Press release

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

Preliminary Results for the year ended 30 June 2009

Southampton, UK – 4 September 2009: Synairgen plc (LSE: SNG), the respiratory drug discovery and development company with a particular focus on viral defence in asthma and COPD, today announces its preliminary results for the year ended 30 June 2009.

Operational highlights

- July 2008, commencement of SG004, a four cohort Phase I safety and pharmacodynamic study of inhaled interferon beta ('IFN-beta') in asthmatic patients;
- September 2008, test for biomarker (neopterin) successfully developed to measure IFN-beta driven anti-viral activity in the lungs. Retrospective analysis of samples from non-asthmatic volunteers from the first Phase I study of inhaled IFN-beta (SG003) showed neopterin was elevated, indicating on target bioactivity of inhaled IFN-beta;
- March 2009, successful completion of SG004 second cohort (a dose level predicted to be efficacious). A significant landmark in our lead programme;
- April 2009, analysis of samples to date from SG004 (second cohort) showed neopterin biomarker to be elevated;
- Activities commenced to initiate two Phase II proof-of-concept studies of inhaled IFN-beta in asthma and chronic obstructive pulmonary disease ('COPD') in Spring 2010;
- August 2009 (post period-end), completion of patient recruitment for fourth and final cohort of SG004; and
- Post period-end, US IFN-beta patent granted.

Financial highlights

- June 2009, fundraising of £6.35 million (gross) completed at 17p per share, representing a 4.2% discount to the closing mid market price prior to announcement, to finance two planned Phase II proof-of-concept studies;
- Research and development expenditure for the year: £2.1 million (2008: £2.0 million);
- Post-tax loss for the year: £2.5 million (2008: £2.2 million); and
- Cash at 30 June 2009: £7.9 million (2008: £4.0 million).

Commenting on the results, Simon Shaw, Chairman of Synairgen, said:
"During this financial year, we have successfully progressed our lead inhaled IFN-beta programme into its second Phase I study and look forward to seeing final results in the late autumn. We have also obtained encouraging biomarker data from our studies and in vitro evidence of activity against RSV. Following our successful fundraising, we have commenced preparations for next year's Phase II proof-of-concept studies that will be pivotal to achieving optimum commercialisation of this exciting programme."

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OPERATING REVIEW

During the financial year Synairgen has focused on advancing its lead programme, inhaled interferon beta ('IFN-beta') for the treatment of viral infection in asthma and chronic obstructive pulmonary disease ('COPD') sufferers. In June 2009, on the back of the successful completion of the second cohort of our Phase I safety trial in asthma (SG004), we raised £6.35 million of additional funds to finance the Company and its Phase II proof-of-concept clinical trials into 2011. The Phase II data for inhaled IFN-beta in asthma and/or COPD will support our optimal commercialisation and development strategy, which is to out-license the product to a third party.

IFN-beta to prevent asthma exacerbations caused by common respiratory viruses

The common cold causes up to 80% of asthma exacerbations and resulting hospitalisations. In the US this equates to an estimated 1.4 million emergency room visits and 400,000 hospital admissions (at an average cost of $9,000 per admission). Despite their commercial success, existing therapies (inhaled corticosteroids, bronchodilators, and leukotriene inhibitors) do not prevent the virus spreading from the nose to the lungs. In laboratory experiments using Synairgen's *in vitro* technology platform, IFN-beta levels were lower in common cold infected cells from asthma patients than non-asthmatics. Restoring IFN-beta levels to normal has been shown to reduce the infection levels in the models. This provided Synairgen with the rationale to develop inhaled IFN-beta as a therapy to boost the lungs' natural defences against these common respiratory viruses. It is in this area of crucial unmet medical need that we will initially position our inhaled IFN-beta product.

The period under review has been dominated by SG004, the Phase I study of inhaled IFN-beta in moderate asthmatic patients, which commenced in July 2008. In March 2009 we announced the significant landmark of completing cohort two in SG004. This achievement was significant because we consider that the dose of IFN-beta taken by the asthmatic volunteers in cohort two over a 14 day period is predicted to be an effective dose to combat virus driven exacerbations. Cohort three was completed in June 2009 and in August 2009, after the period-end, the final volunteers were recruited for the fourth and final cohort. Final results (safety and biomarker) will be announced during late Autumn 2009.

IFN-beta to prevent COPD exacerbations caused by common respiratory viruses

COPD will affect 25% of long term smokers and is characterised by an irreversible loss of lung function until death. By 2030, COPD is predicted to become the third leading cause of death worldwide after ischemic heart disease (heart attack) and cerebrovascular disease (stroke). If a COPD patient catches a cold, there is a 50% chance that it will lead to an exacerbation of their disease. Many exacerbating COPD patients will be hospitalised, with associated health economic consequences. Up to 10% of COPD hospitalisations result in death.

Using the Synairgen *in vitro* model technology platform and COPD cells from the Company's biobank, our researchers established that small amounts of IFN-beta greatly protect lung cells against the common cold virus. Our Phase I IFN-beta trials have been designed to support a transition to proof-of-concept for COPD in long term smokers with or without mild COPD. Our research, and that of our collaborators, has shown that these long term smokers are a suitable surrogate for more severe COPD patients, and provide us with an opportunity to get an early proof-of-concept for our inhaled IFN-beta COPD therapy.

IFN-beta activity against other respiratory viruses

During the last few months, Synairgen has begun to research the effect of IFN-beta on other viruses typically affecting the respiratory tract. The hypothesis is that inhaled IFN-beta could create improvements in the lungs' defence against many viruses beyond the rhinovirus (rhinovirus is the most prevalent of the common cold viruses, accounting for between 60% and 80% of all colds). Other viruses of interest include the less widespread cold viruses and certain flu strains. Our early work indicates a protective effect against Respiratory Syncytial Virus ('RSV') and we expect to add evidence of a broader protective effect against others during the coming year.

Biomarker confirms inhaled IFN-beta anti-viral activity in clinical trial samples

During the period, Synairgen completed the development and qualification of a sputum (phlegm) biomarker assay (test), which can detect IFN-beta-induced anti-viral activity in clinical trials. Historically this biomarker (neopterin) has been measured in blood to support the development of injected IFN-beta for multiple sclerosis. Sputum samples from Synairgen's first inhaled IFN-beta study (SG003) were retrospectively tested and the results confirmed that neopterin was elevated following inhalation of IFN-beta. A similar elevation has been observed in samples received to date from the second Phase I study (SG004). This confirms that many of the challenges faced during inhaled biologic drug development have been overcome, such as maintaining protein activity post aerosolisation and 'landing' the drug on the target. This in turn increases our confidence in being able to demonstrate efficacy in our Phase II proof-of-concept studies.

IFN-beta intellectual property

Post period-end, the patent for inhaled IFN-beta to treat rhinovirus infections in asthma and COPD has been granted in the US. Whilst the IFN-beta patent portfolio is owned by the University of Southampton, Synairgen has the benefit of an exclusive licence.

IFN-beta out-licensing strategy

Synairgen intends to out-license the IFN-beta programme upon demonstration of Phase IIa proof-of-concept in either asthma or COPD. These studies are scheduled to commence in Spring 2010, with results expected approximately 12 months later. Whilst the early evidence of anti-viral biomarker activity improves the attractiveness of this opportunity to potential licensees, based on our ongoing dialogue with potential partners, Synairgen expects that optimal licensing terms will be achievable with Phase II data.

Phase II Proof-of-Concept studies

In the last quarter of the financial year, management's focus turned to designing and financing two Phase II studies, each intended to provide evidence of efficacy in its significant but separate area of clinical need. In asthma, Synairgen plans to conduct SG005, a wild-type study which best reflects the real world circumstances in which the therapy will need to perform. Run through a number of study centres in the UK, each 'exacerbation prone' asthmatic volunteer will use the inhaler with either IFN-beta or placebo on the onset of symptoms of a cold.

In COPD, we plan to conduct 'controlled infection' study SG006, using a virus challenge model on long-term smokers. Volunteers will be infected with the common cold virus having been 'pre-treated' with either IFN-beta or placebo.

Both studies will be subject to ethical and regulatory approval and are expected to commence in Spring 2010.

Core technology platform and biobank

During the year, Synairgen has secured Human Tissue Authority approval for its tissue bank of samples collected from asthmatic, COPD and control populations. Synairgen has conducted over 250 bronchoscopies since its inception and uses this technology platform extensively to support its clinical programmes. Synairgen recognises this technology platform may be of great value to other companies and, so long as it does not distract Synairgen from its core IFN-beta programmes, Synairgen will enter into collaborations that add to Synairgen's intellectual property base.

FINANCIAL REVIEW

Fundraising

In June 2009, the Company raised £6.35 million (gross) through the issue of 37.35 million shares at a price of 17p. The issue price of 17p represented a 4.2% discount to the closing mid-market price on the day before the fundraising was announced. Costs of the issue amounted to £0.16 million (2.4%).

Income Statement

Research and development expenditure for the year amounted to £2.11 million (2008: £2.00 million). The main area of expenditure has continued to be the IFN-beta programme. SG004, the second Phase I study, which is being conducted in Southampton and Manchester, commenced in July 2008 and by 30 June 2009 with three of the four cohorts finished was 75% complete. During the year, SG007, the dual centre study to characterise the common cold model in asthma, has also progressed. Preparation for the two Phase II studies (SG005 and SG006) has commenced. In addition to clinical programme expenditure, further *in vitro* work continues to be undertaken to support both of the asthma and COPD IFN-beta programmes. Whilst the majority of cash resources have been focussed on IFN-beta, some research and development investment has also been made to develop further the Company's platform technology.

Other administrative costs increased from £0.75 million to £0.86 million. Interest receivable fell from £0.29 million to £0.13 million as interest rates and cash balances lowered. The research and development tax credit increased to £0.35 million (2008: £0.32 million). The loss after tax was £2.49 million (2008: £2.15 million) and the loss per share was 10.64p (2008: loss of 9.92p).

Balance Sheet and Cash Flow

At 30 June 2009, net assets amounted to £8.00 million (30 June 2008: £4.19 million), including net funds of £7.94 million (2008: £4.00 million).

The principal elements of the £3.94 million increase (2008: £2.01 million decrease) in net funds were:

- Share issue proceeds (net of costs) of £6.20 million (2008: £nil);
- Cash used in operations of £2.68 million (2008: £2.50 million outflow);
- Research and development tax credits received of £0.33 million (2008: £0.25 million); and
- Interest received of £0.18 million (2008: £0.30 million)

Capital expenditure amounted to £0.08 million (2008: £0.07 million) and comprised investment into patent and licence costs and equipment.

OUTLOOK

Synairgen is focussed on preparing for and conducting the crucial next phase of clinical trials of IFN-beta. We are now well financed and resourced to deliver on this objective. During the forthcoming year the key tasks will be to complete the analysis of the SG004 data, secure regulatory approval for SG005 and SG006, finalise the selection of the appropriate trial centres and commence the two studies. Alongside this, we continue to investigate the breadth of defensive action of inhaled IFN-beta against other viruses and to update potential licensing partners on progress for this exciting dual programme.

Consolidated Income Statement
for the year ended 30 June 2009

	Notes	**Year ended 30 June 2009 £000**	Year ended 30 June 2008 £000
Research and development expenditure		**(2,107)**	(2,004)
Other administrative expenses		**(864)**	(753)
Total administrative expenses		**(2,971)**	(2,757)
Operating loss		**(2,971)**	(2,757)
Finance income		**130**	291
Finance expense		**(1)**	(1)
Loss before tax		**(2,842)**	(2,467)
Tax	2	**348**	315
Loss for the year attributable to equity holders of the parent		**(2,494)**	(2,152)
Loss per ordinary share			
Basic and diluted loss per share (pence)	3	**(10.64)p**	(9.92)p

Consolidated Statement of Changes in Equity
for the year ended 30 June 2009

	Share capital £000	Share premium £000	Merger reserve £000	Retained deficit £000	Total £000
Changes in equity for the year ended 30 June 2008					
Balance at 1 July 2007	217	8,903	483	(3,349)	6,254
Loss for the year	-	-	-	(2,152)	(2,152)
Recognition of share-based payments	-	-	-	85	85
Balance at 30 June 2008	217	8,903	483	(5,416)	4,187
Changes in equity for the year ended 30 June 2009					
Issuance of ordinary shares	380	5,977	-	-	6,357
Transaction costs in respect of share issues	-	(155)	-	-	(155)
Loss for the year	-	-	-	(2,494)	(2,494)
Recognition of share-based payments	-	-	-	104	104
Balance at 30 June 2009	**597**	**14,725**	**483**	**(7,806)**	**7,999**

The loss for the year represents the total recognised income and expense for the year.

Consolidated Balance Sheet
as at 30 June 2009

	30 June 2009 £000	30 June 2008 £000
Assets		
Non-current assets		
Intangible assets	**127**	109
Property, plant and equipment	**81**	122
	208	231
Current assets		
Inventories	**123**	103
Current tax receivable	**320**	300
Trade and other receivables	**75**	136
Other financial assets	**1,977**	3,445
Cash and cash equivalents	**5,963**	557
	8,458	4,541
Total assets	**8,666**	4,772
Liabilities		
Current liabilities		
Trade and other payables	**(662)**	(578)
Obligations under finance leases	**(3)**	(2)
	(665)	(580)
Non-current liabilities		
Obligations under finance leases	**(2)**	(5)
Total liabilities	**(667)**	(585)
Total net assets	**7,999**	4,187
Equity		
Capital and reserves attributable to equity holders of the parent		
Share capital	**597**	217
Share premium	**14,725**	8,903
Merger reserve	**483**	483
Retained deficit	**(7,806)**	(5,416)
Total equity	**7,999**	4,187

Consolidated Cash Flow Statement
for the year ended 30 June 2009

	Year ended 30 June 2009 £000	Year ended 30 June 2008 £000
Cash flows from operating activities		
Loss before tax	**(2,842)**	(2,467)
Adjustments for:		
Finance income	**(130)**	(290)
Finance expense	**1**	1
Depreciation	**64**	68
Amortisation	**43**	15
Share-based payment charge	**104**	85
Cash flows from operations before changes in working capital	**(2,760)**	(2,588)
Increase in inventories	**(20)**	(7)
Decrease/(Increase) in trade and other receivables	**15**	(16)
Increase in trade and other payables	**84**	116
Cash used in operations	**(2,681)**	(2,495)
Interest paid	**(1)**	(1)
Tax credit received	**328**	250
Net cash used in operating activities	**(2,354)**	(2,246)
Cash flows from investing activities		
Interest received	**176**	302
Purchase of property, plant and equipment	**(23)**	(44)
Purchase of intangible assets	**(61)**	(25)
Decrease in other financial assets	**1,468**	1,553
Net cash generated from investing activities	**1,560**	1,786
Cash flows from financing activities		
Proceeds from issuance of ordinary shares	**6,357**	-
Transaction costs in respect of share issues	**(155)**	-
Repayments of obligations under finance leases	**(2)**	(3)
Net cash generated from/(used in) financing activities	**6,200**	(3)
Increase/(Decrease) in cash and cash equivalents	**5,406**	(463)
Cash and cash equivalents at beginning of year	**557**	1,020
Cash and cash equivalents at end of year	**5,963**	557

Notes

1. Basis of preparation

The financial information of the Group set out above does not constitute "statutory accounts" within the meaning of Section 434(3) and Section 435(3) of the Companies Act 2006. The financial information for the year ended 30 June 2009 has been extracted from the Group's audited financial statements which will be delivered to the Registrar of Companies for England and Wales in due course. The financial information for the year ended 30 June 2008 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 in respect of the year ended 30 June 2009 and Section 237(2) or Section 237(3) of the Companies Act 1985 in respect of the year ended 30 June 2008. 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 ('IFRs') as adopted by the European Union, this announcement does not itself contain sufficient information to comply with those IFRSs.

2. Tax

The tax credit of £348,000 (2008: £315,000) relates to research and development tax credits in respect of the years ended 30 June 2009 (£320,000) and 30 June 2008 (£28,000).

3. Loss per ordinary share

	Year ended 30 June 2009	Year ended 30 June 2008
Loss attributable to equity holders of the Company (£000)	**(2,494)**	(2,152)
Weighted average number of ordinary shares in issue	**23,434,742**	21,692,308

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 2009 there were 2,339,663 options outstanding (30 June 2008: 2,805,944 options outstanding).