



## **PRESS RELEASE**

**26 March 2009**

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

## **Interim Results for the six months ended 31 December 2008**

Synairgen plc (LSE: SNG), the drug discovery and development company focused on asthma and chronic obstructive pulmonary disease (‘COPD’), today announces its interim results for the six months ended 31 December 2008.

#### **Operational highlights**

- July 2008, commencement of SG004, the second Phase I study of inhaled IFN-beta in asthmatic patients. Post period-end (March 2009), successful completion of second cohort at a dose predicted to be efficacious. A significant landmark in our lead programme;
- Test for biomarker (neopterin) developed to measure IFN-beta driven anti-viral activity in the lungs. Analysis of samples from non-asthmatic volunteers from the first study of inhaled IFN-beta (SG003) showed biomarker was elevated, indicating on target bioactivity of inhaled IFN-beta;
- Planning for Phase IIa studies of inhaled IFN-beta has commenced, including consideration of all appropriate funding options; and
- Excellent progress made in the development of the Human Tissue Authority licensed biobank, which now contains samples collected from over 250 well-characterised volunteers.

#### **Financial highlights**

- Research and development expenditure for the period: £1.04 million (2007: £1.02 million);
- Post tax loss for the period: £1.14 million (2007: loss of £1.09 million); and
- Net funds at 31 December 2008 of £3.02 million (31 December 2007: £5.13 million), providing a good level of funding for the Company into 2010.

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

*“During the first six months of the financial year, we have successfully advanced our lead inhaled IFN-Beta programme, and continued to standardise and scale up our human model technology platform.*

*“The Company has begun to receive a significant level of interest from the pharmaceutical industry relating to Synairgen’s biobank and in vitro models together with Synairgen’s specialist respiratory biological drug development expertise. We feel this is an exciting development, which endorses the Company’s approach and could form a significant part of this business in the future.*

*"The Board continues its tight control on costs and Synairgen has a robust capital position which takes us well into 2010 and allows us to review options for our longer term financing strategy well in advance of the next phase of IFN-beta trials next year."*

-Ends-

For further information, please contact:

**Synairgen plc**

Richard Marsden, Managing Director  
John Ward, Finance Director

**Tel: + 44 (0) 2380 512 800**

**Threadneedle Communications**

Graham Herring  
Josh Royston

**Tel: + 44 (0) 207 653 9850**

# Chairman's Statement

## OPERATING REVIEW

During the first six months of the financial year Synairgen has focused considerable time and effort into advancing its lead programme, inhaled interferon beta ('IFN-beta') for asthma and COPD, and continuing to develop its human *in vitro* asthma and COPD model platform technology. The Company has continued to manage its existing cash resources efficiently. Whilst its existing resources will comfortably fund the Company into 2010, the Company has already started to consider appropriate financing options to ensure funding is in place to progress the IFN-beta programme into Phase IIa in due course.

### **IFN-beta to prevent asthma exacerbations caused by common respiratory viruses**

The common cold causes up to 80% of asthma exacerbations and resulting hospitalisations. In the US this equates to an estimated 1.4 million emergency room visits, and 400,000 hospital admissions (at an average cost of \$9,000 per admission). This represents a large unmet clinical need. Existing therapies (inhaled corticosteroids, bronchodilators, and leukotriene inhibitors), despite their commercial success, do not prevent the virus spreading from the nose to the lungs and causing these exacerbations. It is in this area of crucial unmet need that we will initially position our inhaled IFN-beta product.

The period under review has been dominated by SG004, the second Phase I study of inhaled IFN-beta in moderate asthmatic patients, which commenced at the end of July. In March 2009 (post period-end) we announced the significant landmark of completing cohort 2 in SG004. This achievement is significant because we consider that the dose of IFN-beta taken by the asthmatic volunteers in cohort 2 over a two week period is likely to be an effective dose to combat virus-driven exacerbations. Subject to there being no material adverse events in the remainder of the trial, Synairgen now has a dosing regimen which it can take forward into Phase II Proof of Concept and planning for this has now commenced. Synairgen will escalate the dose further in cohorts 3 and 4, and complete volunteer enrolment during the summer of 2009.

### **IFN-beta to prevent COPD exacerbations caused by common respiratory viruses**

COPD (Chronic Obstructive Pulmonary Disease, more commonly known as chronic bronchitis and/or emphysema) affects 25% of long term smokers, and is characterised by an irreversible loss of lung function, until death. By 2030, COPD is predicted to become the third leading cause of death worldwide after ischemic heart disease (heart attack) and cerebrovascular disease (stroke).

If a COPD patient catches a cold, there is a 50% chance that it will lead to an exacerbation of their disease. Many exacerbating COPD patients will be hospitalised, with associated health economic consequences. Up to 10% of COPD hospitalisations result in death.

Synairgen, using cells derived from COPD patients in its *in vitro* lung models, has established that simulated aerosolised IFN-beta treatment greatly protects cells against the common cold virus. Our Phase I IFN-beta trials have been designed to support a transition directly to COPD Proof of Concept in "healthy smokers".

### **Anti-viral biomarker confirms inhaled IFN-beta activity in clinical trial samples**

During the period, Synairgen completed the development and qualification of a sputum biomarker assay, which can detect IFN-beta-induced anti-viral activity in clinical trials. This biomarker (neopterin) was initially utilised to support the development of injected IFN-beta for multiple sclerosis. Sputum samples from Synairgen's first inhaled IFN-beta study (SG003) were tested and the results confirmed that neopterin was elevated following inhalation of IFN-beta. This

increases our confidence in being able to demonstrate efficacy in our Phase II Proof of Concept studies. Samples from SG004 will be analysed for this biomarker.

### **IFN-beta out-licensing strategy**

Synaigen intends to out-license the IFN-beta programme upon demonstration of Phase IIa Proof of Concept. These studies are scheduled to commence in early 2010, with results expected approximately 12 months later. Whilst the early evidence of anti-viral biomarker activity improves the attractiveness of this opportunity to potential licensees, based on our ongoing dialogue with potential partners, Synaigen expects that optimal licensing terms will be achievable with Proof of Concept data in addition to the supporting Phase I biomarker package.

### **Progression of technology platform**

During the period, Synaigen has made excellent progress in the development of its unique Human Tissue Authority licensed biobank, which now contains samples collected from over 250 volunteer donors with and without asthma or COPD. Synaigen uses the samples from the biobank to grow *in vitro* (laboratory) models of diseased lung, which can be used:

- to discover new targets;
- to trial new drugs; and
- to refine/inform drug development strategy eg patient selection, mode of delivery.

Aside from the ethical benefits, these models are considered to be superior to conventional rodent models for asthma research because asthma is a human disease and as such cannot be fully replicated in such a model. There have been a number of potential drugs which have appeared to work well in rodent models but have notably failed in human clinical trials. Synaigen's IFN-beta discovery could not have been made in rodent models, as there is no virus exacerbation rodent model. Furthermore Synaigen has continued to use its biobank-based technology to make development decisions which have informed/de-risked and accelerated the IFN-beta programme.

During the period, Synaigen has begun to receive a significant level of interest from the pharmaceutical industry relating to Synaigen's biobank and *in vitro* models together with Synaigen's specialist respiratory biological drug development expertise. We feel this is an exciting development, one that endorses Synaigen's approach and which, subject to the achievement of attractive economics for the potential collaborations, could form a significant part of this business in the future.

## **FINANCIAL REVIEW**

### **Income statement**

The operating loss for the six months ended 31 December 2008 was £1.41 million (2007: loss of £1.42 million). Research and development expenditure increased from £1.02 million to £1.04 million. A greater proportion of this expenditure was focussed on the Company's IFN-beta programme with the commencement of the second multi-centre Phase I study (SG004), and the on-going SG007 and SG008 IFN-beta studies. Other administrative costs were reduced to £0.37 million (2007: £0.40 million). Interest receivable decreased from £0.16 million to £0.09 million on account of lower deposit balances. Research and development tax credits remained constant at £0.18 million (2007: £0.17 million). The loss after tax was £1.14 million (2007: loss of £1.09 million) and the loss per share was 5.17p (2007: loss of 5.04p).

### **Balance sheet and cash flow**

At 31 December 2008, net assets amounted to £3.11 million (31 December 2007: £5.20 million), including net funds of £3.02 million (2007: £5.13 million).

Cash outflow for the six months to 31 December 2008 was £0.98 million (six months ended 31 December 2007: £0.89 million).

We continue to operate a lean financial model and have taken appropriate steps to ensure that our cash resources will last well into 2010, whilst ensuring that the completion of SG004 and the preparation for the IFN-beta Phase II studies continue to plan.

## **OUTLOOK**

Over the coming months we are focusing on three key issues; firstly, the completion of our second Phase I trial (SG004), completion of the biomarker testing and preparation of the two Phase II Proof of Concept trial applications (SG005 and SG006). Secondly, reacting to incoming interest, we will continue to explore potential research collaborations with industry participants using our scaled up and validated technology platform. Finally, we have commenced a review of all the options available to the Company and its shareholders to ensure the successful financing of the IFN-beta programme trials in 2010. With over 12 months' cash on the balance sheet, it is our intention to establish the proposed path well in advance of the MHRA applications being submitted later in the year.

**Simon Shaw**  
Chairman

**Consolidated Income Statement**  
for the six months ended 31 December 2008

	Notes	Unaudited Six months ended 31 December 2008 £000	Unaudited Six months ended 31 December 2007 £000	Audited Year ended 30 June 2008 £000
Research and development expenditure		(1,037)	(1,016)	(2,004)
Other administrative expenses		(370)	(402)	(753)
<b>Total administrative expenses</b>		<b>(1,407)</b>	<b>(1,418)</b>	<b>(2,757)</b>
<b>Loss from operations</b>		<b>(1,407)</b>	<b>(1,418)</b>	<b>(2,757)</b>
Finance income		92	159	291
Finance expense		-	-	(1)
<b>Loss before tax</b>		<b>(1,315)</b>	<b>(1,259)</b>	<b>(2,467)</b>
Tax	2	178	165	315
<b>Loss for the period attributable to equity holders of the parent</b>		<b>(1,137)</b>	<b>(1,094)</b>	<b>(2,152)</b>
<b>Loss per ordinary share</b>				
Basic and diluted loss per share (pence)	3	<b>(5.17)p</b>	(5.04)p	(9.92)p

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

	Share capital £000	Share premium £000	Merger reserve £000	Retained deficit £000	Total £000
At 1 July 2007	217	8,903	483	(3,349)	6,254
Loss for the period	-	-	-	(1,094)	(1,094)
Recognition of share-based payments	-	-	-	38	38
<b>At 31 December 2007</b>	<b>217</b>	<b>8,903</b>	<b>483</b>	<b>(4,405)</b>	<b>5,198</b>
Loss for the period	-	-	-	(1,058)	(1,058)
Recognition of share-based payments	-	-	-	47	47
<b>At 30 June 2008</b>	<b>217</b>	<b>8,903</b>	<b>483</b>	<b>(5,416)</b>	<b>4,187</b>
Issue of ordinary shares	7	-	-	-	7
Loss for the period	-	-	-	(1,137)	(1,137)
Recognition of share-based payments	-	-	-	54	54
<b>At 31 December 2008</b>	<b>224</b>	<b>8,903</b>	<b>483</b>	<b>(6,499)</b>	<b>3,111</b>

The loss for the period represents the total recognised income and expense for the period.

**Consolidated Balance Sheet**  
as at 31 December 2008

	Notes	Unaudited 31 December 2008 £000	Unaudited 31 December 2007 £000	Audited 30 June 2008 £000
<b>Assets</b>				
<b>Non-current assets</b>				
Intangible assets		134	107	109
Property, plant and equipment		98	131	122
		<b>232</b>	<b>238</b>	<b>231</b>
<b>Current assets</b>				
Inventories		131	90	103
Current tax receivable		150	150	300
Trade and other receivables		116	150	136
Other financial assets	4	2,440	4,359	3,445
Cash and cash equivalents		586	774	557
		<b>3,423</b>	<b>5,523</b>	<b>4,541</b>
<b>Total assets</b>		<b>3,655</b>	<b>5,761</b>	<b>4,772</b>
<b>Liabilities</b>				
<b>Current liabilities</b>				
Trade and other payables		(538)	(555)	(578)
Obligations under finance leases		(3)	(2)	(2)
		<b>(541)</b>	<b>(557)</b>	<b>(580)</b>
<b>Non-current liabilities</b>				
Obligations under finance leases		(3)	(6)	(5)
<b>Total liabilities</b>		<b>(544)</b>	<b>(563)</b>	<b>(585)</b>
<b>Total net assets</b>		<b>3,111</b>	<b>5,198</b>	<b>4,187</b>
<b>Equity</b>				
<b>Capital and reserves attributable to equity holders of the parent</b>				
Share capital	5	224	217	217
Share premium		8,903	8,903	8,903
Merger reserve		483	483	483
Retained deficit		(6,499)	(4,405)	(5,416)
<b>Total equity</b>		<b>3,111</b>	<b>5,198</b>	<b>4,187</b>

**Consolidated Cash Flow Statement  
for the six months ended 31 December 2008**

	<b>Unaudited Six months ended 31 December 2008 £000</b>	Unaudited Six months ended 31 December 2007 £000	Audited Year ended 30 June 2008 £000
<b>Cash flows from operating activities</b>			
Loss before tax	(1,315)	(1,259)	(2,467)
Adjustments for:			
Finance income	(92)	(159)	(290)
Finance expense	-	-	1
Depreciation	46	35	68
Amortisation	8	9	15
Share-based payment	54	38	85
Cash flows from operations before changes in working capital	(1,299)	(1,336)	(2,588)
(Increase)/Decrease in inventories	(28)	6	(7)
(Increase) in trade and other receivables	-	(28)	(16)
(Decrease)/Increase in trade and other payables	(40)	92	116
Cash used in operations	(1,367)	(1,266)	(2,495)
Interest paid	-	-	(1)
Tax credit received	328	250	250
Net cash used in operating activities	(1,039)	(1,016)	(2,246)
<b>Cash flows from investing activities</b>			
Interest received	111	170	302
Purchase of property, plant and equipment	(21)	(20)	(44)
Purchase of intangible assets	(33)	(17)	(25)
Decrease in other financial assets	1,005	639	1,553
Net cash generated from investing activities	1,062	772	1,786
<b>Cash flows from financing activities</b>			
Proceeds from issue of ordinary shares	7	-	-
Repayments of obligations under finance leases	(2)	(2)	(3)
Net cash generated from/(used in) financing activities	5	(2)	(3)
<b>Increase/(Decrease) in cash and cash equivalents</b>	<b>29</b>	<b>(246)</b>	<b>(463)</b>
Cash and cash equivalents at beginning of period	557	1,020	1,020
<b>Cash and cash equivalents at end of period</b>	<b>586</b>	<b>774</b>	<b>557</b>

## **Notes to the Financial Statements for the six months ended 31 December 2008**

### **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 30 June 2009 and in accordance with recognition and measurement principles of International Financial Reporting Standards (IFRSs) as endorsed by the European Union and implemented in the UK. 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 30 June 2008.

The IFRSs that will be effective in the financial statements for the year to 30 June 2009 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 30 June 2009.

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 results for the half-year are unaudited. The financial information in this interim announcement does not constitute statutory accounts within the meaning of Section 434 of the Companies Act 2006.

The comparative financial information for the year ended 30 June 2008 does not constitute statutory accounts within the meaning of Section 240 of the Companies Act 1985. The statutory accounts of Synairgen plc for the year ended 30 June 2008 have been reported on by the Company's auditors and have been delivered to the Registrar of Companies. The report of the auditors was unqualified and did not contain an emphasis of matter statement. The auditors' report did not contain statements under Section 237(2) or 272(3) of the Companies Act 1985.

#### **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. The Group's development programmes have anticipated lives beyond the next twelve months and the directors have already started considering options to ensure appropriate financing is in place to progress the IFN-beta programme into Phase IIa in due course.

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 31 December 2008 statements were approved by a duly appointed and authorised committee of the Board of Directors on 25 March 2009.

## 2. Tax

The tax credit of £178,000 (six months ended 31 December 2007: £165,000; year ended 30 June 2008: £315,000) includes £150,000 as an estimate of the research and development tax credit receivable in respect of the current period and £28,000 representing amounts unprovided for in previous periods.

## 3. Loss per ordinary share

	<b>Unaudited Six months ended 31 December 2008</b>	Unaudited Six months ended 31 December 2007	Audited Year ended 30 June 2008
Loss attributable to equity holders of the Company (£000)	<b>(1,137)</b>	(1,094)	(2,152)
Weighted average number of ordinary shares in issue	<b>21,981,438</b>	21,692,308	21,692,308

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 2008 there were 2,440,974 options outstanding (31 December 2007: 2,836,738 options outstanding; 30 June 2008: 2,805,944 options outstanding).

## 4. Other financial assets

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

## 5. Share capital

On 17 October 2008, the Chairman exercised his founder options over 700,000 ordinary shares at an exercise price of 1p each.

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

### **Introduction**

We have been engaged by the company to review the condensed set of financial statements in the half-yearly financial report for the six months ended 31 December 2008 which comprises the Consolidated Income Statement, the Consolidated Statement of Changes in Equity, the Consolidated Balance Sheet, the Consolidated Cash Flow Statement 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 condensed 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 the Alternative Investment Market 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 condensed 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 the Alternative Investment Market 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 condensed set of financial statements in the half-yearly financial report for the six months ended 31 December 2008 is not prepared, in all material respects, in accordance with the rules of the London Stock Exchange for companies trading securities on the Alternative Investment Market.

### **BDO Stoy Hayward LLP**

Chartered Accountants and Registered Auditors  
Southampton  
25 March 2009