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For Immediate Release

27 September 2005

# Synairgen plc Preliminary Results for the year ended 30 June 2005

Synairgen plc ('Synairgen' or the 'Company'), the drug discovery company focused on identifying the underlying causes of, and discovering new treatments for, asthma and chronic obstructive pulmonary disease ('COPD'), today announces its Preliminary Results for the year ended 30 June 2005.

### Financial highlights

- Successful flotation in October 2004 on the Alternative Investment Market which raised £10.0 million for the Company (£9.0 million net of expenses)
- Turnover was £202k (55 weeks ended 30 June 2004: £82k)
- Retained loss for the year was £610k (55 weeks ended 30 June 2004: loss of £153k)
- Cash at 30 June 2005 of £8.7 million (30 June 2004: £0.4 million)

### Operational highlights

- Lead proprietary programme (inhaled interferon beta) on track for commencement of initial clinical trial in final quarter of 2005
- Patent applications for growth factor (September 2004) and barrier function screening assays (post year-end) filed by University of Southampton and exclusively licensed to Synairgen
- New collaborations with an undisclosed North American biotechnology company and Centocor (part of J&J)
- Scale-up of Biobank activity

Commenting on the results Simon Shaw, Chairman of Synairgen, said:  
*"Synairgen's first period as a public company has been successful with an increase in collaborative partnerships and good progress being made on our proprietary programmes. We enter the new financial year with the technical and financial resources both to pursue our current exciting programmes and to generate new opportunities from our proprietary research engine."*

-Ends-

### For further information please call:

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## **PRESS RELEASE**

### **CHAIRMAN'S STATEMENT**

#### **Overview**

This is Synairgen's first set of Preliminary Results following its initial public offering ('IPO') on the Alternative Investment Market ('AIM') of the London Stock Exchange on 26 October 2004. The IPO raised £10 million for the Company (£9.0 million net of expenses) and we are using these funds to enhance our research capabilities, invest in our proprietary programmes and develop our Biobank of disease-relevant samples.

Synairgen is a drug discovery company focused on identifying and out-licensing new pharmaceutical products which address the underlying causes of asthma and chronic obstructive pulmonary disease ('COPD'). There are a limited number of therapies currently available to treat the very significant target markets of severe asthma and COPD. Since asthma and COPD are diseases in which there is a genetic predisposition, our research focuses on the use of disease-derived human tissue in complex *in vitro* models. Thus, unlike traditional animal-based models, these models enable us to replicate important aspects of the actual human disease in the laboratory as a basis for research.

We are progressing a portfolio of programmes, some collaboratively, which we believe will generate intellectual property and offer out-licensing opportunities. It is our intention to out-license this intellectual property at an early stage rather than committing significant capital resources to late-stage clinical trials.

During the year we have made significant progress in developing our lead proprietary programme for inhaled interferon beta ('IFN $\beta$ '), which seeks to protect severe asthmatics from the debilitating attacks and frequent hospitalisations induced by the common cold virus (rhinovirus). We have also entered into a number of new collaborations with pharmaceutical and biotechnology companies.

Based as it is on the world class respiratory research capabilities at the University of Southampton, Synairgen is not short of opportunities to collaborate with significant academic institutions and commercial organisations on interesting research opportunities. During this first period as a public company with reasonable capital to invest, your Board has created a system of review which is designed to ensure that Synairgen selects only those opportunities which have the potential to impact significantly upon the treatment of our target lung diseases and which will, if successful, create significant value for shareholders and partners alike.

Revenue for the year ended 30 June 2005 amounted to £202,000 (2004: £82,000) and the retained loss was £610,000 (2004: loss of £153,000). Our cash outflow before financing was £704,000 (2004: outflow of £216,000) and we ended the year with cash balances of £8.7 million.

#### **Board**

In October 2004, we welcomed John Ward as Finance Director of Synairgen. He joined us from Profile Therapeutics plc where he was Chief Financial Officer. We have also started the process to recruit a new non-executive director to provide an additional independent view to the Board.



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### Outlook

Over the next year, we anticipate:

- completing our first, and commencing the second, safety study on our IFN $\beta$  asthma programme;
- completing our *in vitro* evaluation of IFN $\beta$  for treatment of rhinovirus-induced COPD exacerbations; and
- progressing our ongoing collaborative programmes.

This will be an important year for Synairgen and we enter it with the technical and financial resources not only to do justice to the existing opportunities we have created so far, but also to identify new targets out of our proprietary research engine.

**Simon Shaw**  
Chairman

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## SCIENTIFIC REVIEW

### Asthma and COPD – the current unmet need

In the developed world there are some 80 million asthma sufferers. Over 5 million people in the UK have asthma, which in 10% of cases is severe and not controlled by standard anti-asthma drugs, such as steroids and  $\beta_2$ -agonists. These patients contribute to the majority of the 1,400 deaths due to asthma in the UK every year and 70,000 hospital admissions. Asthma costs the NHS around £900 million per year, with severe and unpredictable worsening of the disease ('exacerbations') consuming a large proportion of these costs. The unpredictability and severity of exacerbations is the major concern of patients that they liken to "living on a knife edge".

Chronic obstructive lung disease (COPD) is another very common lung disorder linked to chronic exposure to tobacco smoke. The disease passes through several phases to a state of total incapacitation. As in asthma, approximately 10% of COPD patients have severe disease. In COPD, this may be progressive and can account for substantial mortality and morbidity in the winter months. Pressure on medical beds in the NHS during the winter is largely due to COPD and related lung disease precipitated by virus infection. Globally, COPD is the fourth most common cause of death and in the UK is on the increase, especially in women.

For the last three decades the main focus of research into asthma has been upon the treatment of symptoms rather than underlying causes. This has resulted in a range of therapies which adequately address mild and moderate asthma. However, apart from anti-IgE for the allergic component of severe disease, none of the existing therapies address the unmet needs of the severe asthma patient. In the case of COPD there have been no significant new developments other than improvement of existing therapies.

### Our approach

I believe that a major part of the reason why there have not been the necessary drug breakthroughs in asthma and COPD is that small animal models consistently fail to reproduce the diseases as they occur in humans, especially their chronicity and exacerbations. In applying tissue engineering to airway cells obtained from real patients with well characterised asthma or COPD, Synairgen has been able to develop a whole



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new way of identifying drug targets and rapidly evaluating potential therapies in the test tube.

Based on 15 years' research at the University of Southampton and elsewhere, it has been established that respiratory virus infections are the major cause of severe worsening of asthma that lead to the hospitalisation of both children and adults. Of these viruses, the common cold virus (rhinovirus) is detectable in over 60% of cases. Most people can tolerate cold virus infections with only upper airway symptoms (such as a runny nose and a sore throat), but in asthma the situation is very different. Within two to three days of developing a cold, the virus moves to the chest to cause an exacerbation that is poorly responsive to steroid treatment and may last up to three or four weeks. This aspect of asthma represents a real unmet clinical need which is especially apparent at the severe end of the disease spectrum.

Building on our clinical research, we have shown that the lining cells (epithelial cells) of asthmatic airways lack the ability to generate interferon- $\beta$  ('IFN $\beta$ '), a small protein that is highly effective at triggering elimination of virally infected cells before the virus can replicate and spread. This may explain why asthmatics are more susceptible to the effects of the common cold. The importance of this study has been strengthened by showing that the addition of IFN $\beta$  to asthmatic epithelial cells restores their ability to limit replication of common cold viruses. Additionally we are investigating early observations that patients with COPD may also have a related defect in their response to respiratory virus infection and this may lead to a potential therapy in this disease area.

Having revealed such an important role for IFN $\beta$  in protecting the lung from respiratory viruses, we are in an excellent position to move this forward into clinical trial especially since we have a seamless interface between our basic and clinical science. Further discoveries are emerging from our disease-related *in vitro* cell cultures, including a defect in the lung's natural "barrier" function that we are already evaluating with potential "repair" therapies. Synairgen is well positioned to develop further these novel discoveries into a new class of therapeutic for asthma and COPD that increases the airway epithelial resistance to environmental insults, rather than waiting for inflammation and symptoms to occur and then trying to reverse them.

For the last ten years the Southampton team has been at the forefront of the changing approach to research into respiratory disease. Synairgen is leading the implementation of the new approach which is directly linked to studying the disease in humans. Synairgen's scientific team, comprising both scientists and practising chest specialists, fundamentally believes that the future management tools for chronic lung disease will come out of this novel approach. We have recorded some early successes which show genuine promise in areas of great unmet need.

**Professor Stephen Holgate**  
Founder and non-executive director



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### MANAGING DIRECTOR'S REPORT

With our IPO, the progression of our proprietary programmes, the execution of four collaborative contracts and the scaling-up of our operations, this has been a very busy year for the Company. This report outlines the operational and financial progress we have made during this period.

#### Proprietary Programmes

- *Interferon Beta* ('IFN $\beta$ ')  
Synairgen is investigating a novel application of inhaled IFN $\beta$  to reduce cold virus-induced asthma exacerbations. This virus is a major trigger for the worsening of asthma symptoms, with eight out of ten exacerbations in children and six out of ten in adults being associated with these viral infections. Currently there are no satisfactory treatments available to address this significant unmet need.

Since flotation, we are delighted with the progress of our IFN $\beta$  programme. Following the patent filing in March last year, describing a novel use for IFN $\beta$  in protecting severe asthmatics from exacerbations induced by the common cold virus, Professor Donna Davies (one of Synairgen's founders) and her team published data in the *Journal of Experimental Medicine* in March 2005. A copy of the paper is available via the *Journal of Experimental Medicine* website: <http://www.jem.org>.

The clinical team has completed the necessary regulatory processes and has received UK Clinical Trial Authorisation for the initial clinical trial of IFN $\beta$  which will commence in the final quarter of 2005. We have selected a formulation of IFN $\beta$  suitable for inhalation and an appropriate aerosol delivery system for these early stage trials. The outcome of this initial trial will be important as it will dictate the extent of safety studies required ahead of the proof of concept clinical trial.

In July of this year, we hosted our inaugural advisory panel meeting of world experts on asthma and rhinovirus as a cause of asthma exacerbations, comprising Professors Jim Gern (Wisconsin, USA), Sebastian Johnston (London, UK), Peter Sterk (Leiden, The Netherlands) and Ratko Djukanovic (Southampton, UK). The panel members will assist us in our IFN $\beta$  programme, increasing our understanding of rhinovirus infections in asthma, and it is intended that their institutions will also participate as trial sites in due course.

The Company is also exploring the use of IFN $\beta$  for the treatment of COPD, for which early laboratory data appear very encouraging.

- *Growth Factor*  
Synairgen believes that severe asthma can be regarded as a chronic "wound" of the conducting airways in which there is an increased susceptibility of the lining of the asthmatic airway (the 'epithelium') to injury and a delayed or impaired epithelial repair response. In September last year, initial research was completed and, as a result, the University of Southampton filed a patent describing a novel growth factor with potential utility to help the asthmatic lung repair itself and rebuild the barrier that protects the lung from damaging environmental factors. This has been exclusively licensed to Synairgen. Since this time, we have identified another growth factor with



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potential utility and we are currently advancing our understanding of the way these factors work in our *in vitro* models.

- **Barrier Function**

Epithelial barrier function has been shown to be lower in asthma. In September 2005, after period-end, we have in-licensed from the University of Southampton a North American patent which describes an *in vitro* model assay (test) which can be used to screen compounds capable of normalising barrier function in asthma. In the first instance we are using this assay to test the utility of the aforementioned growth factors.

### **Collaborations**

Synairgen started the year with two collaboration agreements: the first with Cambridge Antibody Technology Limited ('CAT') and the second with Merck Frosst Canada & Co. In July 2004, we embarked upon a potentially significant collaboration agreement with a major unnamed US biotechnology company, and in March 2005, we announced a new collaboration with Centocor, Inc., part of the Johnson & Johnson group of companies.

The CAT collaboration is now completed, as scheduled. Work with Merck Frosst Canada & Co, the major unnamed US biotechnology company and Centocor, Inc. continues in line with our expectations. Synairgen continues to consider and pursue potential projects with both existing and new partners. We look forward to commencing new projects when it is appropriate to do so, given the resource requirements of our proprietary programmes.

### **Biobank**

In order to recreate features of the asthmatic and COPD lung in the laboratory for research purposes (as described in the Scientific Review), we have been building a Biobank comprising samples of tissue, blood and sputum from volunteers with varying degrees of asthma and COPD, as well as healthy volunteers to act as experimental controls. The ability of Synairgen to call upon stocks of samples for experiments is an attractive proposition for collaborative partnerships and our own proprietary research programmes as it saves substantial time in the experimental process.

The extent of work on the Biobank - collecting and storing samples and developing further our *in vitro* models using disease-derived cells - has increased significantly, with the recruitment of additional staff and we will shortly begin to collaborate with further sites in the UK and in continental Europe to extend the Biobank capability.

### **Intellectual Property**

It is fundamental for the Company to protect its technology platform through the use of patents. Therefore, we are pleased to report that both our proprietary programmes' (IFN $\beta$  and Growth Factor) patents, which are exclusively licensed from the University of Southampton, have proceeded to the Patent Cooperation Treaty ('PCT') stage.

In addition, as described above, Synairgen has recently licensed a patent from the University of Southampton which protects some of the *in vitro* models used as screening assays.



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### Financial Review

#### *Introduction*

The financial information comprises the consolidated results of the Company and Synairgen Research Limited (together the 'Group'), prepared in accordance with UK Generally Accepted Accounting Principles ('GAAP').

In order to effect the IPO, a technical restructuring was required with the formation of a new holding company. This group reconstruction has been accounted for using merger accounting principles and accordingly proforma financial information has been prepared to show the position as if the Company had been in existence and the parent of Synairgen Research Limited throughout the current and prior periods.

The IPO on 26 October 2004 raised £10 million (£9.0 million after expenses) through the issue of 7,692,308 shares at a placing price of 130p. 400,000 shares were also placed on behalf of Southampton Asset Management Limited to meet institutional demand for the shares.

#### *Profit and loss account*

Revenue for the year ended 30 June 2005 was £202k (55 weeks ended 30 June 2004: £82k) and was generated from four contracts. The operating loss for the year was £908k (2004: loss of £166k), in line with our expectations. Research and development expenditure increased from £123k to £557k as the Group built its research and clinical teams up to a total of 10 staff and progressed a wider portfolio of research projects, including the regulatory preparation for the IFN $\beta$  clinical trial programme. The increase in other administrative costs from £107k to £418k reflects the recruitment of additional senior management personnel and the scaling-up of the Group's activities, including the ongoing costs of being a quoted company. Interest receivable increased from £13k to £298k on account of the flotation funds raised. The Group considers that it is entitled to claim research and development tax credits in respect of the year ended 30 June 2005. As this is the Group's first claim, it will be recognised in the profit and loss account when it has been agreed with HM Revenue & Customs. The retained loss for the year was £610k (2004: loss of £153k) and the loss per share was 3.26p (2004: loss of 1.52p).

#### *Balance sheet and cash flow*

At 30 June 2005, net assets amounted to £8.8 million (30 June 2004: £0.5 million) including cash and deposit balances of £8.7 million (2004: £0.4 million).

The principal elements of the £8.3 million increase in cash and deposit balances were:

- share issues (net of expenses) £8,980k (2004: £623k)
- operating cash outflow of £840k (2004: £78k outflow);
- capital expenditure of £60k (2004: £151k); and
- interest received of £196k (2004: £13k).

Capital expenditure comprised investment of £42k in laboratory and IT equipment and £18k on patent and licence costs.



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### *Adoption of International Financial Reporting Standards ('IFRS')*

The Company is considering the impact of the adoption of IFRS on its financial reporting, however it is likely that the Company will take advantage of the exemptions granted to AIM-quoted companies in deferring full adoption until accounting practice under certain standards has become clearer and custom and practice amongst smaller quoted companies in respect of the adoption of IFRS has emerged.

### **Staff**

This year has been one of step change for the Company. We have continued to develop a strong relationship with the University of Southampton. This has allowed us to retain our "lean" philosophy, with our headcount increasing during the period to 13 staff. I would like to thank all staff for their time and commitment to Synairgen's exciting programmes and the collective effort shown to develop our business.

**Richard Marsden**

Managing Director



**PRESS RELEASE**

**Consolidated Profit and Loss Account  
for the year ended 30 June 2005**

	<b>Proforma Year ended 30 June 2005 £000</b>	Proforma 55 weeks ended 30 June 2004 £000
Notes		
<b>Turnover</b>	<b>202</b>	82
Cost of sales	<b>(135)</b>	(18)
<b>Gross profit</b>	<b>67</b>	64
Administrative expenses		
Research and development expenditure	<b>(557)</b>	(123)
Other	<b>(418)</b>	(107)
Total	<b>(975)</b>	(230)
<b>Operating loss</b>	<b>(908)</b>	(166)
Bank interest receivable	<b>298</b>	13
<b>Loss on ordinary activities before taxation</b>	<b>(610)</b>	(153)
Tax on loss on ordinary activities	-	-
<b>Loss on ordinary activities after taxation and retained loss for the year</b>	<b>(610)</b>	(153)
<b>Loss per ordinary share</b>		
Basic and diluted loss per share (pence)	<b>3</b>	<b>(3.26)p</b>
		<b>(1.52)p</b>

During the year the Group carried out a corporate restructuring including the introduction of a new holding company. The profit and loss account has been prepared using merger accounting and is presented on a proforma basis as if the new holding company had been in existence throughout both the current and prior periods. Further information is given in Note 1.

There are no recognised gains and losses other than the loss above and therefore no separate statement of total recognised gains and losses has been presented.

All amounts relate to continuing activities.

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**Consolidated Balance Sheet  
as at 30 June 2005**

	<b>30 June 2005 £000</b>	Proforma 30 June 2004 £000
Notes		
<b>Fixed assets</b>		
Intangible assets	21	4
Tangible assets	154	145
	<u>175</u>	<u>149</u>
<b>Current assets</b>		
Stocks	55	-
Debtors	325	77
Investments: short-term deposits	8,605	350
Cash at bank and in hand	78	57
	<u>9,063</u>	<u>484</u>
<b>Creditors: amounts falling due within one year</b>	<u>(398)</u>	<u>(163)</u>
<b>Net current assets</b>	<u>8,665</u>	<u>321</u>
<b>Total assets less current liabilities</b>	<u>8,840</u>	<u>470</u>
<b>Capital and reserves</b>		
Called up share capital	217	113
Share premium account	8,903	-
Merger reserve	483	510
Profit and loss account	(763)	(153)
<b>Equity shareholders' funds</b>	<u>8,840</u>	<u>470</u>



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**Consolidated Cash Flow Statement  
for the year ended 30 June 2005**

		<b>Proforma Year ended 30 June 2005 £000</b>	Proforma 55 weeks ended 30 June 2004 £000
	Notes		
<b>Net cash outflow from operating activities</b>	5	<b>(840)</b>	(78)
<b>Returns on investments and servicing of finance</b>			
Interest received		196	13
<b>Capital expenditure and financial investment</b>			
Purchase of intangible fixed assets		(18)	(4)
Purchase of tangible fixed assets		(42)	(147)
Net cash outflow from capital expenditure		<u>(60)</u>	<u>(151)</u>
<b>Net cash outflow before management of liquid resources and financing</b>		<b>(704)</b>	(216)
<b>Management of liquid resources</b>			
Increase in short-term deposits		(8,255)	(350)
<b>Financing</b>			
Issues of ordinary share capital		77	1
Share premium received on share issues		9,923	649
Share issue costs		(1,020)	(27)
Cash inflow from financing		<u>8,980</u>	<u>623</u>
<b>Increase in cash</b>		<u>21</u>	<u>57</u>



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### Notes

#### 1. Corporate restructuring

Synairgen plc was incorporated on 16 September 2004 and 2 ordinary shares of 1p each were issued. On 11 October 2004 Synairgen plc acquired the entire issued share capital of Synairgen Research Limited by issuing 13,999,998 ordinary shares of 1p each on the basis of issuing 100 shares for each ordinary share of 1p each held in Synairgen Research Limited. The directors have accounted for this group reconstruction using the merger accounting principles as set out in Financial Reporting Standard 6. Accordingly proforma financial information has been prepared to show the position as if Synairgen plc had been in existence and the parent of Synairgen Research Limited throughout the current and prior periods. The proforma information has been compiled by taking the results of Synairgen Research Limited before the restructuring and adjusting for the capital structure of the new group.

#### 2. Basis of preparation

The financial information on the Group set out above does not constitute "statutory accounts" within the meaning of section 240 of the Companies Act 1985. The financial information for the year ended 30 June 2005 has been extracted from the Group's audited consolidated statutory accounts, which will be delivered to the Registrar of Companies for England and Wales in due course. The report of the auditors on these accounts was unqualified and did not contain a statement under Section 237 (2) or (3) of the Companies Act 1985. Comparative figures are for the 55 weeks ended 30 June 2004 on the basis set out in Note 1.

The annual report will be posted to shareholders in October 2005 and will be laid before shareholders at the Annual General Meeting on 15 November 2005.

The accounts have been prepared in accordance with UK Generally Accepted Accounting Principles.

#### 3. Loss per ordinary share

	<b>Year ended 30 June 2005</b>	55 weeks ended 30 June 2004
Loss on ordinary activities after taxation (£000)	<b>(610)</b>	(153)
Weighted average number of ordinary shares in issue	<b>18,730,993</b>	10,075,980

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 Financial Reporting Standard 14. The comparative figures are proforma based on the number of shares that would have been in issue had the capital structure of the new parent company always been in place.



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### 4. Reconciliation of movements in reserves and shareholders' funds

	Share capital £000	Share premium account £000	Merger reserve £000	Profit and loss account £000	Shareholders' funds £000
At 10 June 2003	-	-	-	-	-
Issue of ordinary shares	113	-	510	-	623
Loss for the period	-	-	-	(153)	(153)
At 30 June 2004	113	-	510	(153)	470
Issue of ordinary shares	104	9,923	(27)	-	10,000
Share issue costs	-	(1,020)	-	-	(1,020)
Loss for the year	-	-	-	(610)	(610)
At 30 June 2005	<b>217</b>	<b>8,903</b>	<b>483</b>	<b>(763)</b>	<b>8,840</b>

The issue of 140,000 1p ordinary shares by Synairgen Research Limited prior to its acquisition by Synairgen plc has been restated to reflect the 100 for 1 share for share exchange which was effected in October 2004. In accordance with the principles of merger accounting the difference between the nominal value of the shares issued in the share exchange and sum of the amounts standing to the issued share capital and share premium accounts has been taken to a merger reserve.

### 5. Reconciliation of operating loss to net cash outflow from operating activities

	Year ended 30 June 2005 £000	55 weeks ended 30 June 2004 £000
Operating loss	(908)	(166)
Depreciation & amortisation	34	2
Increase in stocks	(55)	-
Increase in debtors	(146)	(77)
Increase in creditors	235	163
Net cash outflow from operating activities	<b>(840)</b>	<b>(78)</b>



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### 6. Reconciliation of net cash flow to movement in net funds

	<b>Year ended 30 June 2005 £000</b>	<b>55 weeks ended 30 June 2004 £000</b>
Increase in cash in year	<b>21</b>	57
Increase in short-term deposits	<b>8,255</b>	350
Change in net funds resulting from cash flows and movement in net funds	<b>8,276</b>	407
Net funds at start of year	<b>407</b>	-
Net funds at end of year	<b>8,683</b>	407