Press release

Synairgen plc

('Synairgen' or the 'Company')

Interim results for the six months ended 30 June 2017

Southampton, UK – 27 September 2017: Synairgen plc (LSE: SNG), the respiratory drug discovery and development company, today announces its unaudited interim results for the six months ended 30 June 2017.

Highlights (including post period-end)

Operational

- AZD9412 (SNG001) INEXAS clinical trial update, announcing AstraZeneca's decision to return the rights of inhaled interferon beta (IFN-beta) to Synairgen for strategic reasons, despite positive effects on markers of antiviral activity and lung function

- Exploratory analysis of INEXAS data in patients with a confirmed viral infection revealed significant findings in both lung function and asthma control (see separate press release issued today)

- Strategy for SNG001 to move into the substantial Chronic Obstructive Pulmonary Disease (COPD) market and a Phase II trial is planned (see separate press release issued today)

- Good progress made with Lysyl oxidase-like 2 enzyme (LOXL2) inhibitor programme in collaboration with Pharmaxis following additional positive data generated from two preclinical models of idiopathic pulmonary fibrosis (IPF)

- Following successful completion of preclinical pharmacology and toxicology studies, PXS-5382A, a compound from the anti-fibrotic LOXL2 inhibitor programme, is now being prepared to commence Phase I clinical development

Financial

- Research and development expenditure of £1.09 million (30 June 2016: £1.15 million) as the Company advanced the ongoing LOXL2 collaboration with Pharmaxis through pre-clinical studies

- The loss from operations for the six months ended 30 June 2017 was £1.58 million (30 June 2016: £1.69 million loss)

- Cash and bank deposits of £3.08 million (30 June 2016: £6.31 million)

Richard Marsden, CEO of Synairgen, commented: *"We are extremely excited by the positive findings from the INEXAS Phase II trial in asthma which support our progression of SNG001 into Phase II clinical studies in COPD. In addition, our collaboration with Pharmaxis has made great progress and we are looking forward to entering the clinic with PXS-5382A."*

-Ends-

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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 asthma and COPD, uses its differentiating human biology BioBank platform and world-renowned international academic KOL network to discover and develop novel therapies for respiratory disease. Leveraging its scientific and clinical facilities at Southampton General Hospital, the Company uses *in vitro* and *ex vivo* models to progress opportunities into clinical development. The BioBank of human samples is used in these models to increase confidence in the likelihood of successful drug development. Core to Synairgen's business strategy is the realisation of value via licensing transactions. In August 2015 the Company entered into a collaboration with Pharmaxis to develop an oral LOXL2 inhibitor to reduce fibrosis in patients with idiopathic pulmonary fibrosis (IPF). Synairgen is quoted on AIM (LSE: SNG). For more information about Synairgen, please see www.synairgen.com

Chairman's and Chief Executive Officer's Review

OPERATING REVIEW

Summary

In the first six months of the year we made excellent progress with our anti-fibrotic Lysyl Oxidase-Like 2 enzyme (LOXL2) inhibitor programme in collaboration with our partner Pharmaxis. In March, we reported additional positive preclinical data from the programme supporting the potential of inhibitors in the fatal lung disease idiopathic pulmonary fibrosis (IPF). Post period-end, we reported that a compound had been selected for entry into a Phase I trial in Q4 2017.

In April, AstraZeneca returned the rights to SNG001 (inhaled IFN-beta) to Synairgen for strategic reasons. The asthma exacerbation rate was lower than expected in the INEXAS trial and therefore the effects of the drug on exacerbations could not be determined. However, initial data from the trial suggested improved lung function recovery with inhaled IFN-beta and elevated markers of antiviral defence.

Since then, we have analysed the INEXAS data including only the patients who had a confirmed respiratory virus infection, and gratifyingly we found very similar results to our own original Phase II trial of IFN-beta. The low exacerbation rate in asthma makes development of an antiviral drug solely in asthma challenging from an economic perspective. We are currently planning to move SNG001 into COPD, where we believe it is reasonable to expect that the positive clinical effects observed in asthma will translate across to COPD, a disease where there is a greater opportunity to reduce exacerbation occurrence and associated healthcare costs. See separate press release issued today.

LOXL2 inhibitor programme

Our collaboration with Pharmaxis is focussed on developing small molecular weight inhibitors of LOXL2 in tablet form. LOXL2 is an enzyme that stiffens scar tissue by enabling cross-links to form between collagen fibres (a major constituent of scar tissue). The build-up of scar tissue compromises normal organ function and can lead to organ failure and is the hallmark of the fatal lung disease IPF and fibrotic diseases of the liver, kidney and heart.

Over the past six months, we have continued to generate data in preclinical models to support the development of a LOXL2 inhibitor in IPF, whilst Pharmaxis has been producing data supporting other fibrotic conditions. Our *in vitro* model of IPF used lung cells obtained from patients with IPF, and the data from the study showed that LOXL2 inhibitors reduce cross-link formation of collagen fibres and tissue stiffness. We also completed two successful *in vivo* pharmacology studies, one in partnership with McMaster University and one in association with Aragen Bioscience. In the *in vivo* studies, inhibitors of LOXL2 reduced cross-link formation, reduced the lung fibrosis score, and in the McMaster study, where lung function was measured, we saw a reduction in lung stiffness. Alongside these studies, we also successfully completed the toxicology studies necessary to start human clinical trials and the lead compound for a clinical trial, PXS-5382A, was selected. Post period-end, we announced that the Phase I clinical trial of PXS-5382A is set to commence in Q4 2017, with a completion date set for around mid-2018.

Industry is currently particularly interested in therapies targeting fibrosis, as demonstrated by a cluster of high profile and high value licensing transactions completed over the last two to three years. We are encouraged by the high level of interest from large pharmaceutical companies looking to progress a LOXL2 inhibitor across multiple indications, and discussions with potential partners will progress over

the course of Phase I, as we share further data, with a view to completing a transaction around the end of the clinical trial.

IFN-beta (SNG001)

IFN-beta is a naturally-occurring protein that activates multiple antiviral activities and is released by cells during viral infections. Scientists from the University of Southampton and others have shown that cells from asthmatic and COPD patients are more vulnerable to viral infection and in experiments using cells from patients have shown that adding IFN-beta protects cells from infection.

In April 2017, AstraZeneca returned the rights to SNG001, Synairgen's inhaled IFN-beta product, to Synairgen for strategic reasons as the drug's effects on exacerbations could not be assessed in its Phase II trial in asthma (INEXAS). At that time, the data from the trial showed elevation in a marker of antiviral activity (serum IP-10/CXCL-10) and a faster recovery on the lung function parameter Peak Expiratory Flow Rate (PEFR). Changes in other endpoints were not clinically relevant, providing little opportunity for the drug to have an effect. Importantly, inhaled IFN-beta was again found to be well tolerated.

Synairgen's subsequent analysis of the INEXAS dataset has shown statistically significant changes in lung function and asthma control in the virus-positive 'difficult to treat' patients who received inhaled IFN-beta; the same patient classification in which we had found the positive signal in our previous Phase II clinical trial in asthma (SG005).

INEXAS trial data analysis

The INEXAS trial was stopped early after 121 of the 220 planned patients had been randomised because the number of exacerbations caused by viruses was low to a point where it would not be possible to assess the effect of the drug. From that point onwards decisions on the future of the programme would depend on the other endpoints being assessed such as lung function and asthma control. Data identifying the patients who had a confirmed virus infection enabled an analysis of SNG001's effect on patients who had a confirmed viral infection, and who therefore had an opportunity to benefit from the therapy. 48% of the patients randomised had a confirmed viral infection. We then focussed our exploratory analysis on the patients who came from the BTS 4/5 categorisation of asthma, the population in which we had seen the greatest clinical benefit in Phase II clinical trial SG005. Analysis of the data showed that the drug had a positive effect on lung function as measured by morning Peak Expiratory Flow (difference of 38.59 L/min/day days 1-7, p=0.0208, n=18 in active group, 19 in placebo group) and also on asthma control over the first week of treatment (Asthma Control Questionnaire or ACQ), difference of -0.492, p=0.0320, (n=16 in active group, 21 in placebo group). This data is similar to the findings from our own trial (SG005) of inhaled IFN-beta[1]: PEF change of 31.42 L/min/day days 2-14, p=0.029 (n=22 in active group, 25 in placebo group) and ACQ -0.63 p=0.004 (n=24 in active group, 30 in placebo group).

Two Phase II trials (SG005 and INEXAS) suggest that SNG001 boosts antiviral responses in the lungs, and has a beneficial effect on lung function. In more difficult to treat patients we saw evidence of improved asthma control during cold infections. However, the unexpectedly low exacerbation rate (<10%) in the INEXAS trial population suggests that the economic viability of the drug solely in an asthma indication would be limited. This low rate is similar to the virus-induced exacerbation rate observed in the Aviragen trial, also reported in 2017.

Virally-driven exacerbations of COPD

Viruses have often been isolated from samples collected from patients who have had an exacerbation of COPD and, with COPD being the second most common cause of emergency admissions to hospital[2], it has always had the potential to be a substantial opportunity for a broad spectrum anti-viral. We have already shown in *in vitro* models that SNG001 protects the lung cells of COPD patients when infected with viruses that cause exacerbations such as flu and the common cold. However, up until now, our ability to identify those patients who may benefit from an inhaled antiviral therapy made the design of a prospective study challenging. This is because exacerbations of COPD can be caused by other factors such as bacterial infections. Two key developments during 2017 have changed this landscape, opening up a route to the COPD market place for SNG001 and enhancing the prospects of achieving success in the clinical development phase:

First, studies in COPD patients published in 2017 suggest that, looking at all colds in the study period, the risk that a cold will cause an exacerbation of COPD is around 50%[3] and could be even higher in particular at risk patients[4], making COPD a very attractive market. The exacerbation rate in the INEXAS and Aviragen trials in asthma was below 10%.

Secondly, a novel point of care diagnostic tool has been developed which enables rapid confirmation of the existence of a respiratory viral infection when patients present themselves at the hospital or trial site. This enables us to treat only those patients who are infected with a virus, significantly reducing the number of subjects required to show the potential effect of SNG001. Clearly this has significant benefits in the future, allowing accurate prescribing of an antiviral therapy quickly to those patients who could benefit from treatment.

Synairgen's strategy for its wholly-owned SNG001 programme is to progress into clinical development in COPD. The Company has therefore designed a short trial for the winter of 2017/18 to evaluate the potential of SNG001 in COPD, which is being submitted for regulatory approval. This trial is designed to confirm the safety of SNG001 in the COPD population (SNG001 has been well tolerated in asthma trials), and to confirm that we can enhance antiviral responses in these patients. We will also assess endpoints for their suitability for a Phase IIb trial scheduled for early 2019.

FINANCIAL REVIEW

Statement of Comprehensive Income

The loss from operations for the six months ended 30 June 2017 was £1.58 million (six months ended 30 June 2016: £1.69 million loss, year ended 31 December 2016: £3.44 million loss). Research and development expenditure at £1.09 million remained broadly in line with the comparative period in 2016 (six months ended 30 June 2016: £1.15 million) as the Company advanced the ongoing LOXL2 collaboration with Pharmaxis through pre-clinical studies. Other administrative costs for the period of £0.51 million were also similar to the comparative period (six months ended 30 June 2016: £0.53 million). The research and development tax credit increased from £0.28 million to £0.31 million as a result of a £0.06 million increase in the 2016 full year claim. The loss after tax for the period was £1.26 million (six months ended 30 June 2016: £1.38 million) and the basic loss per share was 1.38p (six months ended 30 June 2016: loss of 1.51p).

Statement of Financial Position and cash flows

At 30 June 2017, net assets amounted to £3.48 million (30 June 2016: £6.05 million, 31 December 2016: £4.69 million), including net funds (comprising cash balances and

bank deposits) of £3.08 million (30 June 2016: £6.31 million, 31 December 2016: £4.77 million).

The principal elements of the £1.68 million decrease in net funds over the six months ended 30 June 2017 (six months ended 30 June 2016: £1.40 million decrease, year ended 31 December 2016: £2.95 million decrease) were:

- Cash used in operations of £1.69 million (six months ended 30 June 2016: £1.75 million outflow; year ended 31 December 2016: £3.32 million outflow); and
- Research and development tax credits received of £nil (six months ended 30 June 2016: £0.33 million; year ended 31 December 2016: £0.33 million). Tax credits of £0.62 million relating to the 2016 research and development claim were received post period-end in August 2017.

OUTLOOK

We look forward to announcing the commencement of the Phase I trial of PXS-5382A (LOXL2 inhibitor), which is directed to the very major conditions such as IPF and NASH, where fibrosis is a significant cause of morbidity and mortality.

We are excited about progressing the development of SNG001 into COPD, with a Phase II trial in targeted "at risk" patients in the final stages of preparation. In parallel, we are considering optimal financing strategies to enable us to progress this exciting development over the medium term.

Simon Shaw — Chairman

Richard Marsden — Chief Executive Officer

26 September 2017

References:

1. Djukanovic R, et al. The Effect of Inhaled IFN-β on Worsening of Asthma Symptoms Caused by Viral Infections. A Randomized Trial. *Am J Respir Crit Care Med* 2014 Jul 15; 190(2): 145–154

2. Department of Health. An Outcomes Strategy for Chronic Obstructive Pulmonary Disease (COPD) and Asthma in England. Published July 2011

3. Johnston NW, *et al*. Colds as predictors of the onset and severity of COPD exacerbations *International Journal of COPD* 2017:12: 839-848

4. Wilkinson TMA, *et al.* A prospective, observational cohort study of the seasonal dynamics of airway pathogens in the aetiology of exacerbations in COPD *Thorax* 2017;**0**:1-9. Doi:10.1136/thoraxjnl=2016-209023

Consolidated Statement of Comprehensive Income
for the six months ended 30 June 2017

	Notes	Unaudited Six months ended 30 June 2017 £000	Unaudited Six months ended 30 June 2016 £000	Audited Year ended 31 December 2016 £000
Revenue		**25**	-	-
Research and development expenditure		**(1,092)**	(1,153)	(2,418)
Other administrative expenses		**(509)**	(533)	(1,024)
Total administrative expenses		**(1,601)**	(1,686)	(3,442)
Loss from operations		**(1,576)**	(1,686)	(3,442)
Finance income		**8**	22	38
Loss before tax		**(1,568)**	(1,664)	(3,404)
Tax credit	2	**308**	282	587
Loss and total comprehensive loss for the period attributable to equity holders of the parent		**(1,260)**	(1,382)	(2,817)
Loss per ordinary share	3			
Basic and diluted loss per ordinary share (pence)		**(1.38)p**	(1.51)p	(3.08)p

Consolidated Statement of Changes in Equity (unaudited)
for the six months ended 30 June 2017

	Share capital £000	Share premium £000	Merger reserve £000	Retained deficit £000	Total £000
At 1 January 2016	913	25,771	483	(19,820)	7,347
Total comprehensive loss for the period	-	-	-	(1,382)	(1,382)
Recognition of share-based payments	-	-	-	84	84
Issuance of ordinary shares	1	-	-	-	1
At 30 June 2016	914	25,771	483	(21,118)	6,050
Total comprehensive loss for the period	-	-	-	(1,435)	(1,435)
Recognition of share-based payments	-	-	-	70	70
At 31 December 2016	914	25,771	483	(22,483)	4,685
Total comprehensive loss for the period	-	-	-	(1,260)	(1,260)
Recognition of share-based payments	-	-	-	59	59
At 30 June 2017	**914**	**25,771**	**483**	**(23,684)**	**3,484**

Consolidated Statement of Financial Position
as at 30 June 2017

	Notes	Unaudited 30 June 2017 £000	Unaudited 30 June 2016 £000	Audited 31 December 2016 £000
Assets				
Non-current assets				
Intangible assets		**53**	71	62
Property, plant and equipment		**10**	17	13
		63	88	75
Current assets				
Inventories		**56**	56	55
Current tax receivable		**868**	255	560
Trade and other receivables		**66**	61	90
Other financial assets – bank deposits	4	**267**	2,500	1,661
Cash and cash equivalents		**2,817**	3,811	3,104
		4,074	6,683	5,470
Total assets		**4,137**	6,771	5,545
Liabilities				
Current liabilities				
Trade and other payables		**(653)**	(721)	(860)
Total liabilities		**(653)**	(721)	(860)
Total net assets		**3,484**	6,050	4,685
Equity				
Capital and reserves attributable to equity holders of the parent				
Share capital		**914**	914	914
Share premium		**25,771**	25,771	25,771
Merger reserve		**483**	483	483
Retained deficit		**(23,684)**	(21,118)	(22,483)
Total equity		**3,484**	6,050	4,685

Consolidated Statement of Cash Flows
for the six months ended 30 June 2017

	Unaudited Six months ended 30 June 2017 £000	Unaudited Six months ended 30 June 2016 £000	Audited Year ended 31 December 2016 £000
Cash flows from operating activities			
Loss before tax	**(1,568)**	(1,664)	(3,404)
Adjustments for:			
Finance income	**(8)**	(22)	(38)
Depreciation	**4**	4	9
Amortisation	**9**	10	19
Share-based payment charge	**59**	84	154
Cash flows from operations before changes in working capital	**(1,504)**	(1,588)	(3,260)
(Increase)/Decrease in inventories	**(1)**	-	1
Decrease in trade and other receivables	**20**	49	17
Decrease in trade and other payables	**(207)**	(215)	(76)
Cash used in operations	**(1,692)**	(1,754)	(3,318)
Tax credit received	**-**	330	330
Net cash used in operating activities	**(1,692)**	(1,424)	(2,988)
Cash flows from investing activities			
Interest received	**12**	24	43
Purchase of property, plant and equipment	**(1)**	(4)	(5)
Decrease in other financial assets	**1,394**	1,222	2,061
Net cash generated from investing activities	**1,405**	1,242	2,099
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	**(287)**	(181)	(888)
Cash and cash equivalents at beginning of period	**3,104**	3,992	3,992
Cash and cash equivalents at end of period	**2,817**	3,811	3,104

Notes to the Interim Financial Information
for the six months ended 30 June 2017

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 2017 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 2016 and with those that the Company expects to apply in its financial statements for the year ending 31 December 2017.

The interim financial information does not include all of the information required for full annual financial statements and does not comply with all the disclosures in IAS 34 'Interim Financial Reporting'. Accordingly, whilst the interim financial information has been prepared in accordance with IFRSs, it cannot be construed as being in full compliance with IFRSs.

The financial information for the year ended 31 December 2016 does not constitute the full statutory accounts for that period. The Annual Report and Financial Statements for the year ended 31 December 2016 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 2016 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 financial forecasts to estimate the likely cash requirements of the Group over the next twelve months. In preparing these financial forecasts, the directors have had to make certain assumptions with regards to the timing and amount of future expenditure and other key factors. The directors have attempted to take a balanced and prudent view in preparing these forecasts, however their accuracy is uncertain.

After due consideration and review of these financial forecasts and current cash resources, the directors consider that the Group 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 interim financial information has been prepared on a going concern basis.

The 30 June 2017 interim financial information was approved by a duly appointed and authorised committee of the Board of Directors on 26 September 2017.

2. Tax credit

The tax credit of £308,000 (six months ended 30 June 2016: £282,000; year ended 31 December 2016: £587,000) includes £247,000 as an estimate of the research and development tax credit receivable in respect of the current period and £61,000 representing amounts unprovided for in previous periods.

3. Loss per ordinary share

	Unaudited Six months ended 30 June 2017	Unaudited Six months ended 30 June 2016	Audited Year ended 31 December 2016
Loss attributable to equity holders of the Company (£000)	**(1,260)**	(1,382)	(2,817)
Weighted average number of ordinary shares in issue	**91,362,612**	91,340,146	91,351,441

3. Loss per ordinary share (continued)

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 earnings 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. At 30 June 2017 there were 5,566,736 options outstanding (30 June 2016: 5,719,762 options outstanding; 31 December 2016: 5,629,647 options outstanding).

4. Other financial assets

Other financial assets comprise Sterling fixed rate bank deposits of greater than three months' maturity at the time of deposit.

INDEPENDENT REVIEW REPORT TO SYNAIRGEN PLC

Introduction

We have been engaged by the company to review the interim set of financial information in the half-yearly financial report for the six months ended 30 June 2017 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 4.

We have read the other information contained in the half-yearly financial report and considered whether it contains any apparent misstatements or material inconsistencies with the information in the interim set of 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 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.

Our responsibility

Our responsibility is to express to the company a conclusion on the interim set of financial information in the half-yearly financial report based on our review.

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 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.

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 Auditing Practices Board 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 Ireland) 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 interim set of financial information in the half-yearly financial report for the six months ended 30 June 2017 is not prepared, in all material respects, in accordance with the rules of the London Stock Exchange for companies trading securities on AIM.

BDO LLP
Chartered Accountants and Registered Auditors
Southampton
United Kingdom

26 September 2017