

## Press release

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

## **Interim results for the six months ended 30 June 2015**

### **~ Progress continued on track with AZD9412 and Pharmaxis collaboration underway ~**

Southampton, UK – 16 September 2015: Synairgen plc (LSE: SNG), the respiratory drug discovery and development company, today announces its unaudited interim results for the six months ended 30 June 2015.

#### **Operational highlights (including post period-end)**

- In July, AstraZeneca commenced its Phase IIa study of AZD9412 (inhaled interferon beta, developed by Synairgen and formerly known as SNG001). The study population will comprise patients with severe asthma, building on the clinical data from Synairgen’s exploratory Phase IIa trial in moderate to severe asthma, which showed that difficult to treat asthma patients appeared to derive most benefit from this therapy
- Continued screening of new development opportunities using Synairgen’s proprietary “BioBank” platform, leveraging Synairgen’s world-class founder and respiratory drug discovery and development expertise
- Research collaboration signed with Pharmaxis to develop a selective inhibitor of the lysyl oxidase type 2 enzyme (LOXL2) to treat the fatal lung disease idiopathic pulmonary fibrosis (IPF)

#### **Financial highlights**

- Research and development expenditure for the period was reduced to £0.48 million (H1 2014: £1.27 million) due to AstraZeneca having taken on the development costs of the interferon beta programme after the out-licensing in June 2014
- Loss after tax for the period of £0.91 million (H1 2014: profit of £1.90 million)
- Cash and deposit balances of £8.73 million at 30 June 2015 (30 June 2014: £6.08 million)

#### **Richard Marsden, CEO of Synairgen, commented:**

*“During the period, Synairgen has been focused on working with AstraZeneca to support the start of the Phase IIa trial in AZD9412, which has now commenced and we look forward to updating you with the results.*

*We have also devoted significant resource to assessing and bringing new programmes into the company and we are delighted to have achieved the first of these, the recently announced collaboration with Pharmaxis in the important indication of Idiopathic Pulmonary Fibrosis.”*

-Ends-

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

### **OPERATING REVIEW**

#### **Summary**

In the first six months of the year Synairgen provided support to AstraZeneca in its preparation to start the Phase IIa trial of AZD9412 in patients with asthma. In line with its strategy Synairgen continues to focus on bringing new programmes into the Company and post period-end has announced its collaboration with Pharmaxis, the first new programme.

#### **AstraZeneca's AZD9412**

In June 2014, Synairgen licensed its SNG001 programme (inhaled interferon-beta (IFN-beta)) programme to AstraZeneca, now referred to as AZD9412, which is potentially worth up to a further \$225 million in development and commercial milestones plus attractive royalties on sales. Since licensing the programme, AstraZeneca has completed the preparatory work to enable the commencement of a Phase IIa clinical trial of AZD9412. The first patient was enrolled in the trial on 22 July 2015. In design, this trial is very similar to Synairgen's Phase II of inhaled IFN-beta, however AstraZeneca is focussing solely on the Global Initiative for Asthma (GINA) Step 4 and Step 5 patients; the patient type in which Synairgen had previously observed significant benefits of therapy. AstraZeneca's trial of AZD9412 is considerably larger than Synairgen's first efficacy study and will include approximately 220 Step 4/5 patients. It is expected to conclude in 2017.

Several studies have been published in recent months which reinforce the observation that there is a dysfunctional response to common respiratory viruses (mainly rhinovirus) in asthmatic patients, supporting the use of inhaled IFN-beta in asthma patients during cold and flu infections. Two of these studies identified possible causes. In the first study<sup>1</sup>, lung samples from asthmatic patients expressed more of the SOCS1 protein, which is known to suppress IFN-beta production. This may explain the lower levels of IFN-beta observed in cells from asthmatic patients when they are exposed to the common cold virus. In a second study<sup>2</sup>, it was shown that corticosteroids (an essential anti-inflammatory asthma therapy) may be compromising the lung's antiviral defences, an unwanted effect that could be overcome through application of IFN-beta. These two papers further support the rationale for using inhaled AZD9412 to boost antiviral defences in asthmatic patients when they are infected with common cold viruses.

#### **Synairgen's new pipeline developments**

Since licensing the SNG001 programme to AstraZeneca, Synairgen has been assessing potential programmes for in-licensing/partnership. The type of opportunity being reviewed by Synairgen reflects our strengths as a development partner:

- Discovering and developing novel respiratory compounds, which are ideally "first in class" with significant clinical and commercial potential
- Synairgen's BioBank platform of human samples from patients with asthma and other lung diseases to validate the target, select compounds and support drug progression towards the clinic, for example by demonstrating mechanism of action, duration of action, or dose selection
- Synairgen's strong academic roots in respiratory cell biology and its Key Opinion Leader network
- Our track record in delivering proof of concept clinical trials in an economical and expeditious manner

Synairgen continues to review a number of opportunities fitting these criteria. Such assessment includes an analysis of the competitive landscape, intellectual property, development capabilities, and the degree to which such opportunities can utilise Synairgen's unique technology platform and competence. For some of the opportunities being assessed, the Company has conducted laboratory screening work of compounds, and this has necessitated investment in the further advancement of the BioBank and *in vitro* model platform, particularly in the field of Idiopathic Pulmonary Fibrosis (IPF). The Company has continued to work closely with the academic team at the University of Southampton in this regard.

### **Research collaboration to develop LOXL2 inhibitor for pulmonary fibrosis with Pharmaxis**

The first of Synairgen's new opportunities, which the Company has been researching for a number of months, was announced on 5 August 2015. This is a collaboration with Pharmaxis Ltd of Australia, which has developed a series of compounds that inhibit lysyl oxidase type 2 enzyme (LOXL2). LOXL2 is a target of interest in the severe lung disease IPF. It is an enzyme that normally locks fibres together in scar tissue, providing a 'scaffolding structure' to aid wound healing. Inhibition of LOXL2 would prevent this fibrosis occurring.

IPF has been described as unwanted wound healing in the lung, where for some unknown reason the lungs form scar tissue, limiting gas exchange, leading to death. Survival from the time of diagnosis is approximately 3 years, worse than many cancers.

In the collaboration, Synairgen will work with Pharmaxis to identify the most suitable compound for the inhibition of LOXL2 in IPF. Synairgen will progress the compound into Phase I and potentially Phase II clinical trials. It is expected that Synairgen will have a 50:50 stake in the collaboration and of any resultant commercialisation by the end of Phase I, which is the earliest point that licensing to a large pharma partner is likely to occur. The compound may have utility beyond IPF in diseases such as Non-alcoholic Steatohepatitis (NASH) and cancer, which will be explored by Pharmaxis. Synairgen will have a minority stake in revenues generated for the IPF compound in diseases outside of IPF.

## **FINANCIAL REVIEW**

### **Statement of Comprehensive Income**

The loss from operations for the six months ended 30 June 2015 was £1.04 million (six months ended 30 June 2014: profit of £1.89 million). The prior period included the £4.25 million upfront payment from the AstraZeneca licensing transaction. Research and development expenditure was reduced to £0.48 million (six months ended 30 June 2014: £1.27 million) due to AstraZeneca having taken on the development costs of the interferon beta programme after the outlicensing in June 2014. We anticipate that the collaboration with Pharmaxis will result in an increase in the level of research and development expenditure going forward. Other administrative costs for the period, including business development costs, amounted to £0.59 million (six months ended 30 June 2014: £1.10 million). The comparative period administrative costs included certain staff costs associated with the completion of the AstraZeneca transaction. The loss after tax for the period was £0.91 million (six months ended 30 June 2014: profit £1.90 million) and the basic loss per share was 1.00p (six months ended 30 June 2014: earnings of 2.46p).

## Statement of Financial Position and cash flows

At 30 June 2015, net assets amounted to £8.60 million (30 June 2014: £4.98 million), including net funds (comprising cash balances and bank deposits) of £8.73 million (30 June 2014: £6.08 million).

The principal elements of the £0.87 million decrease in net funds over the six months ended 30 June 2015 (six months ended 30 June 2014: £4.79 million increase in net funds) were:

- Cash used in operations of £0.90 million (six months ended 30 June 2014: £3.17 million inflow);
- Research and development tax credits received of £nil (six months ended 30 June 2014: £0.20 million); and
- Share issue proceeds (net of costs) of £nil (six months ended 30 June 2014: £1.42 million).

## OUTLOOK

AZD9412 is the first of Synairgen's programmes to have been licensed to a large pharma company and we are delighted with the progress being made by AstraZeneca as AZD9412 advances into the next clinical trial.

In line with the strategy to bring new programmes into the Company for development and future potential licensing, we continue to assess opportunities using our BioBank technology platform. The first of these opportunities has been announced for the disease IPF in a collaboration with Pharmaxis, which is progressing well. We look forward to announcing other new programmes in the future as we continue to broaden our pipeline.

**Simon Shaw**  
Chairman

**Richard Marsden**  
Chief Executive Officer

15 September 2015

### References

- 1 *Gielen V et al. (2015) Increased nuclear suppressor Increased nuclear suppressor of cytokine signaling 1 in asthmatic bronchial epithelium suppresses rhinovirus induction of innate interferons. J Allergy Clin Immunol. 2015 Jul;136(1):177-188.e11.*
- 2 *Thomas BJ et al. (2014) Glucocorticosteroids enhance replication of respiratory viruses: effect of adjuvant interferon. Sci Rep. 2014 Nov 24;4:7176.*

**Consolidated Statement of Comprehensive Income**  
for the six months ended 30 June 2015

	Notes	Unaudited Six months ended 30 June 2015 £000	Unaudited Six months ended 30 June 2014 £000	Audited Year ended 31 December 2014 £000
<b>Revenue</b>		<b>25</b>	4,250	4,290
Research and development expenditure		(475)	(1,266)	(1,649)
Other administrative expenses		(588)	(1,098)	(1,547)
Total administrative expenses		(1,063)	(2,364)	(3,196)
<b>(Loss)/Profit from operations</b>		<b>(1,038)</b>	1,886	1,094
Finance income		26	4	31
<b>(Loss)/Profit before tax</b>		<b>(1,012)</b>	1,890	1,125
Tax credit	2	102	8	63
<b>(Loss)/Profit and total comprehensive (loss)/income for the period attributable to equity holders of the parent</b>		<b>(910)</b>	1,898	1,188
<b>(Loss)/Earnings per ordinary share</b>	3			
Basic (loss)/earnings per ordinary share (pence)		(1.00p)	2.46p	1.42p
Diluted (loss)/earnings per ordinary share (pence)		(1.00p)	2.30p	1.35p

**Consolidated Statement of Changes in Equity (unaudited)**  
for the six months ended 30 June 2015

	Share capital £000	Share premium £000	Merger reserve £000	Retained deficit £000	Total £000
At 1 January 2014	752	19,422	483	(19,078)	1,579
Total comprehensive income for the period	-	-	-	1,898	1,898
Recognition of share-based payments	-	-	-	85	85
Issuance of ordinary shares	34	1,468	-	-	1,502
Transaction costs in respect of share issues	-	(80)	-	-	(80)
At 30 June 2014	786	20,810	483	(17,095)	4,984
Total comprehensive loss for the period	-	-	-	(710)	(710)
Recognition of share-based payments	-	-	-	74	74
Issuance of ordinary shares	127	5,293	-	-	5,420
Transaction costs in respect of share issues	-	(332)	-	-	(332)
At 31 December 2014	913	25,771	483	(17,731)	9,436
Total comprehensive loss for the period	-	-	-	(910)	(910)
Recognition of share-based payments	-	-	-	74	74
<b>At 30 June 2015</b>	<b>913</b>	<b>25,771</b>	<b>483</b>	<b>(18,567)</b>	<b>8,600</b>

**Consolidated Statement of Financial Position**  
as at 30 June 2015

	Unaudited 30 June 2015 £000	Unaudited 30 June 2014 £000	Audited 31 December 2014 £000
Notes			
<b>Assets</b>			
<b>Non-current assets</b>			
Intangible assets	<b>91</b>	112	102
Property, plant and equipment	<b>15</b>	16	17
	<b>106</b>	128	119
<b>Current assets</b>			
Inventories	<b>56</b>	57	56
Current tax receivable	<b>157</b>	-	55
Trade and other receivables	<b>56</b>	161	102
Other financial assets – bank deposits	4 <b>4,710</b>	1,001	6,752
Cash and cash equivalents	<b>4,018</b>	5,078	2,847
	<b>8,997</b>	6,297	9,812
<b>Total assets</b>	<b>9,103</b>	6,425	9,931
<b>Liabilities</b>			
<b>Current liabilities</b>			
Trade and other payables	<b>(503)</b>	(1,441)	(495)
<b>Total liabilities</b>	<b>(503)</b>	(1,441)	(495)
<b>Total net assets</b>	<b>8,600</b>	4,984	9,436
<b>Equity</b>			
<b>Capital and reserves attributable to equity holders of the parent</b>			
Share capital	<b>913</b>	786	913
Share premium	<b>25,771</b>	20,810	25,771
Merger reserve	<b>483</b>	483	483
Retained deficit	<b>(18,567)</b>	(17,095)	(17,731)
<b>Total equity</b>	<b>8,600</b>	4,984	9,436

**Consolidated Statement of Cash Flows**  
for the six months ended 30 June 2015

	Unaudited Six months ended 30 June 2015 £000	Unaudited Six months ended 30 June 2014 £000	Audited Year ended 31 December 2014 £000
<b>Cash flows from operating activities</b>			
(Loss)/Profit before tax	<b>(1,012)</b>	1,890	1,125
Adjustments for:			
Finance income	<b>(26)</b>	(4)	(31)
Depreciation	<b>5</b>	6	12
Amortisation	<b>11</b>	24	35
Loss on derecognised intangible asset	-	164	164
Share-based payment charge	<b>74</b>	85	159
<b>Cash flows from operations before changes in working capital</b>	<b>(948)</b>	2,165	1,464
Decrease in inventories	-	142	143
Decrease/(Increase) in trade and other receivables	<b>39</b>	(117)	(40)
Increase in trade and other payables	<b>8</b>	984	38
<b>Cash (used in)/generated from operations</b>	<b>(901)</b>	3,174	1,605
Tax credit received	-	198	198
<b>Net cash (used in)/generated from operating activities</b>	<b>(901)</b>	3,372	1,803
<b>Cash flows from investing activities</b>			
Interest received	<b>33</b>	3	12
Purchase of property, plant and equipment	<b>(3)</b>	(7)	(14)
Purchase of intangible assets	-	(3)	(4)
Decrease/(Increase) in other financial assets	<b>2,042</b>	(543)	(6,294)
<b>Net cash generated from/(used in) investing activities</b>	<b>2,072</b>	(550)	(6,300)
<b>Cash flows from financing activities</b>			
Proceeds from issuance of ordinary shares	-	1,502	6,922
Transaction costs in respect of share issues	-	(80)	(412)
<b>Net cash generated from financing activities</b>	-	1,422	6,510
<b>Increase in cash and cash equivalents</b>	<b>1,171</b>	4,244	2,013
<b>Cash and cash equivalents at beginning of period</b>	<b>2,847</b>	834	834
<b>Cash and cash equivalents at end of period</b>	<b>4,018</b>	5,078	2,847

## **Notes to the Financial Statements for the six months ended 30 June 2015**

### **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 2015 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 2014 and with those that the Company expects to apply in its financial statements for the year ending 31 December 2015.

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 2014 does not constitute the full statutory accounts for that period. The Annual Report and Financial Statements for the year ended 31 December 2014 have been filed with the Registrar of Companies. The Independent Auditor's Report on the Annual Report and Financial Statements for the year ended 31 December 2014 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 2015 interim financial statements were approved by a duly appointed and authorised committee of the Board of Directors on 15 September 2015.

### **2. Tax credit**

The tax credit of £102,000 is an estimate of the research and development tax credit receivable for the six months ended 30 June 2015.

### **3. (Loss)/Earnings per ordinary share**

Basis (loss)/earnings per share ('LPS' or 'EPS') is calculated by dividing the (loss)/profit attributable to ordinary equity holders of the Company by the weighted average number of ordinary shares in issue during the period.

For diluted earnings per share, the weighted number of ordinary shares in issue is adjusted to assume conversion of the dilutive potential ordinary shares, being share options where the exercise price is less than the average market price of the Company's ordinary shares during the period and where performance conditions have been met or, in the case of options where the performance period is not completed, are being met.

**Notes to the Financial Statements**  
**for the six months ended 30 June 2015 (continued)**

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

Where there is a loss (as for the six months ended 30 June 2015), the loss attributable to shareholders and the weighted average number of ordinary shares for the purposes of calculating the diluted loss per ordinary share are identical to those used for basic loss per share. This is because the exercise of share options would have the effect of reducing the loss per ordinary share and is therefore antidilutive under the terms of IAS33.

The losses/earnings and number of weighted average number of shares used in the calculations are as follows:

	Unaudited Six months ended 30 June 2015			Unaudited Six months ended 30 June 2014			Audited Year ended 31 December 2014		
	Losses £000	Shares 000	LPS pence	Earnings £000	Shares 000	EPS pence	Earnings £000	Shares 000	EPS pence
Basic (loss)/earnings per share	(910)	91,317	(1.00)	1,898	77,166	2.46	1,188	83,899	1.42
Effect of additional shares under option	-	-	-	-	5,310	(0.16)	-	4,279	(0.07)
Diluted (loss)/earnings per share	(910)	91,317	(1.00)	1,898	82,476	2.30	1,188	88,178	1.35

**4. Other financial assets**

Other financial assets comprise Sterling fixed rate bank deposits of greater than three months' maturity at the 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 2015 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 2015 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*

15 September 2015

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