

Press release

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

Interim results for the six months ended 30 June 2014

A period of transformation with lead programme out-licensed to AstraZeneca and novel assets identified for development

Southampton, UK – 25 September 2014: Synairgen plc (LSE: SNG), the respiratory drug discovery and development company, today announces its unaudited interim results for the six months ended 30 June 2014.

Operational highlights

- Global exclusive licence agreement signed in June with AstraZeneca for SNG001 (inhaled interferon beta) for all respiratory indications. \$7.25 million up-front payment and potential development, regulatory and commercial milestones of up to \$225 million plus up to mid-teen tiered royalties on future potential sales
- Phase II clinical data published in the American Journal of Respiratory and Critical Care Medicine: “The effect of inhaled interferon-beta on worsening of asthma symptoms caused by viral infections: a randomised trial” in July 2014
- Screening of new development opportunities using Synairgen’s proprietary “Biobank” platform leveraging Synairgen’s world-class founder and KOL respiratory drug discovery and development expertise

Financial highlights

- Upfront payment from AstraZeneca agreement of \$7.25M (£4.25 million)
- Research and development expenditure for the period was £1.27 million (H1 2013: £0.68 million)
- Post-tax profit for the period of £1.90 million (H1 2013: loss of £1.06 million) largely due to the upfront payment from the AstraZeneca licensing transaction
- Cash and deposit balances of £6.08 million at 30 June 2014 (30 June 2013: £2.14 million) and increase in such balances for the period of £4.79 million (H1 2013: £0.95 million decrease)
- Post period-end fundraising (July 2014) of £5.3 million (before expenses)

Commenting on this transformational period, Simon Shaw, Chairman of Synairgen, said:

“During the period, Synairgen has been focused on signing the right deal for our novel therapeutic, SNG001. We were delighted to announce a global, exclusive development and commercialisation agreement with AstraZeneca in June.

“This transformative deal was major news for our investors and world-leading experts. We delivered a successful fundraise as a result of the deal and are now screening, via our novel Biobank, a number of potentially very exciting respiratory assets to bring into our pipeline.”

-Ends-

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Chairman's and Chief Executive Officer's Review

OPERATING REVIEW

Summary

The first six months of the year saw a transformation for Synairgen with two major achievements for the Company. Firstly, Synairgen signed a global, exclusive licensing agreement for the inhaled interferon (IFN) beta programme, SNG001, for asthma, COPD, and other indications to AstraZeneca; secondly, Synairgen's world-class respiratory team commenced the screening of more than 30 new programmes with the objective of bringing a number in to the pipeline. Beyond the period-end, the Company also delivered a successful fundraising in July 2014 of £5.3 million (before expenses).

Business model

Synairgen's business model continues to apply its proven human biology Biobank platform with its world-leading expertise in lung biology in order to take respiratory drugs from discovery through to clinical trials, and ultimately to out-license them to major pharmaceutical companies or niche respiratory players.

Inhaled IFN-beta, SNG001 and the licensing agreement with AstraZeneca

Synairgen developed an inhaled form of IFN-beta (SNG001), following on from a discovery by the academic team based at the University of Southampton of a deficiency of IFN-beta in cells from the lungs of asthmatic patients. It was hypothesised that, by correcting this deficiency at the time of viral infection through the use of inhaled IFN-beta, antiviral defences should be boosted and patients should have fewer exacerbations.

In SNG001's clinical development programme to date, Synairgen's Phase I trials showed that inhaled IFN-beta boosted the immune system and was well tolerated at varying dose levels. Supportive biomarker testing data was also revealed. In a Phase II trial, the results showed that lung function and asthma control were better in the 'more difficult to treat' asthma patients (representing approximately 15% of the asthma population). These patients also had fewer exacerbations.

These results have now been published in the American Journal of Respiratory and Critical Care Medicine, a prestigious peer-reviewed journal (Djukanovic R, Harrison T, Johnston SL, Gabbay F, Wark P, Thomson NC, Niven R, Singh D, Reddel HK, Davies DE, et al. The effect of inhaled interferon-beta on worsening of asthma symptoms caused by viral infections: a randomised trial. Am J Respir Crit Care Med 2014;190:145–154).

In June 2014, Synairgen signed a global exclusive licence agreement with AstraZeneca for SNG001. Synairgen received an upfront payment of \$7.25 million (£4.25 million), and will receive potential development, regulatory and commercial milestones of up to \$225 million. In addition, Synairgen will receive tiered royalties on sales, which escalate to the mid-teens level. AstraZeneca is now responsible for all future development activities and costs. In AstraZeneca, Synairgen has secured an ideal partner to complete the development and commercialisation of IFN-beta. AstraZeneca will add device and formulation expertise to the programme to ensure maximum commercial success. In 2015 AstraZeneca will commence a Phase II trial in asthma, focussed on the type of patient who benefited most from inhaled IFN-beta in Synairgen's Phase II trial.

AstraZeneca is a major franchise holder in the respiratory field, with brands such as Symbicort® bringing in revenues of \$3.5 billion in 2013. AstraZeneca's pipeline and recent deal activity demonstrates a commitment to developing novel respiratory medicines.

Synairgen's advanced cell models and Biobank: a differentiating translational research platform

Synairgen, in collaboration with the University of Southampton, has developed a number of advanced cell models using tissue and cells from human volunteers. Synairgen has accumulated a Biobank of clinical samples of blood, sputum, biopsies and bronchial epithelial cells obtained from a selection of well-characterised asthma, COPD volunteers and healthy control subjects. Using the cell-based models, Synairgen can analyse the complex interactions between disease and triggers of disease within lung tissue and use this knowledge to discover, develop and validate novel drug targets.

New programmes in respiratory medicine

In tandem with concluding the licensing discussions for SNG001, Synairgen, in conjunction with its world-class academic respiratory network, explored various assets that could potentially be brought into the Company for development. From a list of more than 100 opportunities, 30 were selected for more detailed assessment. The ideal programme for Synairgen is one that brings a novel therapeutic approach in areas of unmet clinical need. In this respect, Synairgen may exploit its proprietary Biobank of asthma and COPD ex vivo tissue to ensure that a given drug target is relevant to the disease. This asset permits the Company, at an early development stage, to minimise the development risk and maximise the benefit by improving the all-important bridge between the laboratory and clinical trials.

Synairgen intends to focus on a selected number of programmes that have the potential to play to the strengths of our unique capabilities and deliver substantial future value. These candidate programmes have not, as yet, been disclosed. Furthermore, to pursue its objectives in this context, Synairgen has, post period-end, raised a further £5.3 million (gross of expenses).

FINANCIAL REVIEW

Statement of Comprehensive Income

The profit from operations for the six months ended 30 June 2014 was £1.89 million (six months ended 30 June 2013: loss of £1.20 million). Revenues of £4.25 million represented the upfront payment from the AstraZeneca licensing transaction. Research and development expenditure amounted to £1.27 million (six months ended 30 June 2013: £0.68 million). Other administrative costs for the period, including business development costs, amounted to £1.10 million (six months ended 30 June 2013: £0.52 million). The profit after tax for the period was £1.90 million (six months ended 30 June 2013: loss £1.06 million) and the basic earnings per share was 2.46p (six months ended 30 June 2013: loss of 1.41p).

Statement of Financial Position and cash flows

At 30 June 2014, net assets amounted to £4.98 million (30 June 2013: £2.46 million), including net funds (comprising cash balances and bank deposits) of £6.08 million (30 June 2013: £2.14 million).

The principal elements of the £4.79 million increase in net funds over the six months ended 30 June 2014 (six months ended 30 June 2013: £0.95 million decrease in net funds) were:

- Cash generated from operations of £3.17 million (six months ended 30 June 2013: £1.19 million outflow);
- Research and development tax credits received of £0.20 million (six months ended 30 June 2013: £0.24 million); and
- Share issue proceeds (net of costs) of £1.42 million (six months ended 30 June 2013: £nil).

OUTLOOK

This has been a very exciting and transformative period for the Company, endorsing the novel respiratory drug discovery platform and business model. We have accomplished a valuable deal for our first programme with an ideal partner in AstraZeneca. We have identified and are screening new potential programmes, leveraging the unique combination of our Biobank platform and Synairgen's founder and KOL expertise in respiratory drug discovery and development, which we expect will yield exciting new treatment options and build substantial value to the Company over the next few years. We look forward to the future with great excitement and thank our investors and scientists for their support.

Simon Shaw
Chairman

Richard Marsden
Chief Executive Officer

24 September 2014

Consolidated Statement of Comprehensive Income
for the six months ended 30 June 2014

	Notes	Unaudited Six months ended 30 June 2014 £000	Unaudited Six months ended 30 June 2013 £000	Audited Year ended 31 December 2013 £000
Revenue		4,250	-	-
Research and development expenditure		(1,266)	(683)	(1,292)
Other administrative expenses		(1,098)	(519)	(986)
Total administrative expenses		(2,364)	(1,202)	(2,278)
Profit/(Loss) from operations		1,886	(1,202)	(2,278)
Finance income		4	7	11
Profit/(Loss) before tax		1,890	(1,195)	(2,267)
Tax credit	2	8	132	224
Profit/(Loss) and total comprehensive income/(loss) for the period attributable to equity holders of the parent		1,898	(1,063)	(2,043)
Earnings/(Loss) per ordinary share	3			
Basic earnings/(loss) per share (pence)		2.46p	(1.41)p	(2.72)p
Diluted earnings/(loss) per share (pence)		2.30p	(1.41)p	(2.72)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 2013	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
At 30 June 2013	752	19,422	483	(18,198)	2,459
Total comprehensive loss for the period	-	-	-	(980)	(980)
Recognition of share-based payments	-	-	-	100	100
Issuance of ordinary shares	-	-	-	-	-
At 31 December 2013	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

Consolidated Statement of Financial Position
as at 30 June 2014

	Unaudited 30 June 2014 £000	Unaudited 30 June 2013 £000	Audited 31 December 2013 £000
Notes			
Assets			
Non-current assets			
Intangible assets	112	318	297
Property, plant and equipment	16	22	15
	128	340	312
Current assets			
Inventories	57	238	199
Current tax receivable	-	98	190
Trade and other receivables	161	101	43
Other financial assets – bank deposits	4 1,001	857	458
Cash and cash equivalents	5,078	1,279	834
	6,297	2,573	1,724
Total assets	6,425	2,913	2,036
Liabilities			
Current liabilities			
Trade and other payables	(1,441)	(454)	(457)
Total liabilities	(1,441)	(454)	(457)
Total net assets	4,984	2,459	1,579
Equity			
Capital and reserves attributable to equity holders of the parent			
Share capital	786	752	752
Share premium	20,810	19,422	19,422
Merger reserve	483	483	483
Retained deficit	(17,095)	(18,198)	(19,078)
Total equity	4,984	2,459	1,579

Consolidated Statement of Cash Flows
for the six months ended 30 June 2014

	Unaudited Six months ended 30 June 2014 £000	Unaudited Six months ended 30 June 2013 £000	Audited Year ended 31 December 2013 £000
Cash flows from operating activities			
Profit/(Loss) before tax	1,890	(1,195)	(2,267)
Adjustments for:			
Finance income	(4)	(7)	(11)
Depreciation	6	8	15
Amortisation	24	27	47
Loss on derecognised intangible asset	164	3	4
Share-based payment charge	85	106	206
Cash flows from operations before changes in working capital	2,165	(1,058)	(2,006)
Decrease/(Increase) in inventories	142	(166)	(127)
(Increase)/Decrease in trade and other receivables	(117)	(26)	32
Increase in trade and other payables	984	63	66
Cash generated from/(used in) operations	3,174	(1,187)	(2,035)
Tax credit received	198	244	244
Net cash generated from/(used in) operating activities	3,372	(943)	(1,791)
Cash flows from investing activities			
Interest received	3	11	15
Purchase of property, plant and equipment	(7)	(3)	(3)
Purchase of intangible assets	(3)	(16)	(16)
(Increase)/Decrease in other financial assets	(543)	574	973
Net cash (used in)/generated from investing activities	(550)	566	969
Cash flows from financing activities			
Proceeds from issuance of ordinary shares	1,502	-	-
Transaction costs in respect of share issues	(80)	-	-
Net cash generated from financing activities	1,422	-	-
Increase/(Decrease) in cash and cash equivalents	4,244	(377)	(822)
Cash and cash equivalents at beginning of period	834	1,656	1,656
Cash and cash equivalents at end of period	5,078	1,279	834

Notes to the Financial Statements for the six months ended 30 June 2014

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 2014 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 2013.

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 2013 does not constitute the full statutory accounts for that period. The Annual Report and Financial Statements for the year ended 31 December 2013 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 2013 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 2014 interim financial statements were approved by a duly appointed and authorised committee of the Board of Directors on 24 September 2014.

2. Tax credit

The tax credit of £8,000 for the six months ended 30 June 2014 represents research and development tax credits unprovided for in previous periods.

3. Earnings/(Loss) per ordinary share

	Unaudited Six months ended 30 June 2014	Unaudited Six months ended 30 June 2013	Audited Year ended 31 December 2013
Profit/(Loss) attributable to equity holders of the Company (£000)	1,898	(1,063)	(2,043)
Weighted average number of ordinary shares in issue	77,165,989	75,184,336	75,186,742

Notes to the Financial Statements

for the six months ended 30 June 2014 (continued)

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

At 30 June 2014 there were 7,107,911 options outstanding (30 June 2013: 8,358,435 options outstanding; 31 December 2013: 7,393,272 options outstanding). In respect of the 2013 comparatives for the six months ended 30 June 2013 and the year ended 31 December 2013, 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.

4. Other financial assets

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

5. Post balance sheet events

On 11 July 2014, the Company raised £5,313,649 (gross of expenses) to assess and prepare new respiratory opportunities to "clinic-ready" stage by issuing 10,627,299 1p ordinary shares at a price of 50p per share. On the same day, the Company issued 1,955,819 1p ordinary shares pursuant to the exercise of options under Company schemes, with exercise prices as follows: 1,285,819 at 1p; 420,000 at 10p; and 250,000 at 20p.

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 2014 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 5.

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 2014 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
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24 September 2014

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