

## Press release

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

## **Interim results for the six months ended 30 June 2013**

Southampton, UK – 12 August 2013: 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 2013.

### **Operational highlights**

- Preparation for the follow-on clinical trial in asthma continues:
  - Working with potential partners to define the regulatory strategy and drug development activities through to commercial launch
  - Both of these are integrated and contingent on the outcome of the business development activity, which continues to progress with a number of parties
- Positive biomarker data from the analysis of samples from the Phase II proof of concept trial of inhaled interferon beta (SNG001) being developed for the treatment or prevention of virus-induced asthma exacerbations, which showed:
  - Increased anti-viral activity in the lungs compared to placebo, confirming mechanism of action
  - Reduction in markers of inflammation in the lungs of patients treated with SNG001
- Following interaction with agencies of the US Government, entered into agreements to provide SNG001 for use in preclinical models aimed at assessing the potential of SNG001 as a broad spectrum anti-viral against Middle East Respiratory Syndrome (MERS) and H7N9, two highly pathogenic viruses that threaten the lungs

### **Financial highlights**

- Research and development expenditure for the period was £0.68 million (H1 2012: £0.75 million)
- Post-tax loss for the period of £1.06 million (H1 2012: £1.15 million)
- Cash and deposit balances of £2.14 million at 30 June 2013 (30 June 2012: £2.25 million) and cash outflow for the period of £0.95 million (H1 2012: £1.10 million outflow)

Simon Shaw, Chairman of Synairgen, commented:

*“Significant progress has been made in the first six months of 2013. The company has been preparing for the commencement of a follow-on clinical trial in asthma, which it intends to conduct in partnership with a pharmaceutical company. This process has been progressing well with a number of parties and the company will update the market in due course.*

*“In parallel, the company has also taken steps which will lead to the assessment of SNG001 in severe viral lung infections with US Government agencies. Although this is at an early stage it is an exciting endorsement of SNG001’s potential in viral defence.”*

-Ends-

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

### **OPERATING REVIEW**

The Company has made significant progress in the six months with continued discussions with potential partners for the follow-on clinical trial in asthma. In addition, we are progressing early stage interest from an agency of the US Government by providing SNG001 to assess its efficacy against the new coronavirus which has emerged from the Middle East ("Middle East Respiratory Syndrome" or "MERS").

There are two scenarios whereby viral lung infections become a serious health threat. Firstly for patients who have a respiratory condition such as asthma or chronic obstructive pulmonary disease (COPD) (the virus can exacerbate their underlying condition), and secondly for anyone who becomes infected with highly pathogenic viruses such as bird flu or MERS.

For asthma and COPD patients, Synairgen's inhaled SNG001 is being developed as a broad spectrum anti-viral therapy to be taken at the onset of cold (or influenza) symptoms to boost the lungs' anti-viral defences. The objective is to treat and/or attenuate a deterioration of asthma or COPD symptoms, by limiting the spread of viral infections to the lung and prevent life-threatening severe exacerbations that require intensive treatment. As a measure of how severe respiratory viruses can be for these patients, it has been reported that approximately 80% of hospitalisations for asthma are linked to common cold infections. In clinical trials, SNG001 has been tested in patients across the asthma spectrum (from moderate to severe). Compared to placebo, in the more severe patients (representing approximately 10% to 20% of asthma patients) SNG001 has significantly reduced asthma symptoms, improved lung function and produced an encouraging reduction in the number of severe exacerbations.

During the first six months of this year we have analysed samples of sputum (phlegm) from patients who were dosed with SNG001 in the phase II trial. Across the whole trial population we were able to demonstrate a significant reduction in markers of inflammation and a significant uplift in anti-viral activity in the lung during a cold infection. This is a significant dataset for the regulatory element of the development programme as it clearly demonstrates that the effects observed in a clinical trial can be explained through the expected mechanism of action.

Closely tied to our business development activity, we are progressing various clinical trial protocols/designs, taking into consideration potential partners' preferences in respect of regulatory strategy and drug development plans.

### **Severe viral lung infections**

SNG001 is being provided to an agency of the US Government so that its efficacy can be assessed against MERS. This new coronavirus has a relatively high mortality rate and there is a concern that it may spread in the way that SARS did in 2003, should it become more transmissible from human to human. Similar experiments are also planned with H7N9, a novel strain of 'bird flu' which emerged in China earlier this year.

### **FINANCIAL REVIEW**

#### **Statement of Comprehensive Income**

The loss from operations for the six months ended 30 June 2013 was £1.20 million (six months ended 30 June 2012: £1.28 million). Research and development

expenditure amounted to £0.68 million (six months ended 30 June 2012: £0.75 million). Other administrative costs for the period, including business development costs, amounted to £0.52 million (six months ended 30 June 2012: £0.53 million). The loss after tax for the period was £1.06 million (six months ended 30 June 2012: £1.15 million) and the loss per share was 1.41p (six months ended 30 June 2012: loss of 1.65p).

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

At 30 June 2013, net assets amounted to £2.46 million (30 June 2012: £2.07 million), including net funds (comprising cash balances and bank deposits) of £2.14 million (30 June 2012: £2.25 million).

The principal elements of the £0.95 million decrease in net funds over the six months ended 30 June 2013 (six months ended 30 June 2012: £1.10 million decrease in net funds) were:

- Cash used in operations of £1.19 million (six months ended 30 June 2012: £1.36 million outflow); and
- Research and development tax credits received of £0.24 million (six months ended 30 June 2012: £0.25 million)

#### **SUMMARY**

The Company's resources are being focused on clinical and regulatory planning in conjunction with potential partners. This is a critical part of SNG001's development as we prepare to commence the next trial in 2014.

**Simon Shaw**  
Chairman

**Richard Marsden**  
Chief Executive Officer

9 August 2013

**Consolidated Statement of Comprehensive Income**  
for the six months ended 30 June 2013

	Notes	Unaudited Six months ended 30 June 2013 £000	Unaudited Six months ended 30 June 2012 £000	Audited Year ended 31 December 2012 £000
Research and development expenditure		<b>(683)</b>	(747)	(1,508)
Other administrative expenses		<b>(519)</b>	(530)	(982)
Total administrative expenses		<b>(1,202)</b>	(1,277)	(2,490)
<b>Loss from operations</b>		<b>(1,202)</b>	(1,277)	(2,490)
Finance income		<b>7</b>	14	27
<b>Loss before tax</b>		<b>(1,195)</b>	(1,263)	(2,463)
Tax credit	2	<b>132</b>	113	213
<b>Loss and total comprehensive loss for the period attributable to equity holders of the parent</b>		<b>(1,063)</b>	(1,150)	(2,250)
<b>Loss per ordinary share</b>				
Basic and diluted loss per share (pence)	3	<b>(1.41)p</b>	(1.65)p	(3.12)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 2012	696	17,128	483	(15,184)	3,123
Total comprehensive loss for the period	-	-	-	(1,150)	(1,150)
Recognition of share-based payments	-	-	-	99	99
At 30 June 2012	696	17,128	483	(16,235)	2,072
Total comprehensive loss for the period	-	-	-	(1,100)	(1,100)
Recognition of share-based payments	-	-	-	94	94
Issuance of ordinary shares	56	2,445	-	-	2,501
Transaction costs in respect of share issues	-	(151)	-	-	(151)
At 31 December 2012	752	19,422	483	(17,241)	3,416
Total comprehensive loss for the period	-	-	-	(1,063)	(1,063)
Recognition of share-based payments	-	-	-	106	106
<b>At 30 June 2013</b>	<b>752</b>	<b>19,422</b>	<b>483</b>	<b>(18,198)</b>	<b>2,459</b>

**Consolidated Statement of Financial Position**  
as at 30 June 2013

	Unaudited 30 June 2013 £000	Unaudited 30 June 2012 £000	Audited 31 December 2012 £000
Notes			
<b>Assets</b>			
<b>Non-current assets</b>			
Intangible assets	<b>318</b>	231	332
Property, plant and equipment	<b>22</b>	36	27
	<b>340</b>	267	359
<b>Current assets</b>			
Inventories	<b>238</b>	79	72
Current tax receivable	<b>98</b>	110	210
Trade and other receivables	<b>101</b>	56	79
Other financial assets – bank deposits	<b>857</b>	1,377	1,431
Cash and cash equivalents	<b>1,279</b>	875	1,656
	<b>2,573</b>	2,497	3,448
<b>Total assets</b>	<b>2,913</b>	2,764	3,807
<b>Liabilities</b>			
<b>Current liabilities</b>			
Trade and other payables	<b>(454)</b>	(692)	(391)
<b>Total liabilities</b>	<b>(454)</b>	(692)	(391)
<b>Total net assets</b>	<b>2,459</b>	2,072	3,416
<b>Equity</b>			
<b>Capital and reserves attributable to equity holders of the parent</b>			
Share capital	<b>752</b>	696	752
Share premium	<b>19,422</b>	17,128	19,422
Merger reserve	<b>483</b>	483	483
Retained deficit	<b>(18,198)</b>	(16,235)	(17,241)
<b>Total equity</b>	<b>2,459</b>	2,072	3,416

**Consolidated Statement of Cash Flows**  
for the six months ended 30 June 2013

	Unaudited Six months ended 30 June 2013 £000	Unaudited Six months ended 30 June 2012 £000	Audited Year ended 31 December 2012 £000
<b>Cash flows from operating activities</b>			
Loss before tax	<b>(1,195)</b>	(1,263)	(2,463)
Adjustments for:			
Finance income	<b>(7)</b>	(14)	(27)
Depreciation	<b>8</b>	12	30
Amortisation	<b>27</b>	17	46
Loss on derecognised intangible asset	<b>3</b>	-	5
Share-based payment charge	<b>106</b>	99	193
<b>Cash flows from operations before changes in working capital</b>	<b>(1,058)</b>	(1,149)	(2,216)
(Increase)/Decrease in inventories	<b>(166)</b>	6	13
(Increase)/Decrease in trade and other receivables	<b>(26)</b>	52	30
Increase/(Decrease) in trade and other payables	<b>63</b>	(271)	(572)
<b>Cash used in operations</b>	<b>(1,187)</b>	(1,362)	(2,745)
Tax credit received	<b>244</b>	253	254
<b>Net cash used in operating activities</b>	<b>(943)</b>	(1,109)	(2,491)
<b>Cash flows from investing activities</b>			
Interest received	<b>11</b>	19	30
Purchase of property, plant and equipment	<b>(3)</b>	-	(9)
Purchase of intangible assets	<b>(16)</b>	(9)	(144)
Decrease in other financial assets	<b>574</b>	1,078	1,024
<b>Net cash generated from investing activities</b>	<b>566</b>	1,088	901
<b>Cash flows from financing activities</b>			
Proceeds from issuance of ordinary shares	-	-	2,501
Transaction costs in respect of share issues	-	-	(151)
<b>Net cash generated from financing activities</b>	-	-	2,350
<b>(Decrease)/Increase in cash and cash equivalents</b>	<b>(377)</b>	(21)	760
<b>Cash and cash equivalents at beginning of period</b>	<b>1,656</b>	896	896
<b>Cash and cash equivalents at end of period</b>	<b>1,279</b>	875	1,656

## Notes to the Financial Statements for the six months ended 30 June 2013

### 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 2013 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 year ended 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 year ended 31 December 2012 does not constitute the full statutory accounts for that period. The Annual Report and Financial Statements for the year ended 31 December 2012 have been filed with the Registrar of Companies. The Independent Auditor's Report on the Report and Financial Statements for the year ended 31 December 2012 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 2013 interim financial statements were approved by a duly appointed and authorised committee of the Board of Directors on 9 August 2013.

### 2. Tax credit

The tax credit of £132,000 (six months ended 30 June 2012: £113,000; year ended 31 December 2012: £213,000) includes £98,000 as an estimate of the research and development tax credit receivable in respect of the current period and £34,000 representing amounts unprovided for in previous periods.

### 3. Loss per ordinary share

	Unaudited Six months ended 30 June 2013	Unaudited Six months ended 30 June 2012	Audited Year ended 31 December 2012
Loss attributable to equity holders of the Company (£000)	<b>(1,063)</b>	(1,150)	(2,250)
Weighted average number of ordinary shares in issue	<b>75,184,336</b>	69,560,064	72,036,917



**Notes to the Financial Statements**  
**for the six months ended 30 June 2013 (continued)**

**3. Loss per ordinary share (continued)**

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 2013 there were 8,358,435 options outstanding (30 June 2012: 7,580,351 options outstanding; 31 December 2012: 7,511,635 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 2013 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 2013 is not prepared, in all material respects, in accordance with the rules of the London Stock Exchange for companies trading securities on AIM.

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9 August 2013

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