Synairgen plc

('Synairgen' or the 'Company')

Interim results for the six months ended 30 June 2023

Southampton, UK – 21 September 2023: Synairgen plc (LSE: SNG), the respiratory company developing SNG001, an investigational formulation for inhalation containing the immunomodulatory broad-spectrum antiviral protein interferon beta, today announces its unaudited interim results for the six months ended 30 June 2023.

Highlights (including post period-end)

Operational

- Progressing the Company's patient identification strategy through biomarker and existing clinical data analysis. This will enable the Company to identify patients at higher risk of disease progression, including those with deficient innate immune response and/or high viral load, who might therefore be more likely to respond to SNG001 in future clinical studies.

- Conducting non-interventional preparatory work to expand hospitalised patient populations for potential treatment with SNG001, which are likely to include: ventilated patients with confirmed viral pneumonia; and patients who are unable to clear virus and become persistent viral "shedders", a majority of whom are immunocompromised. Subject to this preparatory work and regulatory approval timelines, trials are anticipated to start in H1 2024.

- Insights from non-interventional studies and the substantial body of evidence gathered to date from previous clinical trials will inform a robust clinical programme for the development of SNG001.

Financial

- Cash and deposit balances of £14.6 million at 30 June 2023 (30 June 2022: £18.0 million; 31 December 2022: £19.7 million). Post period-end receipt of FY 2022 research and development tax credit of £2.4 million.

- Loss before tax for the six months ended 30 June 2023 was £5.2 million (30 June 2022: £14.0 million loss).

    - Research and development expenditure for the six months ended 30 June 2023 was £3.5 million (30 June 2022: £11.1 million)

as expenditure on the Phase 3 SPRINTER trial, substantially completed in 2022, decreased and manufacturing activities reduced.

- Administrative expenses for the six months ended 30 June 2023 were £2.1 million (30 June 2022: £2.9 million), with the reduction being attributable to the pre-commercialisation activities incurred in 2022.

Richard Marsden, CEO of Synairgen, said: "We are focused on progressing our method of identifying those individuals most likely to respond to SNG001 treatment using the large body of data already gathered through previous trials and new non-interventional research, which is currently underway. We hope to maximise the benefits of treatment with SNG001 by targeting patients most likely to respond to treatment by applying both existing and new technologies for patient selection in our next trials of SNG001. This will enable us to focus on the most appropriate patients which will ultimately lead to trials of SNG001 in more targeted, but still large, patient populations at high risk of severe outcomes."

The information contained within this announcement is deemed to constitute inside information as stipulated under the retained EU law version of the Market Abuse Regulation (EU) No. 596/2014 (the "UK MAR") which is part of UK law by virtue of the European Union (Withdrawal) Act 2018. The information is disclosed in accordance with the Company's obligations under Article 17 of the UK MAR. Upon the publication of this announcement, this inside information is now considered to be in the public domain.

For further enquiries, please contact:
Synairgen plc
Media@synairgen.com
Tel: + 44 (0) 23 8051 2800

Cavendish Capital Markets Limited (NOMAD and Joint Broker)
Geoff Nash, Charlie Beeson (Corporate Finance)
Sunila de Silva (ECM)
Tel: + 44 (0) 20 7220 0500

Numis Securities Limited (Joint Broker)
Freddie Barnfield, Duncan Monteith, Euan Brown
Tel: + 44 (0) 20 7260 1000

ICR Consilium (Financial Media and Investor Relations)
Mary-Jane Elliott, Namrata Taak, Lucy Featherstone
Synairgen@consilium-comms.com
Tel: +44 (0) 20 3709 5700

Notes for Editors

Synairgen is a UK-based respiratory company focused on drug discovery and the development of SNG001 (inhaled interferon beta) as potentially the first host-targeted, broad-spectrum antiviral treatment delivered directly into the lungs for severe viral lung infections.

Millions of people globally are hospitalised every year due to viral lung infections and there are currently no approved antiviral therapies for the majority of these patients. Synairgen is developing SNG001 to address this need.

Synairgen is quoted on AIM (LSE: SNG). For more information about Synairgen, please see www.synairgen.com.

OPERATIONAL REVIEW

Synairgen is progressing with vital foundational work in readiness to commence further clinical trials of SNG001 as a broad spectrum antiviral treatment. This work is based on key learnings from the COVID-19 pandemic, which have accelerated the development of new approaches including the broader application of key virus testing in hospitals for symptomatic patients and the advancement of technologies that increase understanding of how respiratory viruses impact the individual, particularly immune system function, using blood and airway fluid samples.

Before commencing further trials of SNG001, and taking into account our helpful learnings from previous studies, Synairgen is developing a patient identification strategy applying existing and new technologies and biomarkers to identify patients whose disease is being actively driven by virus (high virus load) and/or who are struggling to mount an effective antiviral response (deficient innate immune response). The Company believes that these patients are most likely to demonstrate a response to SNG001, with potential benefits in respect of future trial size, duration and costings. By using Synairgen's proposed targeted approach to patient identification the Company is able to better design studies with fewer subjects and thus reduce cost and timings for its drug development.

A study led by the Universities of Southampton and Leicester, involving over 300 adults hospitalised with viral acute respiratory illness, reported that higher viral loads were associated with a prolonged length of stay in the hospital. This suggests that viral load measured at the point of hospital admission could be used in clinical trials, and potentially in clinical practice, to predict those at risk of extended hospitalisation.[1] Building upon this, Synairgen is exploring the relationship between virus load and other risk factors which predict poor outcome in hospitalised patients to inform the development of SNG001 in the hospital setting.

In addition, the Company is expanding the populations of interest to include mechanically ventilated patients in ICU with confirmed viral pneumonia and patients unable to clear virus and become persistent virus shedders, the majority of whom are immunocompromised.

The overall patient identification approach should lead to trials of SNG001 in more targeted, but still large, patient populations at high risk of deterioration/progression to severe outcomes.

In the first half of 2023, Synairgen continued this foundational work to determine the most relevant trials to support its goals. With respiratory viral infections being responsible for upwards of three million hospitalisations in the US each year[2] the Company remains committed to address this significant unmet need. Despite the great need, there are few therapeutics available to treat the range of viruses that cause these hospitalisations.

Additionally, Synairgen continued to share findings from its trials of SNG001 in COVID-19 patients, including at the American Thoracic Society 2023 conference

in May and, post-period end, at the European Respiratory Society 2023 congress in September. These conferences are an extremely valuable way to build the Company's network and showcase the need for a broad-spectrum antiviral.

In summary, Synairgen is continuing to work at pace, partnering with high quality researchers and collaborators, to ensure it has the right trial designs, equipped with the right diagnostic tools, to be able to identify trial participants potentially most likely to benefit from a broad-spectrum antiviral and SNG001. This work (including biomarker assessments), together with the substantial body of evidence gathered from clinical trials with SNG001 to date, will inform a robust clinical development programme for SNG001. It is the Company's goal to commence trials as soon as possible, subject to approval timelines, and within H1 2024.

FINANCIAL REVIEW

Statement of Comprehensive Income

The loss from operations for the six months ended 30 June 2023 (H1 2023) was £5.5 million (six months ended 30 June 2022 (H1 2022): £14.0 million loss; year ended 31 December 2022 (FY 2022): £20.3 million loss) with research and development expenditure amounting to £3.5 million (H1 2022: £11.1 million; FY 2022: £14.9 million) and other administrative expenses £2.1 million (H1 2022: £2.9 million; FY 2022: £5.4 million).

The reduction in research and development expenditure from £11.1 million to £3.5 million is attributable to the lower expenditure on the Phase 3 SPRINTER trial, which was substantially completed in 2022, and reduced manufacturing activities.

Other administrative expenditure decreased from £2.9 million in H1 2022 to £2.1 million in H1 2023 on account of pre-commercialisation activities incurred in 2022.

The research and development tax credit decreased from £1.6 million in H1 2022 to £0.5 million in H1 2023 on account of the reduced qualifying expenditure and the reduction in the small or medium enterprises (SME) R&D scheme rates effective as of 1 April 2023.

The loss after tax for H1 2023 was £4.7 million (H1 2022: £12.4 million; FY 2022: £17.6 million) and the basic loss per share was 2.36p (H1 2022: 6.16p loss; FY 2022: 8.76p loss).

Statement of Financial Position and Cash Flows

At 30 June 2023, net assets amounted to £16.0 million (30 June 2022: £24.9 million; 31 December 2022: £20.3 million), including cash and deposit balances of £14.6 million (30 June 2022: £18.0 million; 31 December 2022: £19.7 million). Post period-end, in August 2023, the tax credit of £2.4 million in respect of FY 2022 was received.

The principal elements of the £5.1 million reduction in cash and deposit balances during H1 2023 (H1 2022: £15.8 million reduction; FY 2022: £14.2 million reduction) were:

- Cash used in operations £5.3 million (H1 2022: £15.8 million outflow; FY 2022: £23.4 million outflow);
- Research and development tax credits received of £nil (H1 2022: £nil; FY 2022: £9.1 million); and
- Interest received £0.3 million (H1 2022: £nil; FY 2022: £0.1 million).

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

- Current tax receivable: 30 June 2023: £2.9 million; 30 June 2022: £10.6 million; 31 December 2022: £2.4 million on account of the lower research and development tax credit receivable. As noted above, the 2022 tax credit of £2.4 million was received in August 2023.
- Trade and other payables: 30 June 2023: £2.7 million; 30 June 2022: £4.6 million; 31 December 2022: £3.3 million, in line with the reduction in the level of operating expenditure.

The Company's cash resources are sufficient to cover its plans to design and establish data from an observational study and two investigator-led/Synairgen-sponsored Phase 2 clinical trials, including manufacture of active and placebo for use in these trials. Regardless of the outcome of these activities, which are uncertain, the Company's available resources are sufficient to cover existing committed costs and the estimated costs of these activities until at least 30 September 2024, 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.

Change of Name of Nominated Adviser and Joint Broker

The Company also announces that its Nominated Adviser and Joint Broker has changed its name to Cavendish Capital Markets Limited following completion of its own corporate merger.

References

1 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7112535/

2 IQVIA market research Q4 2022; Sources. US CDC, HCUP, IQVIA Claims Data, PubMed; data on file

Consolidated Statement of Comprehensive Income

for the 6 months ended 30 June 2023

	Notes	Unaudited Six months ended 30 June 2023 £000	Unaudited Six months ended 30 June 2022 £000	Audited Year ended 31 December 2022 £000
Research and development expenditure		**(3,463)**	(11,106)	(14,936)
Other administrative expenses		**(2,051)**	(2,903)	(5,364)
Total administrative expenses and loss from operations		**(5,514)**	(14,009)	(20,300)
Finance income		**300**	24	207
Loss before tax		**(5,214)**	(13,985)	(20,093)
Tax credit	2	**466**	1,579	2,448
Loss and total comprehensive loss for the period		**(4,748)**	(12,406)	(17,645)
Loss per ordinary share	3			
Basic and diluted loss per ordinary share (pence)		**(2.36)p**	(6.16)p	(8.76)p

Consolidated Statement of Changes in Equity

for the 6 months ended 30 June 2023

	Share Capital £000	Share premium £000	Merger reserve £000	Retained deficit £000	Total £000
At 1 January 2022	2,013	125,245	483	(90,741)	37,000
Loss and total comprehensive loss for the period	-	-	-	(12,406)	(12,406)
Transactions with equity holders of the Group					
Issue of ordinary shares	1	-	-	-	1
Recognition of share-based payments	-	-	-	323	323
	1	-	-	323	324
At 30 June 2022	2,014	125,245	483	(102,824)	24,918
Loss and total comprehensive loss for the period	-	-	-	(5,239)	(5,239)
Transactions with equity holders of the Group					
Recognition of share-based payments	-	-	-	596	596
At 31 December 2022	2,014	125,245	483	(107,467)	20,275
Loss and total comprehensive loss for the period	-	-	-	(4,748)	(4,748)
Transactions with equity holders of the Group					
Recognition of share-based payments	-	-	-	437	437
At 30 June 2023	**2,014**	**125,245**	**483**	**(111,778)**	**15,964**

Consolidated Statement of Financial Position

as at 30 June 2023

	Unaudited 30 June 2023 £000	Unaudited 30 June 2022 £000	Audited 31 December 2022 £000
Assets			
Non-current assets			
Intangible assets	**92**	48	44
Property, plant and equipment	**42**	130	86
	134	178	130
Current assets			
Current tax receivable	**2,881**	10,634	2,415
Trade and other receivables	**1,060**	710	1,308
Other financial assets – bank deposits	**4,000**	-	3,750
Cash and cash equivalents	**10,631**	18,022	15,926
	18,572	29,366	23,399
Total assets	**18,706**	29,544	23,529
Liabilities			
Current liabilities			
Trade and other payables	**(2,742)**	(4,626)	(3,254)
Total liabilities	**(2,742)**	(4,626)	(3,254)
Total net assets	**15,964**	24,918	20,275
Equity			
Capital and reserves attributable to equity holders of the parent			
Share capital	**2,014**	2,014	2,014
Share premium	**125,245**	125,245	125,245
Merger reserve	**483**	483	483
Retained deficit	**(111,778)**	(102,824)	(107,467)
Total equity	**15,964**	24,918	20,275

Consolidated Statement of Cash Flows

for the 6 months ended 30 June 2023

	Unaudited Six months ended 30 June 2023 £000	Unaudited Six months ended 30 June 2022 £000	Audited Year ended 31 December 2022 £000
Cash flows from operating activities			
Loss before tax	**(5,214)**	(13,985)	(20,093)
Adjustments for:			
Finance income	**(300)**	(24)	(207)
Depreciation of property, plant & equipment	**45**	47	93
Amortisation	**5**	5	9
Share-based payment charge	**437**	323	919
Cash flows from operations before changes in working capital	**(5,027)**	(13,634)	(19,279)
Decrease in trade and other receivables	**242**	825	289
Decrease in trade and other payables	**(512)**	(3,012)	(4,384)
Cash used in operations	**(5,297)**	(15,821)	(23,374)
Tax credit received	**-**	-	9,088
Net cash used in operating activities	**(5,297)**	(15,821)	(14,286)
Cash flows from investing activities			
Interest received	**307**	19	140
Purchase of intangible assets	**(54)**	-	-
Purchase of property, plant and equipment	**(1)**	(4)	(6)
Other financial assets – bank deposits			
New deposits	**(4,000)**	-	(3,750)
Deposit maturities	**3,750**	-	-
Net cash generated from/(used in) investing activities	**2**	15	(3,616)
Cash flows from financing activities			
Proceeds from issuance of ordinary shares	**-**	1	1
Net cash generated from financing activities	**-**	1	1
Decrease in cash and cash equivalents	**(5,295)**	(15,805)	(17,901)
Cash and cash equivalents at beginning of period	**15,926**	33,827	33,827
Cash and cash equivalents at end of period	**10,631**	18,022	15,926

Notes to the Interim Financial Information

for the six months ended 30 June 2023

1. Basis of preparation

Basis of accounting

The condensed financial statements have been prepared using accounting policies consistent with international accounting standards. While the financial figures included in this half-yearly report have been computed in accordance with international accounting standards applicable to interim periods, this half-yearly report does not contain sufficient information to constitute an interim financial report as that term is defined in IAS 34. They do not include all disclosures that would otherwise be required in a complete set of financial statements and should be read in conjunction with the 31 December 2022 Annual Report. The financial information for the half years ended 30 June 2023 and 30 June 2022 does not constitute full financial statements and both periods are unaudited.

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 2022 and those expected to apply for the financial year to 31 December 2023. The Group has not early adopted any standard, interpretation or amendment that has been issued but is not yet effective.

Financial information

The financial information for the year ended 31 December 2022 does not constitute the full statutory accounts for that period. The Annual Report and Financial Statements for the year ended 31 December 2022 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 2022 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.

Financial information is published on the Company's website in accordance with legislation in the United Kingdom governing the preparation and dissemination of financial information, which may vary from legislation in other jurisdictions. The maintenance and integrity of the Company's website is the responsibility of the directors. The directors' responsibility also extends to the ongoing integrity of the financial information contained therein.

Going Concern

The directors have prepared financial forecasts to estimate the likely cash requirements of the Company over the period to 30 September 2024, 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 taken a prudent view in preparing these forecasts.

The Company's available resources at the date of this report are sufficient to cover the Company's plans to design and establish data from an observational study and two investigator-led/Synairgen-sponsored Phase 2 clinical trials, including manufacture of active and placebo for use in these trials. Regardless of the outcome of these activities, which are uncertain, the Company's available resources are sufficient to cover existing committed costs and the estimated costs of these activities until at least 30 September 2024.

Notes to the Interim Financial Information

for the six months ended 30 June 2023 (continued)

1. Basis of preparation (continued)

Going concern (continued)

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.

Approval of financial information

The 30 June 2023 interim financial information was approved by a committee of the Board of Directors on 20 September 2023.

2. Tax credit

The tax credit of £466,000 (six months ended 30 June 2022: £1,579,000; year ended 31 December 2022: £2,448,000) comprises an estimate of the research and development tax credit receivable in respect of the current period.

The deferred tax assets have not been recognised as there is uncertainty regarding when suitable future profits against which to offset the accumulated tax losses will arise. There is no expiration date for the accumulated tax losses.

3. Loss per ordinary share

	Unaudited Six months ended 30 June 2023	Unaudited Six months ended 30 June 2022	Audited Year ended 31 December 2022
Loss attributable to equity holders of the Company (£000)	**(4,748)**	(12,406)	(17,645)
Weighted average number of ordinary shares in issue (000)	**201,345**	201,345	201,360
Basic and diluted loss per share (pence)	**(2.36)**	(6.16)	(8.76)

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 2023 there were 18,119,156 options outstanding (30 June 2022: 8,477,640 options outstanding; 31 December 2022: 14,450,882 options outstanding).

INDEPENDENT REVIEW REPORT TO SYNAIRGEN PLC

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 half-yearly financial report for the six months ended 30 June 2023 is not prepared, in all material respects, in accordance with the London Stock Exchange AIM Rules for Companies.

We have been engaged by the company to review the condensed set of financial statements in the half-yearly financial report for the six months ended 30 June 2023 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.

Basis for conclusion

We conducted our review in accordance with International Standard on Review Engagements (UK) 2410, "Review of Interim Financial Information Performed by the Independent Auditor of the Entity" ("ISRE (UK) 2410"). 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.

As disclosed in note 1, the annual financial statements of the Company are prepared in accordance with UK adopted international accounting standards. The condensed set of financial statements included in this half-yearly financial report is not in accordance with UK adopted International Accounting Standard 34, "Interim Financial Reporting".

Conclusions relating to going concern

Based on our review procedures, which are less extensive than those performed in an audit as described in the Basis for conclusion section of this report, nothing has come to our attention to suggest that the directors have inappropriately adopted the going concern basis of accounting or that the directors have identified material uncertainties relating to going concern that are not appropriately disclosed.

This conclusion is based on the review procedures performed in accordance with ISRE (UK) 2410, however future events or conditions may cause the Company to cease to continue as a going concern.

Responsibilities of directors

The directors are responsible for preparing the half-yearly financial report in accordance with the London Stock Exchange AIM Rules for Companies which require that the half-yearly report 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.

In preparing the half-yearly financial report, the directors are responsible for assessing the 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 company or to cease operations, or have no realistic alternative but to do so.

Auditor's responsibilities for the review of the financial information

In reviewing the half-yearly report, we are responsible for expressing to the Company a conclusion on the condensed set of financial statement in the half-yearly financial report. Our conclusion, including our Conclusions Relating to Going Concern, are based on procedures that are less extensive than audit procedures, as described in the Basis for Conclusion paragraph of this report.

Use of our report

Our report has been prepared in accordance with the terms of our engagement to assist the Company in meeting the requirements of the rules of the London Stock Exchange AIM Rules for Companies 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

Southampton, UK

Date: 20 September 2023