severe disease or death (OSCI≥5 at any time in the first 16 days after first dose)	OR 0·28 (0·07, 1·08)	0·064[a]	OR 0.18 (0.04, 0.93)	0.041[b]
Time to intubation or death (time from first dose until first incidence of OSCI≥6)	HR 0·38 (0·09, 1·65)	0·198	Not calculated as not part of statistical analysis plan	
Odds of intubation or death (OSCI≥6 at any time in the first 16 days after first dose)	OR 0·42 (0·09, 1·83)	0·246[b]	OR 0.31 (0.05, 1.79)	0.189[b]

[a] Using the pre-specified logistic regression analysis, SNG001 reduced the odds of developing severe disease or dying in the ITT population by 79% (OR 0·21; 95% CI: 0·04, 0·97; p=0·046). As quasi-complete separation of data occurred in some model covariates, an additional post-hoc, Firth logistic regression analysis was conducted. This showed there was a trend towards reduced odds of progression to severe disease or death in the ITT population (72% reduction; OR 0·28; 95% CI: 0·07, 1·08; p=0·064) that became significant in the per protocol population (82% reduction; OR 0.18; 95% CI: 0.04, 0.93; p=0.041).

[b] Post hoc analysis using the Firth logistic regression analysis.

Key findings

- SNG001 treatment, when compared to placebo, was associated with greater odds of improvement across the WHO OSCI and with more rapid recovery to a point where patients were no longer limited in their activity, with a greater proportion of patients recovering during the study period. There was a strong trend towards reduced odds of progression to severe disease or death in the ITT population that became significant in the per-protocol population.
- 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 and p=0.007, respectively).

Other findings

- The median duration of COVID-19 symptoms at the point dosing commenced was 10 days, suggesting that there is a wide window for effective treatment.
- 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 the 1 in 20 patients with COVID-19 who experience wide-ranging long term symptoms for at least a month and sometimes longer (known as long, long-haul or long-tail COVID).
- Three patients died during the study; all deaths occurred in patients randomised to placebo, therefore, no modelling analysis was undertaken.
- SNG001 was well tolerated.

Home Trial

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, and before severe lower respiratory tract symptoms have developed. The trial is ongoing, recruiting patients who are either aged 65 or over, or are aged 50 or over with a high-risk comorbidity. Patients must have had symptoms for less than seven (originally two) days. The home trial involves SNG001 (or placebo) being delivered to eligible participants while observing social distancing measures as implemented by the UK Government. In order to minimise risks to patients and healthcare workers in this setting, all visits are conducted by video link.

Patients interact with the trial team using Skype/Teams/Zoom or their preferred choice of video conferencing as soon as COVID-19 symptoms develop, and are informed about the trial and provide online consent. Patients will self-swab under video supervision. Within a few hours of the swab been taken, the virus test results are known. If positive for SARS-CoV-2, the drug (placebo or SNG001), aerosol delivery device, and other trial equipment are despatched to the patient. Each dose is taken under video supervision. Endpoints will also be assessed during the video calls.

This is the first trial of its type to be conducted “remotely” in this way and, if successful, may point towards a potential domiciliary care protocol for this and future viral outbreaks. The trial has however struggled to recruit patients during the summer months due to effective social distancing in the ‘shielded’ patient group. The trial completion will depend on both a second wave in the UK, and governmental support with patient recruitment to succeed.

Managed Access Program

Synairgen and Clinigen Group plc (AIM: CLIN, ‘Clinigen’), the global pharmaceutical and services company, signed an agreement to launch a Managed Access Program for SNG001 in the UK and the EU for the treatment of hospitalised COVID-19 patients – see separate announcement issued today.

Manufacturing Scale Up

In preparation for gaining approvals for SNG001, the Company has made good progress with discussions with a variety of international suppliers to scale up production of SNG001 rapidly, with the aim of being able to produce approximately 100,000 treatments per month in 2021.

Regulatory Next Steps

Synairgen is currently in discussions with regulatory agencies to establish the regulatory route to approval of SNG001 as a treatment for COVID-19.

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. COPD exacerbations are the second most common cause of unplanned hospitalisation in England.

Interferon beta (IFN-beta) applicability to COPD

COPD patients are approximately five times more likely to become severely ill (exacerbate) due to respiratory viruses than asthmatic patients, and have always been recognised as a larger potential market for a broad-spectrum antiviral product which could prevent exacerbations or accelerate recovery from exacerbation. However, half of infectious COPD exacerbations are caused by bacteria, with no virus present. This meant use of SNG001 in the context of COPD would be very challenging without a point-of-care to confirm viral infection. The bioMérieux BioFire FilmArray and other technologies which have subsequently become available, have ensured the selection and treatment of solely those patients where the presence of a virus is confirmed.

The 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 to look in addition 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

The emergence of COVID-19 made it difficult to test for viral activity in COPD patients and to dose them without potentially exposing vulnerable patients and research staff to SARS-CoV-2. Hence in March 2020 the trial was paused, 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 SNG015 trial in COPD patients

On 8 September 2020, Synairgen announced a positive interim analysis of SNG001 in COPD patients. 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 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.

Activities paused to focus on COVID-19

Synairgen's immediate priority is to progress SNG001 as a therapeutic for COVID-19 and as such the COPD programme will remain paused.

LOXL2

Pharmaxis, the Company's Australian-based partner for the antifibrotic LOXL2 inhibitor programme, updated the market on 31 July 2020 stating that it is currently pursuing a number of different partnering options to enable the drug to enter the clinic in Phase 2 trials and will provide more information when the process concludes. Synairgen is entitled to receive circa 17% of Pharmaxis' licence receipts/royalties, net of allowable expenses.

Intellectual Property

Patent filings

Adding to the Company's IP portfolio, patent applications were submitted 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.

FINANCIAL REVIEW

Statement of Comprehensive Income

The loss from operations for the six months ended 30 June 2020 was £5.08 million (six months ended 30 June 2019: £2.21 million loss; year ended 31 December 2019: £4.82 million loss). Research and development expenditure increased from £1.69 million in the six months ended 30 June 2019 to £4.47 million for the six months ended 30 June 2020 as the Company commenced its COVID-19 activities (clinical trials and manufacturing scale-up) and advanced the Phase II study in COPD. Other administrative costs for the period increased to £0.60 million from £0.52 million for the six months ended 30 June 2019 on account of greater public company costs.

The research and development tax credit increased from £0.42 million to £1.11 million on account of the higher research and development activities, equating to 25% of R&D expenditure in both periods.

The loss after tax for the period was £3.96 million (six months ended 30 June 2019: £1.77 million loss) and the basic loss per share was 3.11p (six months ended 30 June 2019: loss of 1.62p).

Fundraising

£14 million (before expenses) was raised in March 2020 by the issue of 40 million ordinary shares at a price of 35p per share to fund the following activities:

- COVID-19 initial clinical trial activity (£7 million);
- Manufacture of SNG001 drug product and other supply chain considerations (£4 million); and
- Strengthened balance sheet for potential partnering discussions, working capital and fees (£3 million).

Statement of Financial Position and cash flows

At 30 June 2020, net assets amounted to £11.58 million (30 June 2019: £4.30 million, 31 December 2019: £2.25 million), including cash balances of £10.88 million (30 June 2019: £3.52 million, 31 December 2019: £2.45 million). Trade and other payables amounted to £1.98 million (30 June 2019: £0.99 million, 31 December 2019: £1.49 million) with the increase from the 30 June 2019 and 31 December 2019 balances being attributable to the COVID-19 research and development activities.

The principal elements of the £8.43 million increase in cash balances over the six months ended 30 June 2020 (six months ended 30 June 2019: £1.76 million decrease, year ended 31 December 2019: £2.88 million decrease) were:

- Cash used in operations of £4.63 million (six months ended 30 June 2019: £1.83 million outflow; year ended 31 December 2019: £3.73 million outflow);
- Research and development tax credits received of £nil (six months ended 30 June 2019: £nil; year ended 31 December 2019: £0.84 million);
- Payments of lease liabilities £0.13 million (six months ended 30 June 2019: £nil; year ended 31 December 2019: £nil); and
- Net proceeds from fundraising of £13.22 million (six months ended 30 June 2019: £nil; year ended 31 December 2019: £nil).

Going concern

The directors have prepared detailed financial forecasts to estimate the likely cash requirements of the Company 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 balanced and prudent view in preparing these forecasts.

In common with many other similar biotechnology companies Synairgen relies on equity financing at key milestone events during the development of its programmes. Events are moving very quickly for the Company as it plans the next phases of development and approval of SNG001 as a therapy for COVID-19 over the shortest possible timescale to meet regulatory requirements and global healthcare demands. The Company and Group currently have enough existing financial resources to meet their currently contracted commitments, as at the date of signing this report, for the next 12 months. On this basis, the Directors have concluded that the going concern basis of accounting is appropriate and that there are no material uncertainties arising within the next 12 months.

Over the next 6-12 months the Company intends to pursue the development of SNG001 as a therapy for COVID-19 through further clinical trial activity and upscaling of manufacturing and supply arrangements. To the extent that such activities are in addition to the Company's current commitments they will require financing. The Directors will investigate all potential sources of finance, including but not limited to, new equity, and remain confident that funding will be available prior to entering into further commitments.

OUTLOOK

The major developments during the first six months of the year have leveraged the significant experience that surrounds Synairgen and we are grateful to our entire team that has worked tirelessly. We are continuing our strategy of progressing inhaled IFN-beta for the treatment of severe viral lung infections. SNG001 shows great promise as a treatment for COVID-19 patients, and we were delighted to announce positive results from the hospital-based trial and to have supplemented that data set with a positive interim analysis of SNG001 in COPD patients in September. The Company is now fully focused on expediting the next steps with SNG001 in COVID-19, including discussions with regulatory agencies to set out a route to approval, and separately working with our manufacturing partners to achieve meaningful scale up.

Our goal is to deliver an effective treatment for COVID-19 and continue to work in the interests of patients and our shareholders.

Consolidated Statement of Comprehensive Income
for the six months ended 30 June 2020

	Notes	Unaudited Six months ended 30 June 2020 £000	Unaudited Six months ended 30 June 2019 £000	Audited Year ended 31 December 2019 £000
Research and development expenditure		**(4,474)**	(1,686)	(3,460)
Other administrative expenses		**(602)**	(520)	(1,357)
Total administrative expenses		**(5,076)**	(2,206)	(4,817)
Loss from operations		**(5,076)**	(2,206)	(4,817)
Finance income		**9**	17	30
Finance expense		**(6)**	-	(6)
Loss before tax		**(5,073)**	(2,189)	(4,793)
Tax credit	2	**1,111**	417	908
Loss and total comprehensive loss for the period		**(3,962)**	(1,772)	(3,885)
Loss per ordinary share	3			
Basic and diluted loss per ordinary share (pence)		**(3.11)p**	(1.62)p	(3.55)p

Consolidated Statement of Changes in Equity (unaudited)
for the six months ended 30 June 2020

	Share capital £000	Share premium £000	Merger reserve £000	Retained Deficit £000	Total £000
At 1 January 2019	1,094	28,262	483	(23,812)	6,027
Recognition of share-based payments	-	-	-	48	48
Total comprehensive loss for the period	-	-	-	(1,772)	(1,772)
At 30 June 2019	1,094	28,262	483	(25,536)	4,303
Recognition of share-based payments	-	-	-	63	63
Total comprehensive loss for the period	-	-	-	(2,113)	(2,113)
At 31 December 2019	1,094	28,262	483	(27,586)	2,253
Issue of ordinary shares	400	13,600	-	-	14,000
Transaction costs in respect of share issue	-	(782)	-	-	(782)
Recognition of share-based payments	-	-	-	67	67
Total comprehensive loss for the period	-	-	-	(3,962)	(3,962)
At 30 June 2020	**1,494**	**41,080**	**483**	**(31,481)**	**11,576**

Consolidated Statement of Financial Position
as at 30 June 2020

	Notes	Unaudited 30 June 2020 £000	Unaudited 30 June 2019 £000	Audited 31 December 2019 £000
Assets				
Non-current assets				
Intangible assets		**11**	22	16
Property, plant and equipment		**292**	333	301
Right-of-use assets		**175**	-	255
		478	355	572
Current assets				
Inventories		**41**	42	41
Current tax receivable		**1,976**	1,212	865
Trade and other receivables		**383**	162	139
Cash and cash equivalents		**10,884**	3,520	2,454
		13,284	4,936	3,499
Total assets		**13,762**	5,291	4,071
Liabilities				
Non-current liabilities				
Lease liabilities		**(43)**	-	(127)
Current liabilities				
Trade and other payables		**(1,978)**	(988)	(1,490)
Lease liabilities		**(165)**	-	(201)
		(2,143)	(988)	(1,691)
Total liabilities		**(2,186)**	(988)	(1,818)
Total net assets		**11,576**	4,303	2,253
Equity				
Capital and reserves attributable to equity holders of the parent				
Share capital		**1,494**	1,094	1,094
Share premium		**41,080**	28,262	28,262
Merger reserve		**483**	483	483
Retained deficit		**(31,481)**	(25,536)	(27,586)
Total equity		**11,576**	4,303	2,253

Consolidated Statement of Cash Flows
for the six months ended 30 June 2020

	Unaudited Six months ended 30 June 2020 £000	Unaudited Six months ended 30 June 2019 £000	Audited Year ended 31 December 2019 £000
Cash flows from operating activities			
Loss before tax	**(5,073)**	(2,189)	(4,793)
Adjustments for:			
Finance income	**(9)**	(17)	(30)
Finance expense	**6**	-	6
Depreciation of property, plant & equipment	**45**	41	83
Depreciation of right-of-use assets	**81**	-	67
Amortisation	**5**	7	13
Share-based payment charge	**67**	48	111
Cash flows from operations before changes in working capital	**(4,878)**	(2,110)	(4,543)
Decrease in inventories	**-**	14	15
(Increase)/Decrease in trade and other receivables	**(243)**	54	81
Increase in trade and other payables	**488**	211	713
Cash used in operations	**(4,633)**	(1,831)	(3,734)
Tax credit received	**-**	-	838
Net cash used in operating activities	**(4,633)**	(1,831)	(2,896)
Cash flows from investing activities			
Interest received	**7**	17	26
Purchase of property, plant and equipment	**(36)**	-	(10)
Decrease in other financial assets	**-**	50	50
Net cash (used in)/generated from investing activities	**(29)**	67	66
Cash flows from financing activities			
Proceeds from issuance of ordinary shares, gross	**14,000**	-	-
Transaction costs in respect of share issues	**(782)**	-	-
Principal paid on lease liabilities	**(123)**		
Interest paid on lease liabilities	**(3)**	-	-
Net cash generated from financing activities	**13,092**	-	-
Increase/(Decrease) in cash and cash equivalents	**8,430**	(1,764)	(2,830)
Cash and cash equivalents at beginning of period	**2,454**	5,284	5,284
Cash and cash equivalents at end of period	**10,884**	3,520	2,454

Notes to the Interim Financial Information
for the six months ended 30 June 2020

1. Basis of preparation

Basis of accounting
The interim financial information, which is unaudited, has been prepared on the basis of the accounting policies expected to apply for the financial year to 31 December 2020 and in accordance with recognition and measurement principles of International Financial Reporting Standards (IFRSs) as endorsed by the European Union. The accounting policies applied in the preparation of this interim financial information are consistent with those used in the financial statements for the year ended 31 December 2019.

The interim financial information does not include all of the information required for full annual financial statements and does not comply with all the disclosure requirements in IAS 34 'Interim Financial Reporting'.

Financial information
The financial information for the year ended 31 December 2019 does not constitute the full statutory accounts for that period. The Annual Report and Financial Statements for the year ended 31 December 2019 have been filed with the Registrar of Companies. The Independent Auditor's Report on the Annual Report and Financial Statements for the year ended 31 December 2019 was unqualified, did not draw attention to any matters by way of emphasis, and did not contain a statement under 498(2) or 498(3) of the Companies Act 2006.

Going Concern
The directors have prepared detailed financial forecasts to estimate the likely cash requirements of the Company 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 balanced and prudent view in preparing these forecasts.

In common with many other similar biotechnology companies Synairgen relies on equity financing at key milestone events during the development of its programmes. Events are moving very quickly for the Company as it plans the next phases of development and approval of SNG001 as a therapy for COVID-19 over the shortest possible timescale to meet regulatory requirements and global healthcare demands. The Company and Group currently have enough existing financial resources to meet their currently contracted commitments, as at the date of signing this report, for the next 12 months. On this basis, the Directors have concluded that the going concern basis of accounting is appropriate and that there are no material uncertainties arising within the next 12 months.

Over the next 6-12 months the Company intends to pursue the development of SNG001 as a therapy for COVID-19 through further clinical trial activity and upscaling of manufacturing and supply arrangements. To the extent that such activities are in addition to the Company's current commitments they will require financing. The Directors will investigate all potential sources of finance, including but not limited to, new equity, and remain confident that funding will be available prior to entering into further commitments.

Approval of financial information
The 30 June 2020 interim financial information was approved by the Board of Directors on 28 September 2020.

2. Tax credit

The tax credit of £1,111,000 (six months ended 30 June 2019: £417,000; year ended 31 December 2019: £908,000) comprises an estimate of the research and development tax credit receivable in respect of the current period.

3. Loss per ordinary share

	Unaudited Six months ended 30 June 2020	Unaudited Six months ended 30 June 2019	Audited Year ended 31 December 2019
Loss attributable to equity holders of the Company (£000)	**(3,962)**	(1,772)	(3,885)
Weighted average number of ordinary shares in issue	**127,318,567**	109,433,442	109,433,422

The loss attributable to shareholders and the weighted average number of ordinary shares for the purposes of calculating the diluted loss 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. At 30 June 2020 there were 10,042,735 options outstanding (30 June 2019: 8,737,515 options outstanding; 31 December 2019: 8,487,515 options outstanding).

The movements on share capital and share premium were as follows:

	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	40,000,000	400	13,600	14,000
Costs of issue of shares	-	-	(782)	(782)
At 30 June 2020	**149,433,442**	**1,494**	**41,080**	**42,574**

INDEPENDENT REVIEW REPORT TO SYNAIRGEN PLC

Introduction

We have been engaged by the Company to review the financial information in the interim results for the six months ended 30 June 2020 which comprises the Consolidated Statement of Comprehensive Income, the Consolidated Statement of Changes in Equity, the Consolidated Statement of Financial Position, the Consolidated Statement of Cash Flows and the related notes 1 to 3.

We have read the other information contained in the interim results and considered whether it contains any apparent misstatements or material inconsistencies with the information in the financial information.

Directors' responsibilities

The interim report, including the financial information contained therein, is the responsibility of and has been approved by the directors. The directors are responsible for preparing the interim report in accordance with the rules of the London Stock Exchange for companies trading securities on AIM which require that the interim results be presented and prepared in a form consistent with that which will be adopted in the Company's annual accounts having regard to the accounting standards applicable to such annual accounts.

Our responsibility

Our responsibility is to express to the Company a conclusion on the financial information in the interim results based on our review.

Scope of review

We conducted our review in accordance with International Standard on Review Engagements (UK and Ireland) 2410, ''Review of Interim Financial Information Performed by the Independent Auditor of the Entity'', issued by the Financial Reporting Council for use in the United Kingdom. A review of interim financial information consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing (UK) and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the condensed set of financial statements in the interim results for the six months ended 30 June 2020 is not prepared, in all material respects, in accordance with the rules of the London Stock Exchange for companies trading securities on AIM.

Use of our report

Our report has been prepared in accordance with the terms of our engagement dated 23 January 2020 to assist the Company in meeting the requirements of the rules of the London Stock Exchange for companies trading securities on AIM and for no other purpose. No person is entitled to rely on this report unless such a person is a person entitled to rely upon this report by virtue of and for the purpose of our terms of engagement or has been expressly authorised to do so by our prior written consent. Save as above, we do not accept responsibility for this report to any other person or for any other purpose and we hereby expressly disclaim any and all such liability

BDO LLP
Chartered Accountants
Reading
United Kingdom

28 September 2020