

## Press release

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

## **Interim results for the six months ended 30 June 2012**

Southampton, UK – 10 August 2012: Synairgen plc (LSE: SNG), the respiratory drug company with a particular focus on viral defence of the lungs, today announces its interim results for the six months ended 30 June 2012.

### **Operational highlights**

- Successful initial results announced in April 2012 from the Phase II proof of concept trial of inhaled interferon beta (SNG001) for the treatment or prevention of virus-induced asthma exacerbations (acute and prolonged worsening of asthma symptoms). The headline results were:
  - Identification that the British Thoracic Society Step 4/5 patients (estimated to represent between 10% and 20% of adult asthma sufferers, who represent the greatest healthcare burden) are most likely to suffer adversely due to common cold virus infections
  - Efficacy across multiple endpoints in the Step 4/5 population
  - Inhaled interferon beta is well tolerated
- Now engaging with potential licensing partners for asthma and COPD programmes
- Efficacy data, safety data and preclinical data to be discussed with government departments who are seeking broad spectrum antivirals to treat or prevent severe viral lung infections

### **Financial highlights**

- Research and development expenditure for the period was £0.75 million (H1 2011: £1.62 million)
- Post-tax loss for the period of £1.15 million (H1 2011: £1.82 million)
- Cash outflow for the period of £1.10 million (H1 2011: £1.01 million inflow) and net funds at 30 June 2012 were £2.25 million (30 June 2011: £4.89 million)
- In July 2012 (post period-end), £2.5 million (gross) raised to strengthen the balance sheet and complete activities to facilitate licensing discussions

Simon Shaw, Chairman of Synairgen, commented:

*“This has been a pivotal and successful six months for the Company. The identification of the ‘difficult to treat’ asthmatics, who are most vulnerable to respiratory viruses, is very important for future trial design for the development of SNG001. The efficacy data and safety data along with strong pre-clinical data opens up the possibility to discuss SNG001 with governments who are seeking broad spectrum antivirals to treat serious respiratory infections.*

*“Following the oversubscribed placing in July, the Company is well funded and well placed to plan the further development of SNG001 and facilitate the licensing process that will deliver this novel therapy.”*

-Ends-

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## Chairman's and Chief Executive Officer's Review

### OPERATING REVIEW

#### Asthma

Common respiratory viruses (common cold viruses) are known to trigger asthma exacerbations; up to 80% of all hospitalisations for asthma are linked to respiratory viruses. This clinical problem has attracted considerable interest over the years. Common viruses can affect patients whose asthma is well controlled despite the use of standard asthma therapies such as inhaled corticosteroids and long acting beta agonists. These exacerbations are a time of great stress for patients, can lead to hospitalisation, and therapeutically there are few options available to the clinical teams. Patients may receive systemic steroids, oxygen, nebulised bronchodilators, and antibiotics to fend off opportunistic bacterial infections. Patients will often be unable to work or go to school, and it can take weeks to fully recover. The only antiviral that a patient is likely to receive would be Tamiflu<sup>®</sup> (a neuraminidase inhibitor) if the viral cause was thought to be a Tamiflu sensitive strain. However on average, we only get one influenza infection every 5 years and in that time we would, as adults, expect to have 15 colds (children get many more colds). Thus it is the cold virus that creates the greatest clinical need in these patients.

Synairgen's interferon beta ('IFN-beta') programme was conceived as a result of an observation made using cells collected from the lungs of asthmatic volunteers. These cells were more vulnerable to infection than cells collected from the lungs of non-asthmatics. The reason was attributed to a deficiency of IFN-beta. This discovery led to patent filings and the initiation of an inhaled IFN-beta programme to treat or prevent virus-induced exacerbations of asthma.

Synairgen has completed a Phase I programme which showed that the SNG001 (SNG001 is Synairgen's inhaled form of IFN-beta) was well tolerated and that there was evidence that the lungs' antiviral defences were boosted at a dosage that is practical to deliver.

#### Results from Phase II Proof of Concept study in asthma (SG005)

Synairgen investigated the efficacy and safety of SNG001 in asthmatics in a randomised double blind placebo controlled trial. Approximately 300 patients were screened and entered into a pool of patients who then waited to catch a cold. From this pool, 147 commenced treatment within 24 hours of cold symptoms first developing and, of these, 134 asthma patients developed a clinically defined cold.

There was a significant relationship between cold symptoms and asthma symptoms, showing that the worse the cold the greater the impact on asthma symptoms.

An analysis of the whole data set showed that there was a small, non-significant, difference between the placebo and SNG001 in favour of SNG001. The surprising finding was that the degree of change using the shortened Asthma Control Questionnaire ('sACQ') was not as great as expected; this gave little opportunity for a therapeutic intervention to demonstrate efficacy. Recognising that this is an exploratory, and indeed pioneering, study, the pre-determined statistical analysis plan allowed for the examination of subgroups.

Patients were split according to British Thoracic Society ('BTS') Steps graded 1 to 5, with 5 being the most intensively and expensively treated (the BTS system is similar to the internationally-recognised Global Initiative for Asthma ('GINA') step grading system). The Step 2 and 3 patients did not suffer as much due to the effects of a common cold as the Step 4 and 5 patients who appeared to have a greater change in symptoms. These Step 4 and 5 patients with 'difficult to treat' asthma, comprised approximately half of the patients in the trial and was the group that significantly

benefited from SNG001 treatment. Step 4 and 5 patients are estimated to represent between 10% and 20% of all adult asthma sufferers and is thus not an insignificant commercial opportunity.

The key trial findings in this 'difficult to treat' Step 4 and 5 category were clinically important and statistically significant differences in favour of SNG001 as compared to placebo across recognised measures of asthma symptom severity and lung function, including:

- prevention of worsening of asthma symptoms during the critical first week of infection and treatment as measured by the sACQ (p=0.004);
- a greater than 50% reduction in the number of exacerbations compared to placebo (p=0.028);
- in the SNG001-treated patients, there was a steady improvement in morning peak expiratory flow, whilst in the placebo-treated patients there was an initial dip during the first week followed by an improvement (p=0.03);
- reduced use of inhaled reliever bronchodilators on SNG001; and
- SNG001 was well tolerated.

Since April we have continued to analyse the data and have looked at other ways to categorise asthma. Generally the worse the asthma, either at screening (virus free) or at the time of treatment initiation in the trial, the better the outcome on SNG001. This makes us feel increasingly confident that the observations relating to the Step 4/5 patients (who remain the strongest predictor of who is most likely to benefit from treatment) is less likely to be a chance finding.

The Company is now preparing the ground for follow-on studies in asthma which will focus on the Step 4/5 patients.

### **COPD**

Patients with Chronic Obstructive Pulmonary Disease (estimated to represent approximately 9-10% of the population aged 40 or over) suffer similarly at the fate of viruses. Synairgen along with the University of Southampton have demonstrated that cells from COPD patients respond well to SNG001. This data (especially combined with the clinical safety data from the Phase II asthma trial) makes us feel confident about progressing into the COPD population, where the consequences of viral infection can be fatal.

### **Business Development**

Synairgen has previously announced its intention to partner the programme for asthma and COPD prior to commencement of follow-on clinical trials. Synairgen has engaged with companies with a respiratory focus, most of whom are in the top 30 pharmaceutical companies by revenue.

### **Inhaled SNG001 for severe viral lung infections**

Hospitals can become overstretched due to patients being admitted with severe viral lung infections, often with viral pneumonia. This is frequently associated with outbreaks of influenza, but the cause on approximately 50% of occasions can be due to other respiratory viruses (common cold viruses). Mainstay antivirals such as Tamiflu will not provide efficacy against these other virus types. There is need for a broad spectrum antiviral to treat these patients as they are admitted to hospital; this therapy could be given in addition to products such as Tamiflu.

We announced in November 2011 that we have generated strong pre-clinical data, which opens up the potential to treat hospitalised patients with SNG001 who have a suspected severe viral lung infection.

Further to this, there may be an opportunity for usage of SNG001 in the post-exposure prophylaxis setting for highly pathogenic viruses. These could be natural emerging virus threats like SARS or H5N1 'Bird Flu', or terrorist threats.

Synairgen recognises that governments are seeking products that have broad spectrum antiviral properties that could be used to treat or prevent severe viral lung infections, and will look to discuss the potential of SNG001 in this area with government departments over the coming months.

## **FINANCIAL REVIEW**

### **Statement of Comprehensive Income**

The loss from operations for the six months ended 30 June 2012 was £1.28 million (six months ended 30 June 2011: £2.03 million). With the completion of the Phase II trial, research and development expenditure for the period reduced to £0.75 million (six months ended 30 June 2011: £1.62 million).

Other administrative costs for the period, including business development costs, amounted to £0.53 million (six months ended 30 June 2011: £0.43 million). With the lower research and development expenditure, the tax credit for the period reduced to £0.11 million (six months ended 30 June 2011: £0.20 million). The loss after tax for the period was £1.15 million (six months ended 30 June 2011: £1.82 million) and the loss per share was 1.65p (six months ended 30 June 2011: loss of 3.00p).

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

At 30 June 2012, net assets amounted to £2.07 million (30 June 2011: £4.99 million), including net funds of £2.25 million (30 June 2011: £4.89 million).

The principal elements of the £1.10 million decrease in net funds over the six months ended 30 June 2012 (six months ended 30 June 2011: £1.01 million increase in net funds) were:

- Cash used in operations of £1.36 million (six months ended 30 June 2011: £1.49 million outflow);
- Research and development tax credits received of £0.25 million (six months ended 30 June 2011: £nil); and
- Share issue proceeds (net of costs) £nil (six months ended 30 June 2011: £2.50 million).

### **Post period-end placing**

In July 2012, Synairgen strengthened its balance sheet by raising £2.50 million (gross) so that it can:

- accelerate analysis of biomarkers that will help further characterise the 'responder population'
- invest in the regulatory/clinical support necessary to maintain momentum on the asthma and COPD programmes

Both of these are considered very important in relation to the commercial discussions with potential partners.

Synairgen will also use some of the proceeds to enable appropriate engagement with governmental departments so that the potential of SNG001 as a broad spectrum antiviral can be explored.

## **OUTLOOK**

This has been a pivotal and successful six months for the Company. The identification of the 'difficult to treat' asthmatics, who are most vulnerable to respiratory viruses, is very important for future trial design for the development of SNG001. The demonstration of efficacy across multiple types of endpoint in the 'difficult to treat' patients is the important catalyst for a licensing transaction/partnership for asthma and COPD. The efficacy data and safety data along with strong pre-clinical data opens up the possibility to discuss SNG001 with governments who are seeking broad spectrum antivirals to treat serious respiratory infections.

**Simon Shaw**  
Chairman

**Richard Marsden**  
Chief Executive Officer

9 August 2012

**Consolidated Statement of Comprehensive Income**  
for the six months ended 30 June 2012

	Notes	Unaudited Six months ended 30 June 2012 £000	Unaudited Six months ended 30 June 2011 £000	Audited Six months ended 31 December 2011 £000
Revenue		-	40	-
Cost of sales		-	(14)	-
Gross profit		-	26	-
Research and development expenditure		<b>(747)</b>	(1,623)	(1,815)
Other administrative expenses		<b>(530)</b>	(434)	(423)
Total administrative expenses		<b>(1,277)</b>	(2,057)	(2,238)
<b>Loss from operations</b>		<b>(1,277)</b>	(2,031)	(2,238)
Finance income		<b>14</b>	15	20
<b>Loss before tax</b>		<b>(1,263)</b>	(2,016)	(2,218)
Tax credit	2	<b>113</b>	195	251
<b>Loss and total comprehensive loss for the period attributable to equity holders of the parent</b>		<b>(1,150)</b>	(1,821)	(1,967)
<b>Loss per ordinary share</b>				
Basic and diluted loss per share (pence)	3	<b>(1.65)p</b>	(3.00)p	(2.83)p

**Consolidated Statement of Changes in Equity (unaudited)**

	Share Capital £000	Share premium £000	Merger reserve £000	Retained deficit £000	Total £000
At 1 January 2011	597	14,725	483	(11,573)	4,232
Issuance of ordinary shares	99	2,551	-	-	2,650
Transaction costs in respect of share issues	-	(148)	-	-	(148)
Recognition of share-based payments	-	-	-	81	81
Total comprehensive loss for the period	-	-	-	(1,821)	(1,821)
At 30 June 2011	696	17,128	483	(13,313)	4,994
Recognition of share-based payments	-	-	-	96	96
Total comprehensive loss for the period	-	-	-	(1,967)	(1,967)
At 31 December 2011	696	17,128	483	(15,184)	3,123
Recognition of share-based payments	-	-	-	99	99
Total comprehensive loss for the period	-	-	-	(1,150)	(1,150)
<b>At 30 June 2012</b>	<b>696</b>	<b>17,128</b>	<b>483</b>	<b>(16,235)</b>	<b>2,072</b>

**Consolidated Statement of Financial Position**  
as at 30 June 2012

	Unaudited 30 June 2012 Notes	Audited 30 June 2011 £000	Audited 31 December 2011 £000
<b>Assets</b>			
<b>Non-current assets</b>			
Intangible assets	231	240	239
Property, plant and equipment	36	60	48
	<b>267</b>	<b>300</b>	<b>287</b>
<b>Current assets</b>			
Inventories	79	216	85
Current tax receivable	110	395	250
Trade and other receivables	56	112	113
Other financial assets – bank deposits	4 1,377	3,401	2,455
Cash and cash equivalents	875	1,492	896
	<b>2,497</b>	<b>5,616</b>	<b>3,799</b>
<b>Total assets</b>	<b>2,764</b>	<b>5,916</b>	<b>4,086</b>
<b>Liabilities</b>			
<b>Current liabilities</b>			
Trade and other payables	(692)	(922)	(963)
<b>Total liabilities</b>	<b>(692)</b>	<b>(922)</b>	<b>(963)</b>
<b>Total net assets</b>	<b>2,072</b>	<b>4,994</b>	<b>3,123</b>
<b>Equity</b>			
<b>Capital and reserves attributable to equity holders of the parent</b>			
Share capital	696	696	696
Share premium	17,128	17,128	17,128
Merger reserve	483	483	483
Retained deficit	(16,235)	(13,313)	(15,184)
<b>Total equity</b>	<b>2,072</b>	<b>4,994</b>	<b>3,123</b>

**Consolidated Statement of Cash Flows**  
for the six months ended 30 June 2012

	Unaudited Six months ended 30 June 2012 £000	Unaudited Six months ended 30 June 2011 £000	Audited Six months ended 31 December 2011 £000
<b>Cash flows from operating activities</b>			
Loss before tax	<b>(1,263)</b>	(2,016)	(2,218)
Adjustments for:			
Finance income	<b>(14)</b>	(15)	(20)
Depreciation	<b>12</b>	16	15
Amortisation	<b>17</b>	17	17
Share-based payment charge	<b>99</b>	81	96
<b>Cash flows from operations before changes in working capital</b>	<b>(1,149)</b>	(1,917)	(2,110)
Decrease in inventories	<b>6</b>	51	131
Decrease in trade and other receivables	<b>52</b>	58	4
(Decrease)/Increase in trade and other payables	<b>(271)</b>	315	41
<b>Cash used in operations</b>	<b>(1,362)</b>	(1,493)	(1,934)
Tax credit received	<b>253</b>	-	396
<b>Net cash used in operating activities</b>	<b>(1,109)</b>	(1,493)	(1,538)
<b>Cash flows from investing activities</b>			
Interest received	<b>19</b>	24	15
Purchase of property, plant and equipment	-	(2)	(3)
Purchase of intangible assets	<b>(9)</b>	(16)	(16)
Decrease/(Increase) in other financial assets	<b>1,078</b>	(700)	946
<b>Net cash generated from/(used in) investing activities</b>	<b>1,088</b>	(694)	942
<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	-	(1)	-
<b>Net cash generated from financing activities</b>	-	2,501	-
<b>(Decrease)/Increase in cash and cash equivalents</b>	<b>(21)</b>	314	(596)
<b>Cash and cash equivalents at beginning of period</b>	<b>896</b>	1,178	1,492
<b>Cash and cash equivalents at end of period</b>	<b>875</b>	1,492	896

## **Notes to the Financial Statements for the six months ended 31 December 2012**

### **1. Basis of preparation**

#### **Basis of accounting**

The interim financial statements, which are unaudited, have been prepared on the basis of the accounting policies expected to apply for the financial year to 31 December 2012 and in accordance with recognition and measurement principles of International Financial Reporting Standards (IFRSs) as endorsed by the European Union. The accounting policies applied in the preparation of these interim financial statements are consistent with those used in the financial statements for the six months ended 31 December 2011.

The IFRSs that will be effective in the financial statements for the year to 31 December 2012 are still subject to change and to the issue of additional interpretation(s) and therefore cannot be determined with certainty. Accordingly, the accounting policies for that annual period that are relevant to this interim financial information will be determined only when the IFRS financial statements are prepared at 31 December 2012.

The interim financial statements do not include all of the information required for full annual financial statements and do not comply with all the disclosures in IAS 34 'Interim Financial Reporting'. Accordingly, whilst the interim statements have been prepared in accordance with IFRSs, they cannot be construed as being in full compliance with IFRSs.

The financial information for the six months ended 31 December 2011 does not constitute the full statutory accounts for that period. The Annual Report and Financial Statements for the six months ended 31 December 2011 have been filed with the Registrar of Companies. The Independent Auditor's Report on the Report and Financial Statements for the six months ended 31 December 2011 was unqualified, did not draw attention to any matters by way of emphasis, and did not contain a statement under 498(2) or 498(3) of the Companies Act 2006.

#### **Going Concern**

The directors have prepared financial forecasts to estimate the likely cash requirements of the Group over the next twelve months. In preparing these financial forecasts, the directors have had to make certain assumptions with regards to the timing and amount of future expenditure and other key factors. The directors have attempted to take a balanced and prudent view in preparing these forecasts, however their accuracy is uncertain.

After due consideration and review of these financial forecasts and current cash resources, the directors consider that the Group has adequate financial resources to continue in operational existence for the foreseeable future (being a period of at least twelve months from the date of this report), and for this reason the financial statements have been prepared on a going concern basis.

The 30 June 2012 interim financial statements were approved by a duly appointed and authorised committee of the Board of Directors on 9 August 2012.

### **2. Tax credit**

The tax credit of £113,000 (six months ended 30 June 2011: £195,000; six months ended 31 December 2011: £251,000) includes £110,000 as an estimate of the research and development tax credit receivable in respect of the current period and £3,000 representing amounts unprovided for in previous periods.

**Notes to the Financial Statements**  
**for the six months ended 31 December 2012 (continued)**

**3. Loss per ordinary share**

	Unaudited Six months ended 30 June 2012	Unaudited Six months ended 30 June 2011	Audited Six months ended 31 December 2011
Loss attributable to equity holders of the Company (£000)	<b>(1,150)</b>	(1,821)	(1,967)
Weighted average number of ordinary shares in issue	<b>69,560,064</b>	60,667,082	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 30 June 2012 there were 7,580,351 options outstanding (30 June 2011: 6,283,487 options outstanding; 31 December 2011: 7,911,787 options outstanding).

**4. Other financial assets**

Other financial assets comprise Sterling fixed rate bank deposits of greater than three months' maturity at time of deposit.

## **INDEPENDENT REVIEW REPORT TO SYNAIRGEN PLC**

### **Introduction**

We have been engaged by the company to review the interim set of financial statements in the half-yearly financial report for the six months ended 30 June 2012 which comprises the Consolidated Statement of Comprehensive Income, the Consolidated Statement of Changes in Equity, the Consolidated Statement of Financial Position, the Consolidated Statement of Cash Flows and the related notes 1 to 4.

We have read the other information contained in the half-yearly financial report and considered whether it contains any apparent misstatements or material inconsistencies with the information in the interim set of financial statements.

### **Directors' responsibilities**

The interim report, including the financial information contained therein, is the responsibility of and has been approved by the directors. The directors are responsible for preparing the interim report in accordance with the rules of the London Stock Exchange for companies trading securities on AIM which require that the half-yearly report be presented and prepared in a form consistent with that which will be adopted in the company's annual accounts having regard to the accounting standards applicable to such annual accounts.

### **Our responsibility**

Our responsibility is to express to the company a conclusion on the interim set of financial statements in the half-yearly financial report based on our review.

Our report has been prepared in accordance with the terms of our engagement to assist the company in meeting the requirements of the rules of the London Stock Exchange for companies trading securities on AIM and for no other purpose. No person is entitled to rely on this report unless such a person is a person entitled to rely upon this report by virtue of and for the purpose of our terms of engagement or has been expressly authorised to do so by our prior written consent. Save as above, we do not accept responsibility for this report to any other person or for any other purpose and we hereby expressly disclaim any and all such liability

### **Scope of review**

We conducted our review in accordance with International Standard on Review Engagements (UK and Ireland) 2410, "Review of Interim Financial Information Performed by the Independent Auditor of the Entity", issued by the Auditing Practices Board for use in the United Kingdom. A review of interim financial information consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing (UK and Ireland) and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

### **Conclusion**

Based on our review, nothing has come to our attention that causes us to believe that the interim set of financial statements in the half-yearly financial report for the six months ended 30 June 2012 is not prepared, in all material respects, in accordance with the rules of the London Stock Exchange for companies trading securities on AIM.

*BDO LLP  
Chartered Accountants and Registered Auditors  
Southampton  
United Kingdom*

9 August 2012

BDO LLP is a limited liability partnership registered in England and Wales (with registered number OC305127).