Press release

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

Preliminary Results for the year ended 30 June 2010

Southampton, UK – 29 July 2010: Synairgen plc (LSE: SNG), the respiratory drug discovery and development company with a particular focus on viral defence, today announces its preliminary results for the year ended 30 June 2010.

Operational highlights

- Successful completion of Phase I study (SG004) and commencement of a Phase II study of inhaled interferon beta ('IFN-beta') in exacerbation-prone asthmatics (SG005)
- Multiple biomarkers from SG004 confirm antiviral proof of mechanism of inhaled IFN-beta
- IFN-beta shown to have utility against established influenza infection in a novel re-infection model, creating a third indication for inhaled IFN-beta. Additional patent filed
- Further evidence from *in vitro* testing of other respiratory viruses (RSV, H1N1 Swine flu and seasonal flu) indicates potential of inhaled IFN-beta as a broad spectrum antiviral therapy
- Patent for the use of IFN-beta granted in US and EU
- Proprietary platform technology further endorsed by external research collaboration commenced post year-end

Financial highlights

- Research and development expenditure for the year: £2.1 million (2009: £2.1 million)
- Post-tax loss for the year: £2.6 million (2009: £2.5 million)
- Cash at 30 June 2010: £5.0 million (2009: £7.9 million)

Commenting on the results, Simon Shaw, Chairman of Synairgen, said:
"I am delighted that we have added influenza as a new third indication for inhaled interferon beta and commenced the Phase II study in asthma. During the forthcoming year, our focus will be on progressing the asthma, influenza and COPD programmes. These activities, together with the process being conducted on our behalf by Deloitte LLP's licensing team, will support the effective execution of our partnering strategy."

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For further information, please contact:

Synairgen plc **Tel: + 44 (0) 23 8051 2800**
Richard Marsden, Chief Executive Officer
John Ward, Finance Director

Matrix Corporate Capital **Tel: + 44 (0) 20 3206 7000**
Alastair Stratton
Anu Tayal

Threadneedle Communications **Tel: + 44 (0) 20 7653 9850**
Graham Herring
Josh Royston

OPERATING REVIEW

During the financial year Synairgen has advanced its lead programme, inhaled interferon beta ('IFN-beta') across three potential therapeutic applications. It has commenced a Phase II study in asthma, continued with preparatory work for a clinical trial in Chronic Obstructive Pulmonary Disease (COPD) and developed a new third indication to treat pulmonary complications triggered by any 'influenza-like illness'.

Influenza-like-illness – a third indication for inhaled IFN-beta

Last year we stated our intention to use our proprietary models of human disease to test the efficiency of IFN-beta against other common viruses associated with exacerbations of respiratory disease. The risks of influenza-like illnesses to both healthy and respiratorily impaired people have long been known, but the Swine flu scare in 2009 highlighted the potential global threat of viral infection. Working with the Health Protection Agency at Porton Down, we showed that our IFN-beta formulation was very effective at protecting cells from Swine flu infection. This discovery led to an enhancement of our planned asthma study SG005 to include subjects contracting influenza. This ensures that the study is conducted in a way which most accurately reflects the real life infection risks facing this patient group.

Recognising the potential of a broad spectrum antiviral therapy against both emerging influenza-like and seasonal viruses, Synairgen embarked on a programme to establish the potential use of IFN-beta in these 'difficult to treat' patients.

Our research to date has included the successful development of a novel influenza 're-infection' model. In this model a small amount of virus is initially introduced to lung cell cultures and over the following days an increasing number of cells become infected. This *in vitro* model is intended to replicate the spread of viruses from the upper (nose and throat) to the lower (lungs) respiratory tract and therefore will be able to predict the impact of therapeutic intervention.

Having developed the *in vitro* re-infection model, we were able to demonstrate a marked reduction in the percentage of infected cells, even when IFN-beta was applied some two days into the infection cycle. This opened up a third novel indication for Synairgen's IFN-beta programme: the use of inhaled IFN-beta for patients with severe lung illness triggered by an initial influenza-like illness. A patent has been filed and this discovery was presented at the American Thoracic Society meeting in May 2010.

The term 'influenza-like illness' is used because as many as 50% of illnesses which are thought to be attributable to influenza virus are actually caused by other viruses such as rhinovirus, parainfluenza virus, Respiratory Syncytial Virus (RSV), or coronavirus (of which SARS is an example). Synairgen's IFN-beta therapy 'boosts' the lungs' natural antiviral defence system and is therefore broader in reach and differs from drugs such as Tamiflu® and Relenza® which solely target the influenza viruses. Thus there appears to be a potentially significant market opportunity for a first in class broad spectrum inhaled antiviral therapy such as inhaled IFN-beta.

In this area, preclinical models have successfully predicted the clinical efficacy of the neuraminidase inhibitors Tamiflu and Relenza. Synairgen is therefore working with a world-leading influenza research group with a view to evaluating the efficacy of lung-delivered IFN-beta in a preclinical model of influenza-induced lung complications. This will be conducted during the coming year.

Asthma

The period under review has been dominated by the successful conclusion of SG004, the Phase I study of inhaled IFN-beta in moderate asthmatic patients, and the commencement of a Phase II study (SG005) in asthma.

In SG004 inhaled IFN-beta was well tolerated over a 14 day period by moderate asthmatics. Results from SG004 also showed that certain antiviral pathways (genes MxA, 2-5-OAS, and IP-10) were markedly activated in cells from asthmatic patients' lungs after dosing.

Upregulation of these genes and detection of elevated levels of the IFN-beta biomarker neopterin in sputum showed the 'switching on' of the body's anti-viral defence mechanism in the lungs and increased the confidence with which we commenced the Phase II clinical development of the product.

Following the completion of SG004 in the autumn of 2009, we ran a study (SG009) of the asthmatic population during the cold and flu season. SG009 enabled us to test the design, practicalities and feasibility of studying these patients as they suffer virus-induced exacerbations. These findings have all been factored into the protocol for our Phase II study (SG005), which commenced in March 2010.

Our discovery that IFN-beta showed *in vitro* efficacy against Swine flu (see above) encouraged us to broaden SG005 to include patients suffering from influenza as well as the common cold. The study will include 120 exacerbation-prone asthmatics, who will commence a 14 day course of inhaled IFN-beta or placebo as soon as cold or flu symptoms develop. To facilitate this, we are recruiting a pool of subjects across a number of Northern Hemisphere sites in the UK and Southern Hemisphere sites in Australia; thus we will continually have access to subjects during a winter season. The study is designed to measure changes in asthma symptoms associated with respiratory viruses and is scheduled to complete by the end of the summer of 2011.

COPD

COPD is a smoking-related disease associated with accelerated lung function decline. It is forecast by the World Health Organisation to become the third leading cause of death worldwide by 2030. Frequent exacerbations of COPD lead to an accelerated deterioration of lung function. The majority of exacerbations are associated with cold or flu infections and/or secondary bacterial infections. Corroborating findings at Synairgen, researchers in the US have found that lung cells from subjects with COPD are more susceptible to infection with the common cold virus. Linking this to the clinical setting, a study at Imperial College in London found that lung cells from COPD subjects produced less IFN-beta in response to infection and that this was associated with increased lung viral load and worse symptoms. Synairgen presented additional data at this year's American Thoracic Society meeting, demonstrating the protective effect of IFN-beta against common cold infection in COPD lung cells. This provides further rationale for progressing the inhaled IFN-beta into COPD as well as asthma.

Our intention, as set out in last year's annual report, had been to conduct a controlled infection study, using a recently developed virus challenge model on some 80 long-term, otherwise healthy, smokers (as a surrogate for COPD patients). In this study, volunteers would be infected with the common cold virus having been pre-treated with either IFN-beta or placebo. During the year, we conducted a pilot study (SG010) to assess the feasibility of our planned proof of concept study for COPD. The pilot study showed that, in order to avoid testing a very large number of volunteers and the associated expenses of conducting such a trial, the virus challenge study would need to be conducted in at least "moderate" COPD patients (GOLD Stage 2 rather than Stage 1). However patients with more severe disease are less willing to be deliberately infected with virus (as the controlled infection trial required). We therefore concluded that the trial, as originally conceived, represented a greater technical and logistical challenge than we could justify, particularly in the face of the new influenza opportunity and its competing claim on Synairgen's capital resources. In the second half of the year our continuing research programme showed, through *in vitro* experiments, that the window for treating patients with viral infection may be longer than had previously been considered possible. This enabled us to reconsider the use of a 'wild type' COPD study, similar in structure to SG005, where patients are treated upon onset of naturally-acquired virus infections. Such a study will involve dosing more subjects than the original SG006 proposal, but suits better the expectations of potential partners, who have more recently expressed a preference for a study of naturally-infected volunteers.

Following consultation with our panel of experts, we are drawing up a protocol to facilitate commencement of the revised SG006 during the winter season.

Key priorities
In 2009 we raised additional finance to fund the Company's then two primary programmes. Since then, we have initiated an influenza programme as a third standalone programme. Operationally we have now prioritised our resources to completing the enhanced asthma trial (SG005) and the pre-clinical influenza programme, both of which will report results during 2011. Over the coming period, we will be finalising the optimal approach to conducting the COPD Phase II study.

IFN-beta intellectual property
The patent for inhaled IFN-beta to treat rhinovirus infections in asthma and COPD has been granted in the US in August 2009 and in the EU in May 2010. Whilst these patents are owned by the University of Southampton, Synairgen has the benefit of an exclusive licence. A patent was filed by the Company during the year in respect of the influenza discovery.

IFN-beta partnering strategy
Having commenced Phase II and added a further potentially valuable programme to the development portfolio over the year, we have engaged the biotechnology licensing team at Deloitte LLP to assist us to implement our business development strategy.

Core technology platform and biobank
Synairgen has long recognised that our proprietary technology platform has significant value to other companies' development programmes and, so long as it either supports, or does not detract from, our core IFN-beta programmes, we are prepared to enter into collaborations that add to Synairgen's intellectual property base or enhance relations with potential partners for the IFN-beta programmes. Post period-end, the Company has entered into one such collaboration with Pfizer Limited to use Synairgen's *in vitro* models to assist in refining a clinical development programme.

FINANCIAL REVIEW

Statement of Comprehensive Income
Research and development expenditure for the year amounted to £2.11 million (2009: £2.11 million). The main area of expenditure during the year has been the continuation of the clinical development programme for the asthma and COPD IFN-beta indications: namely the completion of SG004; the two pilot studies (SG009 and SG010) for the Phase II studies SG005 and SG006; preparation for SG005 and SG006; and the start of SG005. In addition, a significant amount of laboratory work has been undertaken researching into the impact of inhaled IFN-beta on other viruses, including the influenza discovery. During the forthcoming year, expenditure on SG005 will increase as the study continues to be rolled out across other sites and we enter the cold/flu season.

Other administrative costs increased from £0.86 million to £0.88 million. Interest receivable fell from £0.13 million to £0.07 million on account of lower interest rates. The research and development tax credit increased to £0.37 million (2009: £0.35 million). The loss after tax was £2.55 million (2009: £2.49 million) and the loss per share was 4.27p (2009: loss of 10.64p).

Statement of Financial Position and cash flows
Following adoption of the revised IAS1 (Presentation of Financial Statements), the Balance Sheet has been redesignated as the Statement of Financial Position. At 30 June 2010, net assets amounted to £5.56 million (30 June 2009: £8.00 million), including net funds of £5.01 million (2009: £7.94 million).

The principal elements of the £2.93 million decrease (2009: £3.94 million increase) in net funds were:

- Cash used in operations of £3.14 million (2009: £2.68 million outflow);
- Research and development tax credits received of £0.34 million (2009: £0.33 million);
- Capital expenditure of £0.18 million (2009: £0.08 million);
- Interest received of £0.06 million (2009: £0.18 million); and

- Share issue proceeds (net of costs) £nil (2009: £6.20 million).

Capital expenditure during the year comprised investment into patent and licence costs (£0.15 million) and equipment (£0.03 million).

STAFF AND BOARD CHANGES

During the period we restructured the Board in order to better prepare ourselves for the next phase of Synairgen's development. We promoted Dr Phillip Monk to the Board as executive director and Chief Scientific Officer. We were delighted to welcome two new non-executive directors, Paul Clegg and Iain Buchanan, who bring significant biotech expertise to the Board in finance and investment and business development and licensing respectively. We also announced the departure of Sue Sundstrom to take up a new executive role in the West Country and we thank her for her valuable counsel since the inception of the Company.

The strides we have made in the last year would have been impossible without our small but dedicated team of scientists, clinicians and clinical research experts. Our thanks go to all Synairgen's staff, who show the utmost commitment to our mission and dedication to the effective delivery of our development programmes.

OUTLOOK

During the forthcoming year, our focus will be on progressing the asthma, influenza and COPD programmes. These activities, together with the process being conducted on our behalf by Deloitte LLP's licensing team, will support the effective execution of our partnering strategy.

Consolidated Statement of Comprehensive Income
for the year ended 30 June 2010

	Notes	**Year ended 30 June 2010 £000**	Year ended 30 June 2009 £000
Research and development expenditure		**(2,109)**	(2,107)
Other administrative expenses		**(880)**	(864)
Total administrative expenses		**(2,989)**	(2,971)
Loss from operations		**(2,989)**	(2,971)
Finance income		**71**	130
Finance expense		**-**	(1)
Loss before tax		**(2,918)**	(2,842)
Tax	2	**368**	348
Loss and total comprehensive income for the year attributable to equity holders of the parent		**(2,550)**	(2,494)
Loss per ordinary share			
Basic and diluted loss per share (pence)	3	**(4.27)p**	(10.64)p

Consolidated Statement of Changes in Equity
for the year ended 30 June 2010

	Share capital £000	Share premium £000	Merger reserve £000	Retained deficit £000	Total £000
At 1 July 2008	217	8,903	483	(5,416)	4,187
Issuance of ordinary shares	380	5,977	-	-	6,357
Transaction costs in respect of share issues	-	(155)	-	-	(155)
Recognition of share-based payments	-	-	-	104	104
Total comprehensive income for the year	-	-	-	(2,494)	(2,494)
At 30 June 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**

Consolidated Statement of Financial Position
as at 30 June 2010

	30 June 2010 £000	30 June 2009 £000
Assets		
Non-current assets		
Intangible assets	**252**	127
Property, plant and equipment	**81**	81
	333	208
Current assets		
Inventories	**293**	123
Current tax receivable	**345**	320
Trade and other receivables	**106**	75
Other financial assets – bank deposits	**3,680**	1,977
Cash and cash equivalents	**1,334**	5,963
	5,758	8,458
Total assets	**6,091**	8,666
Liabilities		
Current liabilities		
Trade and other payables	**(525)**	(662)
Obligations under finance leases	**(2)**	(3)
	(527)	(665)
Non-current liabilities		
Obligations under finance leases	**-**	(2)
Total liabilities	**(527)**	(667)
Total net assets	**5,564**	7,999
Equity		
Capital and reserves attributable to equity holders of the parent		
Share capital	**597**	597
Share premium	**14,725**	14,725
Merger reserve	**483**	483
Retained deficit	**(10,241)**	(7,806)
Total equity	**5,564**	7,999

Consolidated Statement of Cash Flows
for the year ended 30 June 2010

	Year ended 30 June 2010 £000	Year Ended 30 June 2009 £000
Cash flows from operating activities		
Loss before tax	**(2,918)**	(2,842)
Adjustments for:		
Finance income	**(71)**	(130)
Finance expense	**-**	1
Depreciation	**34**	64
Amortisation	**23**	43
Share-based payment charge	**115**	104
Cash flows from operations before changes in working capital	**(2,817)**	(2,760)
Increase in inventories	**(170)**	(20)
(Increase)/Decrease in trade and other receivables	**(20)**	15
(Decrease)/Increase in trade and other payables	**(137)**	84
Cash used in operations	**(3,144)**	(2,681)
Interest paid	**-**	(1)
Tax credit received	**343**	328
Net cash used in operating activities	**(2,801)**	(2,354)
Cash flows from investing activities		
Interest received	**60**	176
Purchase of property, plant and equipment	**(34)**	(23)
Purchase of intangible assets	**(148)**	(61)
(Increase)/Decrease in other financial assets	**(1,703)**	1,468
Net cash (used in)/generated from investing activities	**(1,825)**	1,560
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	**(3)**	(2)
Net cash (used in)/generated from financing activities	**(3)**	6,200
(Decrease)/Increase in cash and cash equivalents	**(4,629)**	5,406
Cash and cash equivalents at beginning of year	**5,963**	557
Cash and cash equivalents at end of year	**1,334**	5,963

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 2010 has been extracted from the Group's audited financial statements which were approved by the Board of directors on 28 July 2010 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 2009 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 2010 annual report and financial statements.

2. Tax

The tax credit of £368,000 (2009: £348,000) relates to research and development tax credits in respect of the years ended 30 June 2010 (£345,000) and 30 June 2009 (£23,000).

3. Loss per ordinary share

	Year ended 30 June 2010	Year ended 30 June 2009
Loss attributable to equity holders of the Company (£000)	**(2,550)**	(2,494)
Weighted average number of ordinary shares in issue	**59,745,249**	23,434,742

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 2010 there were 4,733,439 options outstanding (30 June 2009: 2,339,663 options outstanding).