Press release

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

Preliminary statement of results for the year ended 30 June 2011

Southampton, UK – 13 September 2011: Synairgen plc (LSE: SNG), the respiratory drug discovery and development company with a particular focus on viral defence of the lungs, today announces its audited results for the year ended 30 June 2011.

Operational highlights

- Phase II trial of inhaled interferon beta ('IFN-beta') in asthma on schedule: last subjects expected to be dosed this Autumn, with results anticipated Q1 2012
- Pre-clinical assessment of the utility of inhaled IFN-beta to treat hospitalised patients with severe viral lung infections on schedule to produce preliminary results in Autumn 2011
- Business development activity for out-licensing of IFN-beta programme being coordinated to coincide with the availability of key pre-clinical and clinical trial data

Financial highlights

- Fundraising of £2.5 million (net of expenses) completed in June 2011 to provide additional finance for the Company's two interferon beta programmes
- Research and development expenditure for the year: £2.9 million (2010: £2.1 million)
- Post-tax loss for the year: £3.2 million (2010: £2.6 million)
- Cash at 30 June 2011: £4.9 million (2010: £5.0 million)

Commenting on the results, Simon Shaw, Chairman of Synairgen, said:
"Synairgen is entering an exciting period where we will see the results of proof-of-concept studies both from the clinical trial in asthma and in the broader field of viral defence, starting with influenza. We expect that a positive outcome from either, or both, of these studies will represent a significant step forward for the Company and pave the way for our successful development."

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OPERATING REVIEW

The last twelve months has seen Synairgen make significant progress towards two 'proof of concept' milestones for its inhaled interferon beta (IFN-beta) programme, namely the outcome of a Phase II clinical trial to evaluate the drug's potential to treat and prevent virus-induced asthma exacerbations (acute and prolonged worsening of asthma symptoms) and, secondly, the generation of pre-clinical data to support clinical development for the treatment of hospitalised patients with severe viral lung infections (mostly influenza). Success in the pre-clinical study would also open up a new opportunity for Synairgen in the arena of biodefence as an early treatment for protection against virus threats such as SARS and H5N1 'bird flu'. Synairgen's business development strategy has ensured that potential large pharma partners are up-to-date with our progress and await the outcome of these key proof-of-concept studies.

Phase II clinical trial – Proof of concept in asthma

The major deliverable for the Company is the Phase II clinical proof of concept study of inhaled IFN-beta to prevent asthma exacerbations caused by respiratory viruses. By delivering the natural and very potent antiviral protein IFN-beta directly to the lungs, we hope to correct a deficiency and restore, or even boost, the lungs' anti-viral defences so that they are able to repel the viruses without succumbing to a respiratory exacerbation. Asthmatic and indeed COPD patients (COPD, Chronic Obstructive Pulmonary Disease, is the combined term for chronic bronchitis and emphysema) are particularly vulnerable to the spread of common respiratory viruses down to their lungs. For example, up to 80% of asthma hospitalisations are attributed to common cold viruses (mainly the rhinovirus) that spread from the nose and throat to the lungs. By delivering inhaled IFN-beta directly to the lungs of asthmatic and COPD patients at the onset of nose and throat symptoms, the antiviral defences in the lungs will be boosted; this should normalise the lungs' response to the virus and reduce disease symptoms.

The Phase II proof of concept study, where we are testing inhaled IFN-beta in exacerbation-prone patients when they first develop cold or flu symptoms, is progressing well. At 30 June 2011, 77 subjects had been dosed, and post year-end at 31 August 2011, this number has risen to 105. We expect to reach our total of approximately 160 randomised subjects during the peak of the rhinovirus season this Autumn. Trial results are anticipated in Q1 2012. The results of this Phase II study are a key requirement for several potential development partners who are reviewing the programme. It is anticipated that a positive outcome from this study would also provide compelling evidence to explore the equally large COPD opportunity.

Severe viral lung infections

Each year many patients with or without a pre-existing medical condition are hospitalised with viral lung infections such as influenza, rhinovirus, coronavirus, adenovirus, parainfluenza virus, and respiratory syncytial virus (RSV). These infections can lead to pneumonia and secondary bacterial infections and there is great need for antiviral drugs that can be used to treat suspected viral lung infections upon admission to hospital. Synairgen has recognised this potential opportunity for inhaled IFN-beta, and, having shown activity against some of the key viruses, has progressed to more advanced experiments to prepare for a clinical trial of inhaled IFN-β in patients hospitalised with viral lung infections.

The other significant proof-of-concept milestone for the Company is due to complete this Autumn. This is a series of pre-clinical studies, using validated models which can predict the efficacy in humans, to test the efficacy of inhaled IFN-beta against the pandemic H1N1 influenza virus ('swine flu'). In these studies inhaled IFN-beta is being administered prior to, or post, infection. These tests simulate the usage of inhaled IFN-beta both prophylactically (preventative treatment before infection) and therapeutically (i.e. 'treatment' once infection has taken hold). Subject to the outcome of one or both of these studies, Synairgen will follow up with a series of experiments using the H5N1 'bird flu' virus. H5N1 infections are more challenging to treat and the mortality rate is approximately 50%.

A positive result when IFN-beta is given post virus infection would support progression directly into a clinical trial of inhaled IFN-beta in patients hospitalised with suspected viral lung infections. We believe that the market potential of a broad spectrum anti-viral treatment is

very substantial and worthy of progression, either in partnership with a large pharmaceutical company or directly through government or health agency funding.

Biodefence – prophylaxis against emerging respiratory viruses such as SARS (Severe Acute Respiratory Syndrome) – a new opportunity
Success in the prophylactic usage element of the pre-clinical studies would provide proof-of-concept data for the potential use of inhaled IFN-beta in the arena of biodefence. In this setting, inhaled IFN-beta could be administered to key workers and indeed military personnel exposed to respiratory viruses such as SARS, or H5N1 'bird flu', or other emerging threats.

Intellectual Property
During the year we received notice of allowance from the United States Patent and Trademark Office for our patent application for the use of inhaled IFN-beta to treat or prevent rhinovirus infections in the elderly (defined as an individual of age 40 plus). We have also (post year-end) received notice that our Japanese patent to treat or prevent rhinovirus exacerbations with inhaled IFN-beta will be granted. We have now secured intellectual property in the key markets of the US, the EU and Japan.

Business Development
During the year, Synairgen has, with the support of Deloitte LLP's pharma licensing team, been progressing the partnering process for inhaled IFN-beta in preparation for the results of the Phase II asthma trial. This process involved identifying and contacting suitable development partners to take the programmes into the later stages of clinical development and, thereafter, to market. Confidential discussions have been held with several parties and varying levels of due diligence have been conducted to date. The objective has been to fully familiarise potential partners with the opportunity prior to the availability of Phase II proof-of-concept data from asthma study in Q1 2012.

FINANCIAL REVIEW

Fundraising
In June 2011 we raised £2.65m gross (£2.5m net of expenses) to enable three initiatives to be financed: firstly to accelerate recruitment of subjects for our Phase II asthma study (so that we can complete the trial during the peak of the common cold season in the Autumn this year); secondly to conduct a series of dosing-related *in vitro* experiments to support common business development related questions; and thirdly to extend the pre-clinical study to include H5N1, a highly pathogenic virus. The Company issued 9.81 million shares at a price of 27p, which represented a 1.8% discount to the closing mid-market price on the day before the fundraising was announced. Costs of the issue amounted to £0.15 million (5.6%).

Statement of Comprehensive Income
The loss from operations for the year ended 30 June 2011 was £3.70 million (2010: £2.99 million). During the current year the Group, using its *in vitro* model technology, undertook service work for Pfizer Limited which generated revenues of £0.16 million. Research and development expenditure for the year amounted to £2.91 million (2010: £2.11 million). The main areas of expenditure have been on the asthma Phase II study (SG005) and the pre-clinical studies in swine flu. We anticipate that the last subjects in SG005 will be dosed during the autumn of 2011 and expenditure on the study will significantly reduce thereafter.

Other administrative costs increased from £0.88 million to £0.90 million. The research and development tax credit increased to £0.43 million (2010: £0.37 million). The loss after tax was £3.23 million (2010: £2.55 million) and the loss per share was 5.37p (2010: loss of 4.27p).

Statement of Financial Position and cash flows
At 30 June 2011, net assets amounted to £4.99 million (30 June 2010: £5.56 million), including net funds, as detailed below in Capital structure and funding, of £4.89 million (2010: £5.01 million).

The principal elements of the £0.12 million decrease (2010: £2.93 million decrease) in net funds were:

- Cash used in operations of £3.02 million (2010: £3.14 million outflow);

- Share issue proceeds (net of costs) £2.50 million (2010: £nil);
- Research and development tax credits received of £0.38 million (2010: £0.34 million); and
- Capital expenditure of £0.03 million (2010: £0.18 million).

SUMMARY

Synairgen is entering an exciting period where we will see the results of proof-of-concept studies both from the clinical trial in asthma and in the broader field of viral defence, starting with influenza. We expect that a positive outcome from either, or both, of these studies will represent a significant step forward for the Company and pave the way for our successful development.

Consolidated Statement of Comprehensive Income
for the year ended 30 June 2011

	Notes	**Year ended 30 June 2011 £000**	Year ended 30 June 2010 £000
Revenue		**155**	-
Cost of sales		**(43)**	-
Gross profit		**112**	-
Research and development expenditure		**(2,907)**	(2,109)
Other administrative expenses		**(904)**	(880)
Total administrative expenses		**(3,811)**	(2,989)
Loss from operations		**(3,699)**	(2,989)
Finance income		**35**	71
Loss before tax		**(3,664)**	(2,918)
Tax	2	**433**	368
Loss and total comprehensive income for the year attributable to equity holders of the parent		**(3,231)**	(2,550)
Loss per ordinary share			
Basic and diluted loss per share (pence)	3	**(5.37)p**	(4.27)p

Consolidated Statement of Changes in Equity
for the year ended 30 June 2011

	Share capital £000	Share premium £000	Merger reserve £000	Retained deficit £000	Total £000
At 1 July 2009	597	14,725	483	(7,806)	7,999
Recognition of share-based payments	-	-	-	115	115
Total comprehensive income for the year	-	-	-	(2,550)	(2,550)
At 30 June 2010	597	14,725	483	(10,241)	5,564
Issuance of ordinary shares	99	2,551	-	-	2,650
Transaction costs in respect of share issues	-	(148)	-	-	(148)
Recognition of share-based payments	-	-	-	159	159
Total comprehensive income for the year	-	-	-	(3,231)	(3,231)
At 30 June 2011	**696**	**17,128**	**483**	**(13,313)**	**4,994**

Consolidated Statement of Financial Position
as at 30 June 2011

	30 June 2011 £000	30 June 2010 £000
Assets		
Non-current assets		
Intangible assets	**240**	252
Property, plant and equipment	**60**	81
	300	333
Current assets		
Inventories	**216**	293
Current tax receivable	**395**	345
Trade and other receivables	**112**	106
Other financial assets – bank deposits	**3,401**	3,680
Cash and cash equivalents	**1,492**	1,334
	5,616	5,758
Total assets	**5,916**	6,091
Liabilities		
Current liabilities		
Trade and other payables	**(922)**	(525)
Obligations under finance leases	**-**	(2)
Total liabilities	**(922)**	(527)
Total net assets	**4,994**	5,564
Equity		
Capital and reserves attributable to equity holders of the parent		
Share capital	**696**	597
Share premium	**17,128**	14,725
Merger reserve	**483**	483
Retained deficit	**(13,313)**	(10,241)
Total equity	**4,994**	5,564

Consolidated Statement of Cash Flows
for the year ended 30 June 2011

	Year ended 30 June 2011 £000	Year ended 30 June 2010 £000
Cash flows from operating activities		
Loss before tax	**(3,664)**	(2,918)
Adjustments for:		
Finance income	**(35)**	(71)
Depreciation	**32**	34
Amortisation	**32**	23
Share-based payment charge	**159**	115
Cash flows from operations before changes in working capital	**(3,476)**	(2,817)
Decrease/(Increase) in inventories	**77**	(170)
Increase in trade and other receivables	**(19)**	(20)
Increase/(Decrease) in trade and other payables	**397**	(137)
Cash used in operations	**(3,021)**	(3,144)
Tax credit received	**383**	343
Net cash used in operating activities	**(2,638)**	(2,801)
Cash flows from investing activities		
Interest received	**48**	60
Purchase of property, plant and equipment	**(11)**	(34)
Purchase of intangible assets	**(20)**	(148)
Decrease/(Increase) in other financial assets	**279**	(1,703)
Net cash generated from/(used in) investing activities	**296**	(1,825)
Cash flows from financing activities		
Proceeds from issuance of ordinary shares	**2,650**	-
Transaction costs in respect of share issues	**(148)**	-
Repayments of obligations under finance leases	**(2)**	(3)
Net cash generated from/(used in) financing activities	**2,500**	(3)
Increase/(Decrease) in cash and cash equivalents	**158**	(4,629)
Cash and cash equivalents at beginning of year	**1,334**	5,963
Cash and cash equivalents at end of year	**1,492**	1,334

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 30 June 2011 has been extracted from the Group's audited financial statements which were approved by the Board of directors on 12 September 2011 and will be delivered to the Registrar of Companies for England and Wales in due course. The financial information for the year ended 30 June 2010 has been extracted from the Group's audited financial statements for that year 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 2011 annual report and financial statements.

2. Tax

The tax credit of £433,000 (2010: £368,000) relates to research and development tax credits in respect of the years ended 30 June 2011 (£395,000) and 30 June 2010 (£38,000).

3. Loss per ordinary share

	Year ended 30 June 2011	Year ended 30 June 2010
Loss attributable to equity holders of the Company (£000)	**(3,231)**	(2,550)
Weighted average number of ordinary shares in issue	**60,202,377**	59,745,249

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 30 June 2011 there were 6,283,487 options outstanding (30 June 2010: 4,733,439 options outstanding).