Analyst and investor conference call
A conference call for analysts and investors will take place today, Tuesday 3 March 2015, at 11:00am GMT. Please contact Consilium Strategic Communications for more details.

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

Preliminary statement of results for the year ended 31 December 2014

Southampton, UK - 3 March 2015: 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 2014.

Operational highlights:

- Global exclusive licence agreement signed in June 2014 with AstraZeneca for SNG001 (inhaled interferon beta) for all respiratory indications:
  - $7.25 million up-front payment
  - potential development, regulatory and commercial milestones of up to $225 million
  - tiered royalties of up to mid-teens on future potential sales
  - AstraZeneca responsible for all future costs
- SNG001 Phase II clinical data published in the American Journal of Respiratory and Critical Care Medicine in July 2014
- Screening of new development opportunities using Synairgen's proprietary "BioBank" platform leveraging Synairgen's world-class founder and KOL respiratory drug discovery and development expertise – several assets identified as potential opportunities for licensing into the Company

Financial highlights:

- Post-tax profit for the year of £1.2 million (2013: loss £2.0 million), driven by initial receipt from AstraZeneca of $7.25M (£4.25 million) received in June 2014
- Research and development expenditure for the year was £1.6 million (2013: £1.3 million)
- Cash and deposit balances of £9.6 million at 31 December 2014 (2013: £1.3 million)
- Current funds support the pre-clinical development of key potential opportunities

Commenting on the results, Simon Shaw, Chairman of Synairgen, said:
"We are delighted with the progress Synairgen has made during what has been a transformational year with the licensing deal of our novel therapeutic, SNG001, for development and commercialisation by AstraZeneca.

"We are engaged in due diligence on a number of novel development opportunities to which Synairgen's platform could add significant value in the

near and medium term and we expect a number of these to enter our development pipeline during the coming period."

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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

The year has been transformational for Synairgen. The successful licensing of Synairgen's inhaled interferon beta (IFN-beta, formerly known as SNG001) programme to AstraZeneca in June demonstrates Synairgen's competence in identifying and developing early stage assets to a point of commercial value and typifies the potential of our business model. During the year, Synairgen's team, including its world-leading respiratory drug discovery and development experts, have screened approximately 30 new assets from around the globe. Some of the assets have been identified as potential opportunities for bringing into the Company for development and then for future licensing out to large pharmaceutical company partners for late stage development and marketing. To support this development activity Synairgen raised an additional £5.3 million in July 2014.

Inhaled IFN-beta and the licensing agreement with AstraZeneca

In June 2014, Synairgen signed a global exclusive licence agreement with AstraZeneca, a major franchise holder in the respiratory sector, for which it received an upfront payment of $7.25 million, and will receive potential further development, regulatory and commercial milestones of up to $225 million. In addition, Synairgen will receive tiered royalties on sales, which escalate to the mid-teens percentage level. Being a novel therapy in an area of respiratory disease where there is a great unmet medical need, it is not possible at this stage to be definitive about the potential size of the market, however, the health economics and the size of the target patient group indicate that an efficacious therapy of this type could command peak sales in excess of $1 billion per annum.

AstraZeneca is now responsible for all future development activities and costs associated with this programme. AstraZeneca's reference for the inhaled IFN-beta programme is AZD9412.

The need for AZD9412

Despite taking inhaled corticosteroids, asthmatics are still susceptible to exacerbations (worsening of asthma symptoms). Respiratory virus infections (e.g. the common cold) are a major trigger for exacerbations and there are limited satisfactory treatments available to address this significant unmet medical need which is associated with a significant proportion of healthcare spending on asthma. Clinical data generated from trials to date shows that this compound supports or boosts the immune system by correcting a deficiency which makes patients vulnerable to respiratory tract viral infections. The clinical need for a drug that helps chronic obstructive pulmonary disease (COPD) patients during viral infections is perhaps even greater due to the high morbidity associated with exacerbations/hospitalisations of their disease.

IFN-beta deficiency

Asthmatics do not get more respiratory viral infections (common colds) than non-asthmatics, but infections are more likely to worsen inflammation in the lungs and cause exacerbations. Professor Donna Davies (one of the three Synairgen academic founders) and colleagues at the University of Southampton and Imperial College London found that lung models using cells from asthmatic volunteers were more vulnerable to virus infection. In these models lung cells from asthmatics produced lower amounts of the key antiviral defence protein IFN-beta during virus infections. This offered a potential explanation for why the lungs of asthmatics are affected more by respiratory virus infections, and by simply adding a small amount of IFN-beta to cultures of lung cells from asthmatics it was shown that antiviral responses were improved. This suggested that direct delivery of IFN-beta to the lungs of asthmatics by inhalation during a respiratory virus infection could limit the spread of the virus to the lungs and also ultimately reduce the number of asthma exacerbations and potentially COPD exacerbations.

Steps completed by Synairgen

Pre-clinical development

Synairgen used its models of lung disease to confirm the potential utility of inhaled IFN-beta against many common respiratory viruses including rhinovirus strains, RSV, and influenza strains, and worked with other groups to test IFN-beta against highly pathogenic strains of influenza and a coronavirus (MERS). Synairgen also used the models to study various dosing regimens and to develop biomarkers for clinical trials in asthmatic patients.

Phase I clinical trials

Synairgen developed an inhaled form of IFN-beta and progressed it into clinical trials. Synairgen's Phase I trials showed that inhaled IFN-beta was well tolerated at varying dose levels. Analysis of biomarkers showed that inhaled IFN-beta successfully boosted the immune system.

Phase II clinical trial

The Phase II trial recruited patients from a broad spectrum of asthma patients and patients were treated with IFN-beta or placebo at the onset of cold symptoms. One of the major findings from the trial was that milder and moderate patients do not appear to suffer the same degree of symptom deterioration (measured with the Asthma Control Questionnaire (ACQ)) as more severe patients (characterised as those taking higher doses of maintenance asthma therapy). The ACQ was used as the primary end point for the trial. A statistically significant difference in ACQ ($p=0.004$) was evident in the more severe patients (defined as Step 4 and Step 5 asthmatics according to the British Thoracic Society classifications), which are estimated to represent between 10% and 20% of all adult asthma sufferers. To put this into context, as there are 19 million adult American asthma sufferers (CDC Summary Health Statistics for U.S. Adults: National Health Interview Survey, 2012) this equates to a potential market of between 1.9 and 3.8 million adult asthma sufferers in the US alone. In these patients, there was also a lung function benefit in favour of inhaled IFN-beta and there appeared to be fewer severe exacerbations. Biomarkers of lung inflammation were also lower in patients receiving inhaled IFN-beta.

These results have now been published in the American Journal of Respiratory and Critical Care Medicine, a prestigious peer-reviewed journal (Djukanovic R, Harrison T, Johnston SL, Gabbay F, Wark P, Thomson NC, Niven R, Singh D, Reddel HK, Davies DE, et al. The effect of inhaled interferon-beta on worsening of asthma symptoms caused by viral infections: a randomised trial. Am J Respir Crit Care Med 2014;190:145–154).

We believe the inhaled IFN-beta programme is considerably de-risked compared to many programmes at this stage of development, firstly because of its use by injection for the last two decades in multiple sclerosis (thereby accumulating a significant safety record), and secondly because it is targeting what is recognised to be the major cause of asthma exacerbations.

AstraZeneca activities

AstraZeneca are due to commence an international Phase II trial during 2015. This Phase II trial is expected to recruit patients from the Step 4 and 5 asthma population who are at particular risk of experiencing exacerbations caused by cold viruses. Synairgen estimates that the trial is expected to produce results in the early part of 2017. AZD9412 also provides the opportunity to expand the clinical programme into other pulmonary diseases, including COPD.

Synairgen's new pipeline developments

As yet undisclosed programmes are currently being assessed by Synairgen. Synairgen is using its expertise, models, and understanding of asthma, COPD and respiratory biology to assess novel opportunities to which our platform and development experience can add significant value. The team has screened approximately 30 new assets from around the globe during the past 12 months and after deeper due diligence, several assets have been identified as potential opportunities for licensing into the Company.

Synairgen will use its BioBank of clinical samples of blood, sputum, biopsies and bronchial epithelial cells obtained from a selection of well-characterised asthma and COPD volunteers and healthy control subjects in models of respiratory disease to validate drug targets, tailor treatment approaches to patient groups (personalised medicine), and use the models to progress compounds towards early stage clinical trials.

A number of the shortlisted programmes are at a stage where initial clinical trials could be commenced in 2016. They are all of a potential market size and utility to be attractive to large pharmaceutical companies – fitting with Synairgen's partnering model.

FINANCIAL REVIEW

Statement of Comprehensive Income

The profit from operations for the year ended 31 December 2014 was £1.09 million (2013: loss £2.28 million). Revenues of £4.29 million (2013: £nil) comprised the upfront payment from AstraZeneca (as discussed above) of £4.25 million and £0.04 million of scientific fee for service work for AstraZeneca.

Research and development expenditure for the year amounted to £1.65 million (2013: £1.29 million) and was incurred in relation to the interferon beta programme and research into the new opportunity candidates.

Other administrative costs for the year amounted to £1.55 million (2013: £0.99 million), with the increase over the prior year being attributable to business development costs and staff costs. On account of the Group being in profit, there was a reduction in the research and development tax credit from £0.22 million to £0.06 million. The profit after tax for the year was £1.19 million (2013: loss of £2.04 million) and the basic earnings per share amounted to 1.42p (2013: loss of 2.72p).

Fundraisings

During the year, there were two fundraisings. In March 2014, the Company raised £1.50 million (gross) through the issue of 3.13 million shares at a price of 48p to provide working capital to progress its out-licensing discussions through to a conclusion. Costs of the issue amounted to £0.08 million. In July 2014, the Company raised a further £5.31 million through the issue of 10.63 million shares at a price of 50p to enable it to progress new development opportunities. Costs of this issue were £0.33 million.

Statement of Financial Position and cash flows

At 31 December 2014, net assets amounted to £9.44 million (2013: £1.58 million), including cash and bank deposit balances of £9.60 million (2013: £1.29 million).

The principal elements of the £8.31 million increase over the year ended 31 December 2014 (2013: £1.80 million decrease) in cash and bank deposit balances were:

- Cash generated from operations of £1.61 million (2013: £2.04 million outflow);
- Research and development tax credits received of £0.20 million (2013: £0.24 million);
- Share issue proceeds (net of costs) £6.51 million (2013: £nil).

OUTLOOK

We are delighted with the progress Synairgen has made this year with the licensing deal of our novel therapeutic, inhaled IFN-beta, for development and commercialisation at AstraZeneca.

We are engaged in due diligence on a number of novel development opportunities to which Synairgen’s platform could add significant value in the near and medium term and we expect a number of these to enter our development pipeline during the coming period.

Consolidated Statement of Comprehensive Income
for the year ended 31 December 2014

	Notes	**Year ended 31 December 2014 £000**	Year ended 31 December 2013 £000
Revenue		**4,290**	-
Research and development expenditure		**(1,649)**	(1,292)
Other administrative expenses		**(1,547)**	(986)
Total administrative expenses		**(3,196)**	(2,278)
Profit/(Loss) from operations		**1,094**	(2,278)
Finance income		**31**	11
Profit/(Loss) before tax		**1,125**	(2,267)
Tax	2	**63**	224
Profit/(Loss) and total comprehensive income/(loss) for the period attributable to equity holders of the parent		**1,188**	(2,043)
Earnings/(Loss) per ordinary share	3		
Basic earnings/(loss) per share (pence)		**1.42p**	(2.72)p
Diluted earnings/(loss) per share (pence)		**1.35p**	(2.72)p

Consolidated Statement of Changes in Equity
for the year ended 31 December 2014

	Share capital £000	Share premium £000	Merger reserve £000	Retained deficit £000	Total £000
At 1 January 2013	752	19,422	483	(17,241)	3,416
Issuance of ordinary shares	-	-	-	-	-
Recognition of share-based payments	-	-	-	206	206
Total comprehensive loss for the year	-	-	-	(2,043)	(2,043)
At 31 December 2013	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**

Consolidated Statement of Financial Position
as at 31 December 2014

	31 December 2014 £000	31 December 2013 £000
Assets		
Non-current assets		
Intangible assets	**102**	297
Property, plant and equipment	**17**	15
	119	312
Current assets		
Inventories	**56**	199
Current tax receivable	**55**	190
Trade and other receivables	**102**	43
Other financial assets – bank deposits	**6,752**	458
Cash and cash equivalents	**2,847**	834
	9,812	1,724
Total assets	**9,931**	2,036
Liabilities		
Current liabilities		
Trade and other payables	**(495)**	(457)
Total liabilities	**(495)**	(457)
Total net assets	**9,436**	1,579
Equity		
Capital and reserves attributable to equity holders of the parent		
Share capital	**913**	752
Share premium	**25,771**	19,422
Merger reserve	**483**	483
Retained deficit	**(17,731)**	(19,078)
Total equity	**9,436**	1,579

Consolidated Statement of Cash Flows
for the year ended 31 December 2014

	Year ended 31 December 2014 £000	Year ended 31 December 2013 £000
Cash flows from operating activities		
Profit/(Loss) before tax	**1,125**	(2,267)
Adjustments for:		
Finance income	**(31)**	(11)
Depreciation	**12**	15
Amortisation	**35**	47
Loss on derecognised intangible asset	**164**	4
Share-based payment charge	**159**	206
Cash flows from operations before changes in working capital	**1,464**	(2,006)
Decrease/(Increase) in inventories	**143**	(127)
(Increase)/Decrease in trade and other receivables	**(40)**	32
Increase in trade and other payables	**38**	66
Cash generated from/(used in) operations	**1,605**	(2,035)
Tax credit received	**198**	244
Net cash generated from/(used in) operating activities	**1,803**	(1,791)
Cash flows from investing activities		
Interest received	**12**	15
Purchase of property, plant and equipment	**(14)**	(3)
Purchase of intangible assets	**(4)**	(16)
(Increase)/Decrease in other financial assets	**(6,294)**	973
Net cash (used in)/generated from investing activities	**(6,300)**	969
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/(Decrease) in cash and cash equivalents	**2,013**	(822)
Cash and cash equivalents at beginning of the year	**834**	1,656
Cash and cash equivalents at end of the year	**2,847**	834

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 2014 has been extracted from the Group's audited financial statements which were approved by the Board of directors on 2 March 2015 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 2013 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 2014 report and financial statements.

2. Tax

The tax credit of £63,000 (2013: £224,000) relates to research and development tax credits in respect of the year ended 31 December 2014 (£55,000) and an adjustment in respect of prior periods (£8,000).

3. Earnings/(Loss) per ordinary share

Basic earnings/(loss) per share ('EPS' or 'LPS') is calculated by dividing the profit/(loss) 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 2013), 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 earnings/losses and number weighted average number of shares used in the calculations are as follows:

	Earnings £'000	**Shares '000**	**2014 EPS pence**	Losses £'000	Shares '000	2013 LPS pence
Basic earnings/(loss) per share	1,188	83,899	1.42	(2,043)	75,187	(2.72)
Effect of additional shares under option	-	4,279	(0.07)	-	-	-
Diluted earnings/(loss) per share	1,188	88,178	1.35	(2,043)	75,187	(2.72)