

## Press release

### **Synairgen plc** (‘Synairgen’ or the ‘Company’)

## **Preliminary statement of results for the six months ended 31 December 2011**

Southampton, UK – 1 February 2012: 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 six months ended 31 December 2011 following the change of year-end to that date.

### **Operational highlights**

Significant progress on core development programmes:

- Phase II trial of inhaled interferon beta (‘IFN-beta’) in asthma on schedule: last subjects were dosed in December 2011, with results anticipated in March 2012
- Positive results from pre-clinical study completed in November 2011 showing that aerosolised IFN-beta reduced virus-induced pneumonia, suggesting that inhaled IFN-beta may have potential in two further areas:
  - as a broad spectrum antiviral for use in patients admitted to hospital with suspected viral lung infections; and
  - as a post-exposure prophylactic defence against a lethal virus threat to the lungs
- Business development activity for out-licensing of IFN-beta programme being coordinated to coincide with the availability of key clinical trial data

### **Financial highlights**

- Research and development expenditure for the period: £1.8 million (year ended 30 June 2011: £2.9 million)
- Post-tax loss for the period: £2.0 million (year ended 30 June 2011: £3.2 million)
- Cash at 31 December 2011: £3.4 million (30 June 2011: £4.9 million)

Commenting on the results, Simon Shaw, Chairman of Synairgen, said:

*“Positive data from the Phase II asthma trial in March 2012 will be a pivotal requirement for us to pursue the further development of inhaled IFN-beta with a licensing partner. Such a partnership would be a significant commercial milestone for the Company and we have an ongoing dialogue with several potential development and commercialisation partners.”*

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## OPERATING REVIEW

Following the change of year-end, this report covers the six month period to December 2011, during which time the Company has made significant progress with its Phase II study in asthma and its pre-clinical study of viral pneumonia.

In December 2011 Synairgen completed recruitment for its Phase II proof of concept trial of inhaled interferon beta ('IFN-beta') for the prevention of virus-induced asthma exacerbations (acute and prolonged worsening of asthma symptoms). During January and February 2012, the data will be audited and entered into the database. The results are expected in March 2012.

We announced in November 2011 that, independent of the asthma development programme, the Company had generated strong pre-clinical data, which opens up the potential for two additional indications related to viral infection in the overall population. These are:

1. Hospitalised patients with a suspected severe viral lung infection; and
2. Post-exposure prophylaxis for:
  - a. Highly pathogenic viruses (for example SARS-like viruses)
  - b. Common respiratory viruses (for example swine flu) in vulnerable populations

These are attractive potential markets, for which there is today little or no effective therapy. Indeed the area of defence against highly pathogenic viruses has become a focus for a number of governments around the world, which are prepared to commit resource to appropriate programmes. We will be investigating this area during 2012.

### Asthma and COPD

#### ***Phase II clinical trial – Proof of concept in asthma***

Common respiratory viruses are the major cause of asthma exacerbations. Many different viruses, including RSV, parainfluenza virus, coronavirus, over 200 different types of rhinovirus, and many others, are loosely termed 'common cold' or 'flu' viruses. Influenza infections tend to be more severe and yet not all suspected influenza infections turn out to be influenza at all; many of the suspected influenza infections will be caused by one of the common cold viruses, and vice versa.

In asthmatic patients, and those with other respiratory diseases such as COPD (chronic obstructive pulmonary disease) or cystic fibrosis, the lungs are unable to defend themselves adequately against these common viruses and an exacerbation can ensue. The poor defence appears to be due to compromised IFN-beta-driven immunity. This can be corrected by introducing a small amount of IFN-beta to help cells defend themselves against viruses. This has been demonstrated in Synairgen's *in vitro* models, using cells from volunteers with asthma (Synairgen's Biobank). It is very important to note that these vulnerable patients do not become severely ill on account of cold symptoms such as a really bad sore throat or very blocked nose. These patients become ill because of the viral infection in their lungs and the way this interacts with their pre-existing lung disease. Synairgen is developing inhaled IFN-beta for delivery directly to the lungs in the form of an aerosol and is not trying to modulate the incidence or severity of symptoms in the nose and throat.

Many therapeutic approaches to tackling viral respiratory infections have failed due to the great diversity and adaptability of these very contagious viruses. Tamiflu® and Relenza® are successful examples of the 'one drug one bug' approach, the bug being influenza. However influenza only accounts for approximately 5 - 10% of all respiratory infections and there remains a concern about progressive resistance; Synairgen's inhaled IFN-beta has the advantage of boosting the body's powerful 'virus agnostic' defences in the lung. It has demonstrated activity against all of the common respiratory viruses and some highly pathogenic viruses such as H5N1 'Bird Flu' and the coronavirus SARS. Thus Synairgen's inhaled IFN-beta is increasingly proving itself as an inhaled broad spectrum antiviral defence. Furthermore it is considered that resistance to the activity of IFN-beta is highly unlikely to emerge.

Synairgen has been fortunate in that the development of inhaled IFN-beta is a re-profiling exercise. IFN-beta has been administered by injection to thousands of patients with multiple sclerosis over the years, since its first approval in 1993. This significantly de-risks the inhaled programme as any drug which passes through the lungs to the blood system is unlikely to cause any unexpected adverse events. Furthermore, through its exclusive supply and licence arrangement with the Rentschler Group (a manufacturer of IFN-beta), Synairgen has access to a pH neutral formulation suitable for inhalation.

In the Phase I safety and pharmacodynamic clinical trial, conducted in 2008/09, inhaled IFN-beta was well tolerated in moderate asthmatics. There was also convincing biomarker evidence that even in the absence of a virus inhaled IFN-beta 'switched on' the antiviral defences. This provided the Company with 'proof of mechanism', i.e. that the drug could switch on antiviral defences in the lungs of patients with an IFN-beta deficiency.

The Phase II study reporting results in March 2012 will hopefully confirm that there is benefit in boosting/restoring the IFN-beta-driven antiviral defences in asthmatics. In this blinded clinical trial approximately 150 exacerbation-prone asthmatics have been treated with inhaled IFN-beta or placebo at the onset of cold or flu symptoms. The objective is to boost the lungs' immunity so that, as the virus infection builds in the nose and throat, the lungs are able to defend themselves adequately. The primary endpoint is the sACQ (shortened Asthma Control Questionnaire), which is a measure of asthma symptoms. There are a number of secondary endpoints which may also be very informative for signalling the future development strategy for the drug. These are the AI (the Asthma Index - an alternative measure of asthma symptoms), lung function, virus load, markers of pulmonary inflammation and drug safety.

#### ***Phase II clinical trial – Proof of concept in COPD***

Synairgen has developed a Phase II clinical trial protocol for the COPD population. This study has been approved by the relevant authorities, although it will not commence until a partner has been found through the business development licensing activity.

#### ***Business development for the asthma and COPD programmes***

Synairgen has regularly discussed its IFN-beta programme with major pharmaceutical companies and input from these companies has contributed to the design of the overall development programme. Synairgen has, over the years, generated a package of material necessary for the out-licensing of these programmes for asthma and COPD. This package includes safety data, *in vitro* efficacy data, granted patents in the US, EU and Japan and biomarker data demonstrating proof of mechanism. The most important pieces of information yet to come will be the analysed outcomes of the Phase II trial in asthma, which are anticipated in March 2012. It is Synairgen's intention to out-license the asthma and COPD programmes on the back of the Phase II results and our continuous interactions with potential business development partners have been designed to expedite this process.

#### **Use of inhaled IFN-beta outside of asthma and COPD**

During 2011, Synairgen has completed a series of experiments that have demonstrated reduced lung viral load and reduced cell damage in an advanced viral pneumonia pre-clinical model. The drug was given either prior to infection or post infection. These data open up two new significant applications:

##### ***1. Hospitalised patients with suspected severe viral lung infections***

Inhaled IFN-beta could be used to treat patients as a therapy (prior to the identification of the virus) upon admission to hospital with breathing difficulties caused by a viral lung infection. The broad spectrum antiviral properties of the drug would be advantageous as it takes some time to identify the causative pathogen. As this is an area of great unmet clinical need, Synairgen believes that, subject to an acceptable safety profile from the Phase II asthma trial, it could be in the interest of a government to support this work either through a grant or an award.

##### ***2. Post-exposure prophylaxis***

- ***against high pathogenic respiratory viruses***

The threat posed by emerging respiratory viruses such as SARS or terrorist-manufactured virus threats such as aerosolised Ebola or a variant of H5N1 'bird flu' remains one of significant concern to governments. We understand that governments may be interested in funding the development of a broad spectrum inhaled antiviral that can be stockpiled in sufficient quantities to be issued to people in the event of exposure to lethal viruses, such as key workers or people placed in quarantine following contact with an infected person (for example on a flight). Synairgen will engage with governmental organisations over the coming months to gauge interest and map out a potential development programme.

- ***against common respiratory viruses in vulnerable populations***

Vulnerable patients, for example transplant patients, pregnant women, the elderly, and the very young, can suffer lung complications due to common viruses migrating from the nose and throat to the lungs. Inhaled IFN-beta could be given to these patients as and when they believe they have been exposed to a viral infection. Such exposure could be from a work colleague or somebody they live with. Synairgen will consider the future development of inhaled IFN-beta for this indication following the results of the Phase II asthma trial.

## **FINANCIAL REVIEW**

### **Change of Accounting Reference Date**

The Group has brought forward its financial year-end from 30 June to 31 December for administrative reasons to expedite the production of its annual report and accounts. As a result the audited financial statements cover the six months ended 31 December 2011 with comparative financial information being given for the year ended 30 June 2011.

### **Statement of Comprehensive Income**

The loss from operations for the six months ended 31 December 2011 was £2.24 million (year ended 30 June 2011: £3.70 million). Research and development expenditure for the period amounted to £1.82 million (year ended 30 June 2011: £2.91 million). The main areas of expenditure have been on the asthma Phase II study (SG005) and the pre-clinical study in viral pneumonia. The last subject was recruited into SG005 in December 2011 and the results are anticipated in March 2012. The significant majority of costs on the pre-clinical study were also incurred prior to 31 December 2011 and therefore expenditure on both these projects will reduce significantly during the first half of 2012.

Other administrative costs for the period amounted to £0.42 million (year ended 30 June 2011: £0.90 million). The research and development tax credit for the period was £0.25 million (year ended 30 June 2011: £0.43 million). The loss after tax for the period was £1.97 million (year ended 30 June 2011: £3.23 million) and the loss per share was 2.83p (year ended 30 June 2011: loss of 5.37p).

### **Statement of Financial Position and cash flows**

At 31 December 2011, net assets amounted to £3.12 million (30 June 2011: £4.99 million), including net funds of £3.35 million (30 June 2011: £4.89 million).

The principal elements of the £1.54 million decrease over the six months ended 31 December 2011 (year ended 30 June 2011: £0.12 million decrease) in net funds were:

- Cash used in operations of £1.93 million (year ended 30 June 2011: £3.02 million outflow);
- Research and development tax credits received of £0.40 million (year ended 30 June 2011: £0.38 million); and

Share issue proceeds (net of costs) £nil (year ended 30 June 2011: £2.50 million).

## **SUMMARY**

Positive data from the Phase II asthma trial in March 2012 will be a pivotal requirement for us to pursue the further development of inhaled IFN-beta with a licensing partner. Such a

partnership would be a significant commercial milestone for the Company and we have an ongoing dialogue with several potential development and commercialisation partners.

Independent of an asthma and COPD licensing transaction, we have a programme to investigate the potential development of inhaled IFN-beta as a broad spectrum antiviral for use in patients admitted to hospital with suspected viral lung infections, and also as a post-exposure prophylactic defence against a lethal virus threat to the lungs.

**Consolidated Statement of Comprehensive Income**  
for the six months ended 31 December 2011

	6 months ended 31 December 2011 £000	Year ended 30 June 2011 £000
Revenue	-	155
Cost of sales	-	(43)
Gross profit	-	112
Research and development expenditure	<b>(1,815)</b>	(2,907)
Other administrative expenses	<b>(423)</b>	(904)
Total administrative expenses	<b>(2,238)</b>	(3,811)
<b>Loss from operations</b>	<b>(2,238)</b>	(3,699)
Finance income	<b>20</b>	35
<b>Loss before tax</b>	<b>(2,218)</b>	(3,664)
Tax	2	433
<b>Loss and total comprehensive income for the year attributable to equity holders of the parent</b>	<b>(1,967)</b>	(3,231)
<b>Loss per ordinary share</b>		
Basic and diluted loss per share (pence)	3	(2.83)p
		(5.37)p

**Consolidated Statement of Changes in Equity**  
for the six months ended 31 December 2011

	Share capital £000	Share premium £000	Merger reserve £000	Retained deficit £000	Total £000
At 1 July 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
Recognition of share-based payments	-	-	-	96	96
Total comprehensive income for the period	-	-	-	(1,967)	(1,967)
<b>At 31 December 2011</b>	<b>696</b>	<b>17,128</b>	<b>483</b>	<b>(15,184)</b>	<b>3,123</b>

**Consolidated Statement of Financial Position**  
as at 31 December 2011

	31 December 2011 £000	30 June 2011 £000
<b>Assets</b>		
<b>Non-current assets</b>		
Intangible assets	239	240
Property, plant and equipment	48	60
	<u>287</u>	<u>300</u>
<b>Current assets</b>		
Inventories	85	216
Current tax receivable	250	395
Trade and other receivables	113	112
Other financial assets – bank deposits	2,455	3,401
Cash and cash equivalents	896	1,492
	<u>3,799</u>	<u>5,616</u>
<b>Total assets</b>	<u>4,086</u>	<u>5,916</u>
<b>Liabilities</b>		
<b>Current liabilities</b>		
Trade and other payables	(963)	(922)
<b>Total liabilities</b>	<u>(963)</u>	<u>(922)</u>
<b>Total net assets</b>	<u>3,123</u>	<u>4,994</u>
<b>Equity</b>		
<b>Capital and reserves attributable to equity holders of the parent</b>		
Share capital	696	696
Share premium	17,128	17,128
Merger reserve	483	483
Retained deficit	(15,184)	(13,313)
<b>Total equity</b>	<u>3,123</u>	<u>4,994</u>

**Consolidated Statement of Cash Flows**  
for the six months ended 31 December 2011

	6 months ended 31 December 2011 £000	Year ended 30 June 2011 £000
<b>Cash flows from operating activities</b>		
Loss before tax	(2,218)	(3,664)
Adjustments for:		
Finance income	(20)	(35)
Depreciation	15	32
Amortisation	17	32
Share-based payment charge	96	159
<b>Cash flows from operations before changes in working capital</b>	<b>(2,110)</b>	<b>(3,476)</b>
Decrease in inventories	131	77
Increase in trade and other receivables	4	(19)
Increase in trade and other payables	41	397
<b>Cash used in operations</b>	<b>(1,934)</b>	<b>(3,021)</b>
Tax credit received	396	383
<b>Net cash used in operating activities</b>	<b>(1,538)</b>	<b>(2,638)</b>
<b>Cash flows from investing activities</b>		
Interest received	15	48
Purchase of property, plant and equipment	(3)	(11)
Purchase of intangible assets	(16)	(20)
Decrease in other financial assets	946	279
<b>Net cash generated from investing activities</b>	<b>942</b>	<b>296</b>
<b>Cash flows from financing activities</b>		
Proceeds from issuance of ordinary shares	-	2,650
Transaction costs in respect of share issues	-	(148)
Repayments of obligations under finance leases	-	(2)
<b>Net cash generated from financing activities</b>	<b>-</b>	<b>2,500</b>
<b>(Decrease)/Increase in cash and cash equivalents</b>	<b>(596)</b>	<b>158</b>
<b>Cash and cash equivalents at beginning of the period</b>	<b>1,492</b>	<b>1,334</b>
<b>Cash and cash equivalents at end of the period</b>	<b>896</b>	<b>1,492</b>

## 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 six months ended 31 December 2011 has been extracted from the Group’s audited financial statements which were approved by the Board of directors on 31 January 2012 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 2011 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 December 2011 report and financial statements.

### 2. Tax

The tax credit of £251,000 (year ended 30 June 2011: £433,000) relates to research and development tax credits in respect of the period ended 31 December 2011 (£250,000) and the year ended 30 June 2011 (£1,000).

### 3. Loss per ordinary share

	<b>6 months ended 31 December 2011</b>	Year ended 30 June 2011
Loss attributable to equity holders of the Company (£000)	<b>(1,967)</b>	(3,231)
Weighted average number of ordinary shares in issue	<b>69,560,064</b>	60,202,377

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 2011 there were 7,911,787 options outstanding (30 June 2011: 6,283,487 options outstanding).