Analyst conference call
An analyst briefing and conference call will take place today, Tuesday 22 March 2016, at 9:30am GMT to discuss the Company's Preliminary Results and LOXL2 update (see separate press release issued today). Please contact Consilium Strategic Communications for more details.

Synairgen plc
('Synairgen' or the 'Company')

Preliminary statement of results for the year ended 31 December 2015

Southampton, UK - 22 March 2016: Synairgen plc (LSE: SNG), the respiratory drug discovery and development company, today announces its preliminary statement of audited results for the year ended 31 December 2015.

Operational highlights:

- In July, AstraZeneca commenced its Phase IIa study of AZD9412 (inhaled interferon beta, developed by Synairgen). The study is progressing according to plan and results are expected in 2017
- In August, a research collaboration was signed with Pharmaxis to develop a selective inhibitor of the lysyl oxidase type 2 enzyme (LOXL2) to treat the fatal lung disease idiopathic pulmonary fibrosis (IPF)
- Continued screening of new development opportunities using Synairgen's proprietary BioBank platform, leveraging Synairgen's world-class founder and respiratory drug discovery and development expertise

Financial highlights:

- Loss from operations for the year ended 31 December 2015 was £2.61 million (2014: profit £1.09 million). The prior year profit was driven by the one-off upfront licensing payment from AstraZeneca of £4.25 million
- Research and development expenditure for the year was £1.36 million (2014: £1.65 million)
- Cash, cash equivalents and deposit balances of £7.71 million at 31 December 2015 (2014: £9.60 million). The Group remains debt free
- Current funds support the ongoing search and identification of new potential molecule opportunities

Post period-end highlight:

- Positive results from Pharmaxis collaboration with LOXL2 inhibitors – see separate announcement issued today

Commenting on the Annual Results, Simon Shaw, Chairman of Synairgen, said: "We are pleased with the progress made this year across our collaborations and in screening new opportunities. Our primary asset, AZD-9412, is being progressed through the clinic by AstraZeneca with results expected in 2017. Our collaboration with Pharmaxis, has begun to yield positive results and we anticipate a Phase I clinical trial starting in 2017 in this very exciting area of respiratory medicine. Finally, our strong balance sheet positions

us well for progressing further collaborative programmes during the coming year."

Ends

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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 scientific and clinical trial facilities at the University of Southampton and 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 – validated in June 2014 by the SNG001 agreement formed with AstraZeneca. 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

Our business model is centred around a deep understanding of respiratory biology. Our focus is on the discovery and development of novel therapies for respiratory diseases particularly in the areas of highest unmet medical need, including severe asthma, COPD and IPF. Our strategy is to take drugs through to proof of concept stage and then partner them. Synairgen's first novel development programme to enter the clinical stage (AZD9412) is an inhaled interferon beta (IFN-beta) therapy which was out-licensed to AstraZeneca in 2014 for further clinical development and commercialisation. AstraZeneca started a confirmatory Phase II clinical trial in July 2015 and results are expected in 2017.

In August 2015 we announced a research collaboration with Pharmaxis Ltd (Pharmaxis), based in Sydney, Australia, to progress their anti-fibrotic LOXL2 inhibitor compounds for idiopathic pulmonary fibrosis (IPF). Since that time the two companies have been working well together to progress the programme and positive results were reported at the time of the Company's Preliminary results in March 2016.

Our strategy is to continue to build a portfolio of assets, to which we can add value, in collaboration with market leaders and other specialist biotechnology companies, all with the common goal of improving the health and well-being of respiratory disease sufferers.

Inhaled IFN-beta being developed by AstraZeneca

In June 2014, Synairgen signed a global exclusive licence agreement with AstraZeneca worth up to $232 million in milestone payments plus tiered royalties. AstraZeneca is responsible for all development, regulatory and commercial activities and on-going costs associated with this programme. The licence agreement with AstraZeneca also provides the opportunity to expand the clinical programme into other pulmonary diseases, including COPD.

In July 2015 AstraZeneca enrolled the first patient into a Phase II clinical trial which is designed to confirm the efficacy signal in the target population which was first observed in our pilot Phase II study SG005. The global trial will dose approximately 220 asthmatic patients who develop cold symptoms and is expected to complete in 2017. Half of the patients will receive placebo and half AZD-9412, which is designed to boost antiviral defences in the lungs to prevent these common viruses 'taking hold' and causing a deterioration in asthma symptoms, known as exacerbations. The primary outcome for the trial is the number of severe asthma exacerbations. Secondary outcomes will include lung function, asthma symptoms, safety and biomarkers relevant to the underlying biology.

AstraZeneca is a world leader in the respiratory sector, with a strong market presence and pipeline. This strength in respiratory medicine is of great benefit to Synairgen, and considerable effort and expertise is being applied to this programme over and beyond the ongoing clinical trial.

During the year, various academic groups from universities around the world have generated data that is helpful in understanding not only the problem that these common respiratory viruses cause to patients with asthma, but also to patients with the other major lung disease of chronic obstructive pulmonary disease (COPD). COPD affects approximately 25% of people who have smoked. The common cold virus is similarly implicated in causing exacerbations of COPD and is an unmet area of clinical need that is of great interest to AstraZeneca. In particular these studies have focussed on the mechanisms which may contribute to a deficiency in antiviral defences caused by lower or delayed production of IFN-beta. In the first study[1], lung samples from asthmatic patients expressed more of the SOCS1 protein, which is known to suppress IFN-beta production. This may explain the lower levels of IFN-beta observed in cells from asthmatic patients when they are exposed to the common cold virus. In a second study[2], it was shown that corticosteroids (an essential anti-inflammatory asthma therapy) may be compromising the lung's antiviral defences, an unwanted effect that could be overcome through application of IFN-beta. A third paper[3] describes why lung cells from COPD patients may be more susceptible to flu infection. These papers further support Synairgen's original work in establishing the rationale for using inhaled AZD9412 to boost antiviral defences in asthmatic and COPD patients when they are infected with common respiratory viruses. This makes us increasingly confident that AZD-9412 should be of significant benefit to such patients in an area of unmet need worldwide.

LOXL2 inhibitor to reduce fibrosis in patients with idiopathic pulmonary fibrosis (IPF)

In August 2015, Synairgen entered into a collaboration with Pharmaxis to identify and develop an oral inhibitor of the LOXL2 enzyme which has been implicated in lung fibrosis, in particular IPF, and other fibrotic conditions.

Idiopathic Pulmonary Fibrosis (IPF) is a rare and poorly understood lung condition that manifests in scarring (fibrosis) of the lungs. As this scarring gets worse, the lungs find it more difficult to function, compromising the uptake of oxygen into the blood, resulting in the symptoms of IPF. Symptoms include shortness of breath (even when performing day-to-day activities), which gets worse over time, and a persistent dry cough. The median survival is two to five years from the time of diagnosis[4]. IPF affects in the region of 100,000 people in the US[5] and at least this number in Europe[6].

Inhibition of Lysyl Oxidase-like protein 2 (LOXL2) is an attractive target in treatment of IPF. Scar tissue is composed of collagen fibres, which are produced by a type of cell called a fibroblast. LOXL2 is an enzyme released from fibroblasts that links collagen fibres together to stiffen scar tissue. Excessive production and linking of collagen fibres results in fibrosis. LOXL2 levels are increased in the lungs of patients with IPF, and higher levels are associated with more rapid disease progression. Pharmaxis has identified a novel family of compounds that selectively inhibit the LOXL2 enzyme.

Two new treatments have recently been approved for the treatment of IPF: pirfenidone (Roche); and nintedanib (Boehringer Ingelheim). However, there remains a clear unmet need for more effective and better tolerated drugs.

Importantly LOXL2 inhibitors, due to their differentiated mechanism of action, have the potential to provide additional benefit to these treatments.

To date we have used our proprietary *in vitro* models (using lung cells from IPF patients) to demonstrate the ability of the Pharmaxis compounds to inhibit the cross-linking of collagen fibres. We are currently conducting numerous pre-clinical tests prior to the selection of a candidate. In March 2016, we provided an update (see separate announcement issued today) which shows that the Pharmaxis enzyme inhibitors, by inhibiting LOXL2, are able to reduce cross-linking of collagen fibres in a dose dependent manner. Additionally it has also been found that collagen fibres were less organised in the presence of the inhibitors. It is hypothesised that this will result in less "stiff" lung tissue and that this may beneficially alter the course of this devastating disease. We are very excited at the prospect of progressing one of the Pharmaxis compounds into a Phase I clinical trial, which we anticipate commencing during 2017.

The deal terms with Pharmaxis recognise the extensive work already completed in building up the library of compounds. The objective of the collaboration is to build value through application of our pre-clinical models and clinical expertise, and to license the programme to a large pharmaceutical company at the end of Phase I or Phase IIa. Pharmaxis and Synairgen will share any licensing revenues in accordance with the ratio of total investment by the two companies at that time. The share of licensing revenues is expected to be approximately equal for a compound licensed for IPF after early clinical development. Synairgen will also receive a share of the licensing revenues paid by a licensee to Pharmaxis for collaboration compounds developed in other fibrotic indications outside the respiratory field such as non-alcoholic steatohepatitis (NASH) or kidney fibrosis.

Synairgen's new pipeline developments

We continue to assess new opportunities in our laboratories in parallel to discussing commercial terms and conducting due diligence in relation to bringing such opportunities into the Group. The ideal programme for us:

- has sufficient novelty such that it could achieve sales exceeding $1 billion per annum;
- has been progressed and produced promising initial data ; and
- needs the validation of our BioBank technology platform and Synairgen's wider clinical and commercial competence to progress to a proven value inflection point, ready for licensing to a large pharma company.

We use our BioBank and tissue models to increase confidence in the rationale for progressing such an asset and work to produce the scientific data required by large pharma licensees. We have a high due diligence threshold and a number of potential assets have been explored but declined. There are a number of opportunities from academic groups, small biotech companies, and some currently residing within large pharma, which we are continuing to review in depth. A number of these assets are at the clinical stage.

We expect to be able to bring at least one such collaboration into the Group in the coming year.

FINANCIAL REVIEW

Statement of Comprehensive Income

The loss from operations for the year ended 31 December 2015 was £2.61 million (2014: profit £1.09 million). The Group reported a profit in 2014 on account of the recognition of the AstraZeneca licensing transaction £4.25 million upfront payment. Revenues in the current year to 31 December 2015, representing scientific fee for service work for AstraZeneca, amounted to £0.03 million, were down from the 2014 revenues of £4.29 million (comprising the licence receipt of £4.25 million and fee for service income of £0.04 million). Research and development expenditure for the year amounted to £1.36 million (2014: £1.65 million), with a higher rate of expenditure in the second half of the year following the commencement of the LOXL2 programme with Pharmaxis in August 2015. There has been continuing expenditure during the year on research into new opportunity candidates.

Other administrative costs for the year amounted to £1.28 million (2014: £1.55 million), with the reduction over the prior year being attributable to lower staff costs. The research and development tax credit amounted to £0.30 million (2014: £0.06 million). The 2014 tax research and development tax credit was restricted on account of the Group being in profit. The loss after tax for 2015 was £2.26 million (2014: profit of £1.19 million) and the basic loss per share amounted to 2.47p (2014: basic earnings per share of 1.42p).

Statement of Financial Position and cash flows

At 31 December 2015, net assets amounted to £7.35 million (2014: £9.44 million), including cash and bank deposit balances of £7.71 million (2014: £9.60 million).

The principal elements of the £1.89 million decrease over the year ended 31 December 2015 (2014: £8.31 million increase) in net funds were:

- Cash used in operations of £1.99 million (2014: £1.61 million inflow);
- Research and development tax credits received of £0.06 million (2014: £0.20 million);
- Share issue proceeds (net of costs) £nil (2014: £6.51 million).

OUTLOOK

Our primary asset, AZD-9412, is in a confirmatory Phase II trial being conducted by AstraZeneca, with results from this trial expected in 2017.

During 2016, we expect to increase the data package around the LOXL2 inhibitor, building on the positive results already announced, and prepare for a Phase I clinical trial to start during 2017. Jointly with Pharmaxis, we have started to engage with large pharma companies, who are showing a strong interest in this programme.

We retain a strong balance sheet to enable us to continue to both develop existing programmes and screen new opportunities.

References

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3. Hsu AC *et al.* Impaired antiviral stress granule and IFN-β enhanceosome formation enhances susceptibility to influenza infection in COPD epithelium. *Am J Respir Cell Mol Biol.* 2016; [Epub ahead of print]
4. Meltzer E and Noble P. Idiopathic pulmonary fibrosis. *Orphanet J Rare Dis.* 200; 3:8
5. https://ghr.nlm.nih.gov/condition/idiopathic-pulmonary-fibrosis. Accessed March 2016
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Consolidated Statement of Comprehensive Income
for the year ended 31 December 2015

	Notes	**Year ended 31 December 2015 £000**	Year ended 31 December 2014 £000
Revenue		**25**	4,290
Research and development expenditure		**(1,355)**	(1,649)
Other administrative expenses		**(1,279)**	(1,547)
Total administrative expenses		**(2,634)**	(3,196)
(Loss)/Profit from operations		**(2,609)**	1,094
Finance income		**50**	31
(Loss)/Profit before tax		**(2,559)**	1,125
Tax	2	**304**	63
(Loss)/Profit and total comprehensive (loss)/income for the period attributable to equity holders of the parent		**(2,255)**	1,188
(Loss)/Earnings per ordinary share	3		
Basic (loss)/earnings per share (pence)		**(2.47p)**	1.42p
Diluted (loss)/earnings per share (pence)		**(2.47p)**	1.35p

Consolidated Statement of Changes in Equity
for the year ended 31 December 2015

	Share capital £000	Share premium £000	Merger reserve £000	Retained deficit £000	Total £000
At 1 January 2014	752	19,422	483	(19,078)	1,579
Issuance of ordinary shares	161	6,761	-	-	6,922
Transaction costs in respect of share issues	-	(412)	-	-	(412)
Recognition of share-based payments	-	-	-	159	159
Total comprehensive income for the year	-	-	-	1,188	1,188
At 31 December 2014	913	25,771	483	(17,731)	9,436
Recognition of share-based payments	-	-	-	166	166
Total comprehensive loss for the year	-	-	-	(2,255)	(2,255)
At 31 December 2015	**913**	**25,771**	**483**	**(19,820)**	**7,347**

Consolidated Statement of Financial Position
as at 31 December 2015

	31 December 2015 £000	31 December 2014 £000
Assets		
Non-current assets		
Intangible assets	**81**	102
Property, plant and equipment	**17**	17
	98	119
Current assets		
Inventories	**56**	56
Current tax receivable	**303**	55
Trade and other receivables	**112**	102
Other financial assets – bank deposits	**3,722**	6,752
Cash and cash equivalents	**3,992**	2,847
	8,185	9,812
Total assets	**8,283**	9,931
Liabilities		
Current liabilities		
Trade and other payables	**(936)**	(495)
Total liabilities	**(936)**	(495)
Total net assets	**7,347**	9,436
Equity		
Capital and reserves attributable to equity holders of the parent		
Share capital	**913**	913
Share premium	**25,771**	25,771
Merger reserve	**483**	483
Retained deficit	**(19,820)**	(17,731)
Total equity	**7,347**	9,436

Consolidated Statement of Cash Flows
for the year ended 31 December 2015

	Year ended 31 December 2015 £000	Year ended 31 December 2014 £000
Cash flows from operating activities		
(Loss)/Profit before tax	**(2,559)**	1,125
Adjustments for:		
Finance income	**(50)**	(31)
Depreciation	**10**	12
Amortisation	**21**	35
Loss on derecognised intangible asset	**-**	164
Share-based payment charge	**166**	159
Cash flows from operations before changes in working capital	**(2,412)**	1,464
Decrease in inventories	**-**	143
Increase in trade and other receivables	**(18)**	(40)
Increase in trade and other payables	**441**	38
Cash (used in)/generated from operations	**(1,989)**	1,605
Tax credit received	**56**	198
Net cash (used in)/generated from operating activities	**(1,933)**	1,803
Cash flows from investing activities		
Interest received	**58**	12
Purchase of property, plant and equipment	**(10)**	(14)
Purchase of intangible assets	**-**	(4)
Decrease/(Increase) in other financial assets	**3,030**	(6,294)
Net cash generated from/(used in) investing activities	**3,078**	(6,300)
Cash flows from financing activities		
Proceeds from issuance of ordinary shares	**-**	6,922
Transaction costs in respect of share issues	**-**	(412)
Net cash generated from financing activities	**-**	6,510
Increase in cash and cash equivalents	**1,145**	2,013
Cash and cash equivalents at beginning of the year	**2,847**	834
Cash and cash equivalents at end of the year	**3,992**	2,847

Notes

1. Basis of preparation

The financial information of the Group set out above does not constitute "statutory accounts" for the purposes of Section 435 of the Companies Act 2006. The financial information for the year ended 31 December 2015 has been extracted from the Group's audited financial statements which were approved by the Board of directors on 21 March 2016 and will be delivered to the Registrar of Companies for England and Wales in due course. The financial information for the year ended 31 December 2014 has been extracted from the Group's audited financial statements for that period which have been delivered to the Registrar of Companies for England and Wales. The reports of the auditors on both these financial statements were unqualified, did not include any references to any matters to which the auditors drew attention by way of emphasis without qualifying their report and did not contain a statement under Section 498(2) or Section 498(3) of the Companies Act 2006. Whilst the financial information included in this preliminary announcement has been prepared in accordance with the recognition and measurement criteria of International Financial Reporting Standards ('IFRSs') as adopted by the European Union, this announcement does not itself contain sufficient information to comply with those IFRSs. This financial information has been prepared in accordance with the accounting policies set out in the December 2015 report and financial statements.

2. Tax

The tax credit of £304,000 (2014: £63,000) relates to research and development tax credits in respect of the year ended 31 December 2015 (£303,000) and an adjustment in respect of prior periods (£1,000).

3. (Loss)/Earnings per ordinary share

Basic (loss)/earnings per share ('LPS' or 'EPS') is calculated by dividing the (loss)/profit attributable to ordinary equity holders of the parent company by the weighted average number of ordinary shares in issue during the year.

For diluted earnings per share, the weighted number of ordinary shares in issue is adjusted to assume conversion of dilutive potential ordinary shares, being share options where the exercise price is less than the average market price of the Company's ordinary shares during the year and where performance conditions have been met or, in the case of options where the performance period is not completed, are being met.

Where there is a loss (as for the year ended 31 December 2015), the loss attributable to ordinary shareholders and weighted average number of ordinary shares for the purpose of calculating the diluted earnings per ordinary share are identical to those used for basic loss per share. This is because the exercise of share options would have the effect of reducing the loss per ordinary share and is therefore antidilutive under the terms of IAS 33.

The losses/earnings and number weighted average number of shares used in the calculations are as follows:

	Losses £'000	**Shares '000**	**2015 LPS Pence**	Earnings £'000	Shares '000	2014 EPS pence
Basic (loss)/earnings per share	(2,255)	91,317	**(2.47)**	1,188	83,899	1.42
Effect of additional shares under option	-	-	**-**	-	4,279	(0.07)
Diluted (loss)/earnings per share	(2,255)	91,317	**(2.47)**	1,188	88,178	1.35