Press release

Synairgen plc

('Synairgen' or the 'Company')

Interim results for the six months ended 30 June 2016

~ Clinical development of AZD9412 with AstraZeneca on track and Pharmaxis collaboration progressing towards the clinic ~

Southampton, UK – 22 September 2016: Synairgen plc (LSE: SNG), the respiratory drug discovery and development company, today announces its unaudited interim results for the six months ended 30 June 2016.

Operational highlights

- AstraZeneca's Phase II clinical trial with AZD9412, an inhaled interferon beta for asthma and COPD, continues to progress well and is on track to read out in 2017

- Positive results from the collaboration with Pharmaxis to develop an orally bioavailable LOXL2 inhibitor to treat patients with fibrotic conditions; is on course to start Phase I clinical trials in 2017

Financial highlights

- Research and development expenditure increased to £1.15 million (30 June 2015: £0.48 million) as the Company advanced the ongoing LOXL2 collaboration with Pharmaxis

- The loss from operations for the six months ended 30 June 2016 was £1.69 million (30 June 2015: £1.04 million loss)

- Cash and bank deposits of £6.31 million (30 June 2015: £8.73 million)

Richard Marsden, CEO of Synairgen, commented: *"We are pleased with the progress we have made over the past six months, including the clinical progress AstraZeneca is making with our primary asset AZD9412 in the Phase II trial which reads out next year.*

"In addition, there has been good momentum with our collaboration with Pharmaxis, who continue to advance the development of an oral LOXL2 inhibitor to treat patients with lung fibrosis.

"As we move into the second half of the year, we remain focused on screening new development opportunities which leverage our unique BioBank platform and expertise."

-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. This approach has been validated by the licensing agreement formed with AstraZeneca in June 2014 for Synairgen's SNG001 (AZD9412) programme in asthma/COPD. 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

During the first six months of 2016, AstraZeneca has continued to advance AZD9412, an asthma and COPD programme originally developed by Synairgen, which was licensed to AstraZeneca in 2014. A key Phase II clinical trial is due to read out in 2017.

Synairgen has also made very good progress in collaboration with Pharmaxis to develop an orally bioavailable LOXL2 inhibitor to treat patients with fibrosis and we remain on track to commence clinical trials in 2017.

AstraZeneca's AZD9412

In June 2014, Synairgen licensed its SNG001 programme (inhaled interferon-beta (IFN-beta)) programme to AstraZeneca, now referred to as AZD9412. AstraZeneca is making good progress in a Phase II clinical trial, which is on schedule to read out in 2017. The rationale to administer the antiviral defence protein IFN-beta directly to the lungs of asthma patients came from work conducted by Synairgen's academic founders and colleagues. They found that lung cells from asthma patients were less able to defend themselves from cold viruses than cells from non-asthmatics, mirroring the clinical setting where exacerbations of asthma ('asthma attacks') are mostly caused by respiratory viruses. They pinned the problem down to a deficiency of IFN-beta in an *in vitro* asthma model (the IFN-beta levels were about two thirds lower in cell cultures from asthmatics compared to those from non-asthmatic subjects). Correcting the deficiency by normalising the level of IFN-beta in the *in vitro* cell culture model allowed the asthma cells to mount a protective antiviral response. This observation could only have been made using lung cells obtained from asthma and non-asthmatic volunteers in an *in vitro* model system; it is this approach that Synairgen has further developed to build its BioBank platform. Synairgen developed an inhaled version of IFN-beta and completed two clinical trials before licensing it to AstraZeneca.

AstraZeneca's Phase II trial is designed to confirm the efficacy signal observed in Synairgen's own exploratory Phase II trial. In Synairgen's trial, inhaled IFN-beta provided benefits over placebo in terms of lung function, asthma control, inflammation and the number of exacerbations in a subgroup of 54 patients with more difficult to treat asthma from the total 147 patients in the trial who received either inhaled placebo or inhaled IFN-beta at the onset of cold symptoms. The subgroup comprised Step 4/5 asthma patients (as defined by the British Thoracic Society[1]), who use higher doses of standard asthma therapies to control their asthma. In the trial, Synairgen demonstrated that this subgroup of patients suffer most when cold infections take hold in the lungs. AstraZeneca is aiming to recruit 220 patients into their trial, focussing entirely on this subgroup population, with the primary endpoint being a reduction in the number of exacerbations. The trial is being conducted in seven countries and is due to read out in 2017.

In addition to asthma, AstraZeneca is interested in the potential of AZD9412 in patients with chronic bronchitis and emphysema (collectively known as Chronic Obstructive Pulmonary Disease (COPD)). Viruses are known to precipitate exacerbations in this disease too. COPD exacerbations can be particularly problematic because in addition to the viral component they are vulnerable to bacterial chest infections. COPD patients hospitalised due to an exacerbation have a poor prognosis, with mortality of 11%[2]. If AZD9412 is progressed into COPD by AstraZeneca it is hoped that it will lead to fewer bacterial exacerbations, and also fewer prescriptions of antibiotics which may help with the battle against antibiotic resistance.

Research collaboration to develop LOXL2 inhibitor for pulmonary fibrosis with Pharmaxis

In August 2015, Synairgen entered into a collaboration with Pharmaxis Ltd of Australia to develop an orally bioavailable (tablet form) compound that inhibits lysyl oxidase like 2 enzyme (LOXL2). LOXL2 is an enzyme implicated in many severe diseases where fibrosis (build-up of scar tissue) is a problem such as the lung disease Idiopathic Pulmonary Fibrosis (IPF), the liver disease Non-alcoholic Steatohepatitis (NASH), and kidney fibrosis. In all of these diseases the unwanted fibrosis causes the organ to stop functioning, and there are currently no known cures.

LOXL2 appears to play a key role in linking together the collagen fibres that make up scar tissue, increasing the stiffness of scar tissue ('collagen cross-links'). In IPF, fibrosis causes the lungs to become stiffer and less elastic, making them more difficult to inflate, and alters the structure of the air sacs, reducing the lung's ability to take up oxygen. In patients with IPF, the median survival from time of diagnosis is three years, highlighting a clear need for a directly anti-fibrotic drug.

In the US there are approximately 100,000 people with IPF, with 30,000 to 40,000 new cases diagnosed each year[3]. NASH, which affects 2-3% of the population[4], can lead to liver fibrosis. Due to the high mortality and prevalence of fibrotic diseases there is significant interest from global pharmaceutical companies to identify anti-fibrotic compounds for development as evidenced recently by a number of transactions.

Since we commenced the collaboration with Pharmaxis a year ago we have made excellent progress. A number of potent orally bioavailable LOXL2-selective irreversible inhibitors have been identified. In March we announced that, in collaboration with the University of Southampton, we have shown that this family of compounds inhibits the formation of collagen cross-links in a dose-dependent manner. This work was conducted in an *in vitro* fibroblastic foci model (a bundle of fibroblast cells in their collagen matrix, which is the hallmark of the IPF lung). The model used cells from patients with IPF and it provided us with *in vitro* proof of concept. We expect to produce further pharmacology data later this year relevant to IPF and we expect that Pharmaxis will generate data relevant to liver fibrosis. As a measure of the success of this collaboration we expect to commence Phase I clinical trials in 2017, just two years after the commencement of the collaboration.

It is anticipated that Synairgen and Pharmaxis will each have approximately a 50:50 stake in the IPF element of the collaboration by the end of Phase I, which is the earliest point that licensing to a large pharma partner is likely to occur. The compound may have utility beyond IPF in diseases such as NASH, kidney fibrosis and cancer, which will be explored by Pharmaxis. Synairgen has a smaller, but still potentially financially significant interest in non-IPF indications.

New opportunities

Synairgen continues to seek out new opportunities where its BioBank and *in vitro* model platform can add significant value to a partner's programme. These will be in the respiratory field and ideally, opportunities that are close to the clinic. We would hope to use our technology to: provide *in vitro* proof of concept; select a compound for further development; and identify biomarkers for use in Phase I trials. We have the clinical skills to complete Phase I and if necessary Phase II clinical trials before partnering for late stage clinical development.

FINANCIAL REVIEW

Statement of Comprehensive Income

The loss from operations for the six months ended 30 June 2016 was £1.69 million (six months ended 30 June 2015: £1.04 million loss). Research and development expenditure increased to £1.15 million (six months ended 30 June 2015: £0.48 million) as the Company advanced the ongoing LOXL2 collaboration with Pharmaxis. Other administrative costs for the period of £0.53 million remained broadly in line with the comparative period (six months ended 30 June 2015: £0.59 million). The research and development tax credit increased from £0.10 million to £0.28 million in line with the increase in research and development expenditure. The loss after tax for the period was £1.38 million (six months ended 30 June 2015: £0.91 million) and the basic loss per share was 1.51p (six months ended 30 June 2015: loss of 1.00p).

Statement of Financial Position and cash flows

At 30 June 2016, net assets amounted to £6.05 million (30 June 2015: £8.60 million), including net funds (comprising cash balances and bank deposits) of £6.31 million (30 June 2015: £8.73 million).

The principal elements of the £1.40 million decrease in net funds over the six months ended 30 June 2016 (six months ended 30 June 2015: £0.87 million decrease) were:

- Cash used in operations of £1.75 million (six months ended 30 June 2015: £0.90 million outflow); and
- Research and development tax credits received of £0.33 million (six months ended 30 June 2015: £nil).

Impact of Brexit

The referendum vote in the UK to leave the EU took place during this period under review. The main short term impact of the Brexit decision that we can identify, at this early stage, concerns the future costs on the LOXL2 collaboration denominated in foreign currencies. Chemistry work is paid for in Australian dollars and manufacturing primarily in US dollars. The other major near term expenditure on toxicology studies will be paid for in Sterling.

OUTLOOK

We are very pleased with the progress AstraZeneca is making with AZD9412 in asthma and look forward to the results being announced in 2017.

We are also very encouraged by the progress being made in the collaboration with Pharmaxis. Early data suggests that the compounds reduce cross-link formation in IPF tissue models, providing *in vitro* proof of concept. We are on schedule to start a Phase I clinical trial in 2017.

We continue to seek out programmes where we can add value through the use of our BioBank and *in vitro* models.

Simon Shaw	**Richard Marsden**
Chairman	Chief Executive Officer

21 September 2016

References

1. Sourced from the British Guideline on the Management of Asthma. A national clinical guideline. May 2008. Revised January 2012 (www.brit-thoracic.org.uk)
2. Anzueto A. Impact of exacerbations on COPD. *European Respiratory Review* 2010; 19: 113-18
3. Navaratnam VFK, West J, Smith CJ, Jenkins RG, Fogarty A, Hubbard RB. The rising incidence of idiopathic pulmonary fibrosis in the UK. Thorax 2011; 66: 462-467
4. Bellentani S, Scaglioni F, Marino M, Bedogni G. Epidemiology of Non-Alcoholic Fatty Liver Disease. Digestive Diseases 2010; 28: 155-161

Consolidated Statement of Comprehensive Income
for the six months ended 30 June 2016

	Notes	Unaudited Six months ended 30 June 2016 £000	Unaudited Six months ended 30 June 2015 £000	Audited Year ended 31 December 2015 £000
Revenue		**-**	25	25
Research and development expenditure		**(1,153)**	(475)	(1,355)
Other administrative expenses		**(533)**	(588)	(1,279)
Total administrative expenses		**(1,686)**	(1,063)	(2,634)
Loss from operations		**(1,686)**	(1,038)	(2,609)
Finance income		**22**	26	50
Loss before tax		**(1,664)**	(1,012)	(2,559)
Tax credit	2	**282**	102	304
Loss and total comprehensive loss for the period attributable to equity holders of the parent		**(1,382)**	(910)	(2,255)
Loss per ordinary share	3			
Basic and diluted loss per ordinary share (pence)		**(1.51)p**	(1.00)p	(2.47)p

Consolidated Statement of Changes in Equity (unaudited)
for the six months ended 30 June 2016

	Share capital £000	Share premium £000	Merger reserve £000	Retained deficit £000	Total £000
At 1 January 2015	913	25,771	483	(17,731)	9,436
Total comprehensive loss for the period	-	-	-	(910)	(910)
Recognition of share-based payments	-	-	-	74	74
At 30 June 2015	913	25,771	483	(18,567)	8,600
Total comprehensive loss for the period	-	-	-	(1,345)	(1,345)
Recognition of share-based payments	-	-	-	92	92
At 31 December 2015	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**

Consolidated Statement of Financial Position
as at 30 June 2016

	Notes	Unaudited 30 June 2016 £000	Unaudited 30 June 2015 £000	Audited 31 December 2015 £000
Assets				
Non-current assets				
Intangible assets		**71**	91	81
Property, plant and equipment		**17**	15	17
		88	106	98
Current assets				
Inventories		**56**	56	56
Current tax receivable		**255**	157	303
Trade and other receivables		**61**	56	112
Other financial assets – bank deposits	4	**2,500**	4,710	3,722
Cash and cash equivalents		**3,811**	4,018	3,992
		6,683	8,997	8,185
Total assets		**6,771**	9,103	8,283
Liabilities				
Current liabilities				
Trade and other payables		**(721)**	(503)	(936)
Total liabilities		**(721)**	(503)	(936)
Total net assets		**6,050**	8,600	7,347
Equity				
Capital and reserves attributable to equity holders of the parent				
Share capital		**914**	913	913
Share premium		**25,771**	25,771	25,771
Merger reserve		**483**	483	483
Retained deficit		**(21,118)**	(18,567)	(19,820)
Total equity		**6,050**	8,600	7,347

Consolidated Statement of Cash Flows
for the six months ended 30 June 2016

	Unaudited Six months ended 30 June 2016 £000	Unaudited Six months ended 30 June 2015 £000	Audited Year ended 31 December 2015 £000
Cash flows from operating activities			
Loss before tax	**(1,664)**	(1,012)	(2,559)
Adjustments for:			
Finance income	**(22)**	(26)	(50)
Depreciation	**4**	5	10
Amortisation	**10**	11	21
Share-based payment charge	**84**	74	166
Cash flows from operations before changes in working capital	**(1,588)**	(948)	(2,412)
Decrease/(Increase) in trade and other receivables	**49**	39	(18)
(Decrease)/Increase in trade and other payables	**(215)**	8	441
Cash used in operations	**(1,754)**	(901)	(1,989)
Tax credit received	**330**	-	56
Net cash used in operating activities	**(1,424)**	(901)	(1,933)
Cash flows from investing activities			
Interest received	**24**	33	58
Purchase of property, plant and equipment	**(4)**	(3)	(10)
Decrease in other financial assets	**1,222**	2,042	3,030
Net cash generated from investing activities	**1,242**	2,072	3,078
Cash flows from financing activities			
Proceeds from issuance of ordinary shares	**1**	-	-
Net cash generated from financing activities	**1**	-	-
(Decrease)/Increase in cash and cash equivalents	**(181)**	1,171	1,145
Cash and cash equivalents at beginning of period	**3,992**	2,847	2,847
Cash and cash equivalents at end of period	**3,811**	4,018	3,992

Notes to the Financial Statements
for the six months ended 30 June 2016

1. Basis of preparation

Basis of accounting
The interim financial statements, which are unaudited, have been prepared on the basis of the accounting policies expected to apply for the financial year to 31 December 2016 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 these interim financial statements are consistent with those used in the financial statements for the year ended 31 December 2015 and with those that the Company expects to apply in its financial statements for the year ending 31 December 2016.

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

The financial information for the year ended 31 December 2015 does not constitute the full statutory accounts for that period. The Annual Report and Financial Statements for the year ended 31 December 2015 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 2015 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 financial statements have been prepared on a going concern basis.

The 30 June 2016 interim financial statements were approved by a duly appointed and authorised committee of the Board of Directors on 21 September 2016.

2. Tax credit

The tax credit of £282,000 (six months ended 30 June 2015: £102,000; year ended 31 December 2015: £304,000) includes £255,000 as an estimate of the research and development tax credit receivable in respect of the current period and £27,000 representing amounts unprovided for in previous periods.

3. Loss per ordinary share

	Unaudited Six months ended 30 June 2016	Unaudited Six months ended 30 June 2015	Audited Year ended 31 December 2015
Loss attributable to equity holders of the Company (£000)	**(1,382)**	(910)	(2,255)
Weighted average number of ordinary shares in issue	**91,340,146**	91,316,671	91,316,671

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 2016 there were 5,719,762 options outstanding (30 June 2015: 5,373,435 options outstanding; 31 December 2015: 6,587,094 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 statements in the half-yearly financial report for the six months ended 30 June 2016 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 statements.

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 statements 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 statements in the half-yearly financial report for the six months ended 30 June 2016 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

21 September 2016