Press release

Synairgen plc

('Synairgen' or the 'Company')

Preliminary statement of results for the year ended 31 December 2012

Southampton, UK – 13 February 2013: Synairgen plc (LSE: SNG), the respiratory drug discovery and development company with a focus on viral defence of the lungs, today announces its audited results for the year ended 31 December 2012.

Operational highlights

- Positive data announced in April 2012 from the Phase II proof of concept trial of inhaled interferon beta (SNG001) being developed for the treatment or prevention of virus-induced asthma exacerbations, which showed:
    - British Thoracic Society Step 4/5 patients (estimated to represent between 10% and 20% of adult asthma sufferers, who are the greatest healthcare burden) suffer most due to cold viruses
    - Significant benefit across multiple endpoints in the Step 4/5 population
    - Inhaled interferon beta is well tolerated
- The positive Phase II clinical trial data triggered comprehensive business development activity. Multiple parties are conducting detailed technical and commercial evaluations of SNG001. We aim to finalise arrangements with a primary partner to enable commencement of follow-on clinical trial activity during the 2013 – 2014 virus season
- Biomarker analysis of Phase II study samples commenced
- We are continuing to map out the different regulatory and clinical paths required to progress SNG001 to market in asthma and COPD. This is being progressed in parallel with our business development discussions
- We have commenced engagement with the US government to investigate the potential of SNG001 as a broad spectrum anti-viral treatment
- Expansion of patent portfolio, including grant of US patent for compounds that induce interferon beta to treat or prevent rhinovirus (common cold)-induced exacerbations in asthma or COPD

Financial highlights

- Balance sheet strengthened with fundraising of £2.5 million (gross) completed in July 2012
- Research and development expenditure for the year: £1.5 million (six months ended 31 December 2011: £1.8 million)
- Post-tax loss for the year: £2.3 million (six months ended 31 December 2011: £2.0 million)
- Cash at 31 December 2012: £3.1 million (31 December 2011: £3.4 million)

Commenting on the results, Simon Shaw, Chairman of Synairgen, said:
"In 2012 our interferon beta programme achieved a significant milestone, generating persuasive efficacy data within the group of asthma patients that we are seeking to treat. We are now planning the further development of this exciting therapy and are focussed on securing the right partnership to help us deliver it."

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OPERATING REVIEW

This has been a pivotal year for Synairgen, as its primary programme, SNG001 (inhaled interferon beta) to treat or prevent exacerbations of asthma and COPD, has produced positive Phase II clinical trial data. We also raised further funds to strengthen the balance sheet whilst we explore partnering opportunities.

Synairgen's inhaled SNG001 is being developed as a broad spectrum anti-viral therapy to be taken by asthmatic and COPD patients at the onset of cold (or influenza) symptoms. It is designed to treat and/or attenuate a deterioration of asthma or COPD symptoms and prevent severe exacerbations that require intensive treatment with oral therapies such as steroids or antibiotics. It has long been established that common viruses are a major cause of exacerbations and hospitalisations in these diseases. The rationale for developing inhaled SNG001 came from the observation that cells from asthmatic patients and COPD patients' lungs respond poorly to viruses, and do not produce enough of the key anti-viral protein interferon beta. Adding interferon beta to the cells restores and boosts the anti-viral defences.

Results of Phase II trial

In April we announced preliminary results from the trial. Since then we have continued to review the mass of data generated by this study alongside key opinion leaders in the field. The results were presented by Prof. Ratko Djukanovic at the European Respiratory Society in September 2012 and were well received. The results have also recently been submitted for publication.

In the trial, 147 patients with a wide range of asthma severity were treated with either SNG001 or placebo at the early signs of a cold infection. Of the 147, 132 went on to develop a full cold (the other 15 patients either did not provide data to be able to confirm a cold, or the cold symptoms did not materialise).

Various endpoints were assessed to establish whether SNG001 was providing benefit to these asthmatic patients during respiratory virus infections. The primary endpoint was a measure of change in asthma symptoms during the first week of treatment using the shortened Asthma Control Questionnaire (sACQ). In the treated population who got colds, there appeared to be minimal benefit. Essentially the cold infection was not impacting on patients' asthma as seriously as expected, thus there was little opportunity for an intervention to demonstrate efficacy and there was no statistically significant difference. However for lung function (morning peak expiratory flow, a secondary/exploratory endpoint) there was a statistically significant benefit for patients receiving SNG001. This in itself is very encouraging.

A review of patients whose asthma deteriorated to the point where they were prescribed oral steroids (or antibiotics) to treat their exacerbation showed that five patients receiving placebo and one patient receiving SNG001 required this more serious level of intervention to treat their asthma exacerbation. One of the patients on placebo was hospitalised for five days for their asthma.

Of particular interest to us was that all five of the placebo patients who received oral corticosteroids or antibiotics to treat their exacerbation were in the British Thoracic Society (BTS) Step 4 classification. The BTS Step classification system ranges from 1 to 5, with Step 1 patients being least intensively treated to Step 5 being the most intensively treated. BTS Step 4 patients, who are recognised as 'difficult to treat', receive close to maximal routine inhaled therapies (i.e. higher doses of inhaled corticosteroids - an anti-inflammatory - and a long acting beta agonist (bronchodilator) as a minimum). None of the Step 4 or Step 5 SNG001-treated patients required this higher level of intervention (i.e. oral steroids or antibiotics). This led us to investigate the possibility that this population may be the patient group who not only suffer most during respiratory virus infections, but also respond best to SNG001 treatment.

Analysis of sub populations according to BTS Step group

The first observation was that there were disproportionately more (approaching half) Step 4 and Step 5 patients in the trial than one would find in the general asthma population, where 10% to 20% would be expected. We believe the trial radio advert recruitment wording, "Does your asthma get worse when you get a cold?", created a positive bias that resulted in the selection of patients whose asthma deteriorates most when they get a cold.

An assessment of asthma control using the sACQ (as used for the primary endpoint) showed that in the first week of the cold there was a marked worsening in patients on placebo, whereas patients on SNG001 showed a movement returning towards their screening (uninfected) level of control. The difference on the sACQ scale of 0.63 in favour of SNG001 exceeded the threshold considered to be clinically relevant (> 0.5) and was statistically significant (p=0.002).

A similar subgroup analysis of the lung function (morning peak expiratory flow) changes, which were significantly better for the overall population in the trial (as referred to above), showed that the positive effects of SNG001 were minimal for the 'milder' Step 2 patients (difference of 6 litres/min), approaching clinical relevance (17 litres/min) for the Step 3 patients, and exceeding the clinically relevant different of 20 litres/min in the Step 4 patients (31 litres/min).

This trial has been successful on three counts:

- Firstly, we have identified the patient group which appears to suffer most due to cold viruses; this is the Step 4 and Step 5 patients. Patients at lower Steps have other therapeutic options: they have greater scope to increase the doses of their existing routine daily medication, and it is also quite possible that compliance to medication may increase at times of infection. It appears that Step 4 patients are more likely to use more potent drugs, such as oral corticosteroids.
- Secondly, in these Step 4/5 patients, treatment with SNG001 was beneficial in terms of the number of patients requiring oral therapies, improvement in asthma control, and accelerating the recovery in lung function.
- Thirdly, SNG001 appears to be well tolerated, and there was no evidence of systemic absorption.

Business Development

The positive data from the Phase II clinical trial has triggered comprehensive business development activity. This process has identified multiple parties with established commercial respiratory franchises who are interested in this therapeutic area. During the period, we have devoted significant time and resource to enable potential partners to conduct technical and commercial evaluations of SNG001. Given the novelty of this potential treatment we have worked up a number of options regarding clinical and regulatory development pathways for SNG001. We aim to secure the right partnership arrangement to enable commencement of follow-on clinical trial activity during the 2013 – 2014 virus season and we are confident that this process can achieve that goal.

Biomarker analysis of Phase II samples

We are also progressing well with the analysis of samples from our Phase II study in asthma. A panel of possible gene and protein biomarkers have been identified and are the subject of further investigations. We shall provide updates on this activity which is designed to underpin the clinical observations, and also identify potential prognostic biomarkers**.**

Clinical development plan

We are making very good progress with regard to preparation of materials (e.g. protocols) for follow-on studies in asthma and COPD. These are being progressed in parallel with our business development discussions. Each potential partner has a slightly different view on how this should be progressed, but all are still valid approaches for this innovative programme.

Intellectual property

During the year, a US patent was granted for compounds that induce interferon beta to treat or prevent rhinovirus (common cold)-induced exacerbations in asthma or COPD. This is important intellectual property for the Company, as it prevents inducers of interferon beta, such as toll receptor agonists, being developed to do the same role as SNG001.

Severe viral lung infections

We submitted an application to the US National Institutes of Health to support activity that will progress inhaled SNG001 towards the non-asthma, non-COPD market, which is to treat patients hospitalised with severe viral lung infections. We expect to hear whether we have been successful during this summer.

FINANCIAL REVIEW

Change of Accounting Reference Date in prior period

During the previous accounting period, the Group brought forward its financial year-end from 30 June to 31 December and as a result comparative financial information in this preliminary statement is for the six months ended 31 December 2011.

Statement of Comprehensive Income

The loss from operations for the year ended 31 December 2012 was £2.49 million (six months ended 31 December 2011: £2.24 million). Research and development expenditure for the year amounted to £1.51 million (six months ended 31 December 2011: £1.82 million). The proportionate reduction in research and development expenditure was due to the completion early in the year of both the asthma Phase II study (SG005) and the pre-clinical study in viral pneumonia. The most significant item of continuing research and development during the year has been the analysis of data and samples collected from SG005.

Other administrative costs for the year amounted to £0.98 million (six months ended 31 December 2011: £0.42 million). The research and development tax credit for the year, in line with the reduction in expenditure, was £0.21 million (six months ended 31 December 2011: £0.25 million). The loss after tax for the year was £2.25 million (six months ended 31 December 2011: £1.97 million) and the loss per share was 3.12p (six months ended 31 December 2011: loss of 2.83p).

Fundraising

In July 2012, the Company raised £2.50 million (gross) through the issue of 5.56 million shares at a price of 45p per share. Costs of the issue amounted to £0.15 million (6.0%).

Statement of Financial Position and cash flows

At 31 December 2012, net assets amounted to £3.42 million (31 December 2011: £3.12 million), including net funds, as detailed below in Capital structure and funding, of £3.09 million (31 December 2011: £3.35 million).

The principal elements of the £0.26 million decrease over the year ended 31 December 2012 (six months ended 31 December 2011: £1.54 million decrease) in net funds were:

- Cash used in operations of £2.75 million (six months ended 31 December 2011: £1.93 million outflow);
- Research and development tax credits received of £0.25 million (six months ended 31 December 2011: £0.40 million);
- Investment into intangible assets (patents and licences) £0.14 million (six months ended 31 December 2011: £0.02 million); and
- Share issue proceeds (net of costs) £2.35 million (six months ended 31 December 2011: £nil).

SUMMARY

In 2012 our interferon beta programme achieved a significant milestone, generating persuasive efficacy data within the group of asthma patients that we are seeking to treat. We are now planning the further development of this exciting therapy and are focussed on securing the right partnership to help us deliver it.

Consolidated Statement of Comprehensive Income
for the year ended 31 December 2012

	Notes	**Year ended 31 December 2012 £000**	6 months ended 31 December 2011 £000
Research and development expenditure		**(1,508)**	(1,815)
Other administrative expenses		**(982)**	(423)
Total administrative expenses		**(2,490)**	(2,238)
Loss from operations		**(2,490)**	(2,238)
Finance income		**27**	20
Loss before tax		**(2,463)**	(2,218)
Tax	2	**213**	251
Loss and total comprehensive income for the period attributable to equity holders of the parent		**(2,250)**	(1,967)
Loss per ordinary share			
Basic and diluted loss per share (pence)	3	**(3.12)p**	(2.83)p

Consolidated Statement of Changes in Equity
for the year ended 31 December 2012

	Share capital £000	Share premium £000	Merger reserve £000	Retained deficit £000	Total £000
At 1 July 2011	696	17,128	483	(13,313)	4,994
Recognition of share-based payments	-	-	-	96	96
Total comprehensive income for the period	-	-	-	(1,967)	(1,967)
At 31 December 2011	696	17,128	483	(15,184)	3,123
Issuance of ordinary shares	56	2,445	-	-	2,501
Transaction costs in respect of share issues	-	(151)	-	-	(151)
Recognition of share-based payments	-	-	-	193	193
Total comprehensive income for the year	-	-	-	(2,250)	(2,250)
At 31 December 2012	**752**	**19,422**	**483**	**(17,241)**	**3,416**

Consolidated Statement of Financial Position
as at 31 December 2012

	31 December 2012 £000	31 December 2011 £000
Assets		
Non-current assets		
Intangible assets	**332**	239
Property, plant and equipment	**27**	48
	359	287
Current assets		
Inventories	**72**	85
Current tax receivable	**210**	250
Trade and other receivables	**79**	113
Other financial assets – bank deposits	**1,431**	2,455
Cash and cash equivalents	**1,656**	896
	3,448	3,799
Total assets	**3,807**	4,086
Liabilities		
Current liabilities		
Trade and other payables	**(391)**	(963)
Total liabilities	**(391)**	(963)
Total net assets	**3,416**	3,123
Equity		
Capital and reserves attributable to equity holders of the parent		
Share capital	**752**	696
Share premium	**19,422**	17,128
Merger reserve	**483**	483
Retained deficit	**(17,241)**	(15,184)
Total equity	**3,416**	3,123

Consolidated Statement of Cash Flows
for the year ended 31 December 2012

	Year ended 31 December 2012 £000	6 months ended 31 December 2011 £000
Cash flows from operating activities		
Loss before tax	**(2,463)**	(2,218)
Adjustments for:		
Finance income	**(27)**	(20)
Depreciation	**30**	15
Amortisation	**46**	17
Loss on derecognised intangible asset	**5**	-
Share-based payment charge	**193**	96
Cash flows from operations before changes in working capital	**(2,216)**	(2,110)
Decrease in inventories	**13**	131
Decrease in trade and other receivables	**30**	4
(Decrease)/Increase in trade and other payables	**(572)**	41
Cash used in operations	**(2,745)**	(1,934)
Tax credit received	**254**	396
Net cash used in operating activities	**(2,491)**	(1,538)
Cash flows from investing activities		
Interest received	**30**	15
Purchase of property, plant and equipment	**(9)**	(3)
Purchase of intangible assets	**(144)**	(16)
Decrease in other financial assets	**1,024**	946
Net cash generated from investing activities	**901**	942
Cash flows from financing activities		
Proceeds from issuance of ordinary shares	**2,501**	-
Transaction costs in respect of share issues	**(151)**	-
Net cash generated from financing activities	**2,350**	-
Increase/(Decrease) in cash and cash equivalents	**760**	(596)
Cash and cash equivalents at beginning of the period	**896**	1,492
Cash and cash equivalents at end of the period	**1,656**	896

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 2012 has been extracted from the Group's audited financial statements which were approved by the Board of directors on 12 February 2013 and will be delivered to the Registrar of Companies for England and Wales in due course. The financial information for the six months ended 31 December 2011 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 2012 report and financial statements.

2. Tax

The tax credit of £213,000 (six months ended 31 December 2011: £251,000) relates to research and development tax credits in respect of the year ended 31 December 2012 (£210,000) and an adjustment in respect of prior periods (£3,000).

3. Loss per ordinary share

	Year ended 31 December 2012	6 months ended 31 December 2011
Loss attributable to equity holders of the Company (£000)	**(2,250)**	(1,967)
Weighted average number of ordinary shares in issue	**72,036,917**	69,560,064

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 not dilutive under the terms of IAS 33. At 31 December 2012 there were 7,511,635 options outstanding (31 December 2011: 7,911,787 options outstanding).