

**NeuTec Pharma plc**  
**Preliminary Statement**  
**Year Ended 30 June 2004**

**Neutec Pharma plc**

**Preliminary Results for the Year Ended 30 June 2004**

**12 July, 2004 – Manchester, UK:** *NeuTec Pharma plc*, the biopharmaceutical company targeting drug-resistant infections, today announces its preliminary results for the year ended 30 June 2004.

*NeuTec* is developing a portfolio of antibody-based therapeutic products directed towards life threatening infections, particularly hospital-acquired infections such as invasive candidiasis and MRSA, which are increasingly resistant to conventional antibiotics.

**Results**

For the year ended 30 June 2004 the Company recorded a loss on ordinary activities before taxation of £3,057,000, compared with a loss in the corresponding period of £2,945,000, reflecting continuing investment in its clinical trials and development programmes. Cash outflow during the year was £2,885,000 (*2003: £1,330,000*) and cash balances at the year end were £7.9 million (*2003: £10.8 million*).

**Key Points**

- Mycograb<sup>®</sup>, which targets invasive yeast infections:
  - announced today the successful achievement of clinical end points from a multi-national, double-blind, placebo-controlled trial involving 10 European countries and the USA.
- Aurograb<sup>®</sup>, which targets methicillin resistant *Staphylococcus aureus* (“MRSA”), a hospital ‘superbug’:
  - has commenced a pan-European double-blind, placebo-controlled, phase III study.
- Intellectual Property:
  - the Company has further strengthened its intellectual property portfolio which now includes IP protection for Mycograb<sup>®</sup> in Europe, the US and Japan.
- Product pipeline:
  - the Company is continuing to develop other potential targets and has obtained in vitro data which suggests possible therapeutic benefit of Mycograb<sup>®</sup> in the treatment of breast cancer.

**Summary**

Anthony Martin, Chairman, commented:

“*NeuTec Pharma* has continued to make significant progress during the past year. We are particularly pleased with the results of the confirmatory study for Mycograb<sup>®</sup> which has been reported separately today. The current financial year will see the Company preparing for the commercial launch of that product.

The pan-European phase III trial for our second product, Aurograb<sup>®</sup>, commenced in May 2004. MRSA is widely regarded as a growing problem and the infection is widening its reach into the community.

We remain very confident for the prospects of the Company in the coming year.”

***For further details please contact:***

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*Financial Dynamics*  
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## **Chairman's Statement and Operating Review**

I am pleased to report that NeuTec Pharma plc has continued to make significant progress in developing its portfolio of products to prevent deaths from antibiotic-resistant and hospital-acquired infections. In particular, we are delighted with the results of the successful multi-national, confirmatory clinical trial of the Company's lead product, Mycograb<sup>□</sup>.

### **Clinical Trials – Mycograb<sup>®</sup>**

Mycograb<sup>□</sup> is a “grab” against heat shock protein 90 (“hsp90”) which has been developed for the treatment of invasive candidiasis. This is a life-threatening fungal infection, due to species of the yeast *Candida*, which has an overall mortality of around 40 per cent.

The Company has today reported the successful conclusion of a multi-national, double-blind, placebo-controlled trial involving 10 European countries and the US. Both primary and secondary end points show a highly statistically significant difference in the overall response rates, such that on the basis of this study, NeuTec intends to submit an application for market authorisation in Europe for the following clinical indication - "Mycograb<sup>□</sup> in combination with amphotericin B for the treatment of invasive candidiasis in immunocompetent intensive care patients."

NeuTec Pharma has also been investigating the use of Mycograb<sup>□</sup> in combination with other antifungal drugs and against other fungi using the same type of *in vitro* assays as used to assess conventional antifungal drugs. This work has shown that Mycograb<sup>□</sup> not only shows synergy with amphotericin B against all *Candida* species tested but also with caspofungin against the two commonest species, *Candida albicans* and *Candida glabrata*, and the species most likely to show resistance to caspofungin, *Candida parapsilosis*. There is also synergy between amphotericin B and Mycograb<sup>□</sup> and caspofungin and Mycograb<sup>□</sup> against *Cryptococcus neoformans*.

Additionally, hsp90 is a target molecule in a range of cancers including breast, prostate, melanoma, colon and lung. The epitope to which Mycograb<sup>□</sup> binds is conserved with human hsp90 and the extra cellular presence of this in carcinoma of the breast suggests that this could be a potential target for Mycograb<sup>□</sup>. This would be part of a combinatorial attack and *in vitro* data recently obtained within the Company points to possible drug combinations which would improve outcome, prevent the emergence of chemotherapeutically resistant cancers, avoid the toxicity inherent in the use of multiple agents and allow the use of existing agents at much lower doses to achieve the same endpoints.

### **Clinical Trials – Aurograb<sup>®</sup>**

Aurograb<sup>®</sup> targets methicillin resistant *Staphylococcus aureus* (“MRSA”), the hospital ‘superbug’. Since 2002, a consensus view has developed that MRSA is now the most important hospital-acquired infection and according to the Centers for Disease Control in the US, some 100,000 people are hospitalised with this infection each year.

Two phase II studies reported upon in 2003 found the drug to be well tolerated and demonstrated a profile that supports likely activity against MRSA in man. Aurograb<sup>®</sup> has activity on its own against strains of MRSA, but when combined with vancomycin, the current “gold standard” treatment, is more effective than either drug used on its own. This activity is also evident with strains with partial or complete resistance to vancomycin or linezolid.

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A double-blind, placebo-controlled, prospective study commenced in May 2004 to determine whether the overall response, clinical and bacterial, to Aurograb<sup>□</sup> plus vancomycin is greater than the overall response to placebo plus vancomycin in hospitalised patients with severe, deep-seated staphylococcal infections, particularly MRSA. This phase III study will involve up to 250 patients from at least six European countries with the patients being stratified on study entry on the basis of their primary site of infection.

**Research and Development Programme**

The Company has continued to develop its research programmes targeted at other serious infections using its platform technology, FABTEC<sup>□</sup>. This work forms the basis of the Company's pre-clinical research programmes, which endeavour to develop new genetically recombinant antibodies ("grabs") against a range of infections.

**Intellectual Property**

Substantial progress has been made in securing additional patents to protect the Company's intellectual property portfolio. The Company has recently been granted patents against fungal hsp90 in Canada and Japan and hsp90 variants in Europe and Japan, as well as the first patents covering Aurograb<sup>®</sup> in Australia, New Zealand and the US.

**Financial Results**

For the year ended 30 June 2004 the Company recorded a loss on ordinary activities before taxation of £3,057,000, compared with a loss in the corresponding period of £2,945,000, reflecting continuing investment in its clinical trials and development programmes. Cash outflow during the year was £2,885,000 (2003: £1,330,000) and cash balances at the year end were £7.9 million (2003: £10.8 million). The Company continues to be managed on a tight fiscal control basis.

**Corporate**

Encouraged by the safety and efficacy profile showed from the clinical data on Mycograb<sup>□</sup> and the clear near term opportunities available to create significant shareholder value, the Company intends to raise additional equity funds to augment the existing cash balance.

**Prospects**

The Board is greatly encouraged by the recent results from the Mycograb<sup>□</sup> clinical study and during the course of the current financial year the Company will be preparing for the commercial launch of that product. In addition, the Company will be continuing to recruit patients into its phase III trial on Aurograb<sup>®</sup> and further progressing its research and development programme into other therapeutic areas.

**Anthony Martin Ph.D.**  
Chairman  
12 July 2004

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**Profit and loss account**

	<i>Note</i>	<b>Year ended 30 June 2004 £'000</b>	As restated Year ended 30 June 2003 £'000
Administrative expenses (including research and development costs)		<b>(3,428)</b>	(3,415)
<b>Operating loss</b>		<b>(3,428)</b>	(3,415)
Other interest receivable and similar income		<b>371</b>	470
<b>Loss on ordinary activities before taxation</b>		<b>(3,057)</b>	(2,945)
Tax on loss on ordinary activities		<b>143</b>	161
<b>Loss on ordinary activities after taxation</b>		<b>(2,914)</b>	(2,784)
Retained loss for the year		<b>(2,914)</b>	(2,784)
<b>Loss per ordinary share</b>			
Basic and diluted	3	<b>(12.9 pence)</b>	(12.4 pence)

All amounts relate to continuing activities

There are no recognised gains or losses other than the loss attributable to the shareholders of £2,914,000 (2003: a loss of £2,784,000) in the year and therefore no statement of total recognised gains and losses has been presented.

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**Balance sheet**

	<b>As at 30 June 2004</b>	As restated at 30 June 2003
<b>Fixed assets</b>		
Tangible assets	<b>199</b>	160
 <b>Current assets</b>		
Debtors	<b>269</b>	255
Cash at bank and in hand	<b>7,921</b>	10,806
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	<b>8,190</b>	11,061
 <b>Creditors:</b> amounts falling due within one year	<b>(1,671)</b>	(1,637)
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 <b>Net current assets</b>	<b>6,519</b>	9,424
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<b>Total assets less current liabilities</b>	<b>6,718</b>	9,584
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 <b>Capital and reserves</b>		
Called up share capital	<b>5,935</b>	5,911
Share premium account	<b>10,537</b>	10,513
Profit and loss account	<b>(9,753)</b>	(6,839)
Investment in own shares	<b>(1)</b>	(1)
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<b>Equity shareholders' funds</b>	<b>6,718</b>	9,584
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**Cash flow statement**

	<b>Year ended 30 June 2004 £'000</b>	Year ended 30 June 2003 £'000
Operating loss	<b>(3,428)</b>	(3,415)
Depreciation charges	<b>40</b>	29
Share option charges	<b>-</b>	283
Decrease in debtors	<b>54</b>	36
Increase in creditors	<b>34</b>	1,000
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<b>Net cash outflow from operating activities</b>	<b>(3,300)</b>	(2,067)
<b>Returns on investment and servicing of finance</b>		
Interest received	<b>285</b>	564
<b>Taxation</b>		
Taxation repayment received	<b>161</b>	180
<b>Capital expenditure</b>		
Payments to acquire tangible fixed assets	<b>(79)</b>	(16)
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<b>Cash outflow before financing</b>	<b>(2,933)</b>	(1,339)
<b>Financing</b>		
Issue of ordinary share capital	<b>48</b>	9
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<b>Decrease in cash in the year</b>	<b>(2,885)</b>	(1,330)
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**Reconciliation of net cash flow to movement in net funds**

	<b>2004 £'000</b>	2003 £'000
<b>Net funds at the start of the year</b>	<b>10,806</b>	12,136
Decrease in cash in the year	<b>(2,885)</b>	(1,330)
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<b>Net funds at the end of the year</b>	<b>7,921</b>	10,806
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**Reconciliation of movements in shareholders' funds**

	Year ended 30 June 2004 £000	Year ended 30 June 2003 £000
<b>Loss for the financial year</b>	<b>(2,914)</b>	<b>(2,784)</b>
Add back of charge in relation to share related rewards	-	283
New share capital subscribed	<b>48</b>	9
Movement in share premium account	-	6
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<b>Net reduction in shareholders' funds</b>	<b>(2,866)</b>	<b>(2,486)</b>
Opening shareholders' funds (previously reported as £12,071,000 before deducting prior year adjustment of £1,000)	<b>9,584</b>	12,070
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<b>Closing shareholders' funds</b>	<b>6,718</b>	9,584
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**Notes**

**1 Nature of Financial Information**

The financial information set out above does not constitute the Company's statutory accounts for the years ended 30 June 2003 and 30 June 2004 (but is derived from those accounts). Statutory accounts for 2003 have been delivered to the registrar of companies and those for 2004 will be delivered to the registrar of companies following the company's annual general meeting. The auditors have reported on the 2004 accounts: their report was unqualified and did not contain statements under section 237(2) or (3) of the Companies Act 1985.

**2 Basis of preparation**

The accounting policies have been applied consistently in dealing with items which are considered material in relation to the company's financial statements except as noted below.

The company has adopted the provisions of Urgent Issues Task Force (number 38) – Accounting for ESOP trusts for the first time in these financial statements. This has resulted in the investment in own shares being shown as a deduction from shareholders' funds rather than as an investment of the company. A prior year adjustment has been made. A prior year adjustment has also been made to restate the loss per ordinary share to account for the shares held by the Employee Benefit Trust in accordance with FRS 14.

The financial statements have been prepared in accordance with applicable accounting standards and in accordance with the historical cost accounting rules.

**3 Loss per share**

The basic loss per share of 12.9 pence (*30 June 2003: 12.4 pence*) is calculated by reference to the loss for the year of £2,914,000 (*30 June 2003: £2,784,000*) and to a weighted average of 22,504,295 (*30 June 2003: 22,472,660*) ordinary shares in issue during the year.

The weighted average number of shares reflects the subdivision of the ordinary shares of 50p each into two ordinary shares of 25p each on 20 February 2002.

The calculation of the diluted loss per ordinary share is identical to that used for the basic loss per ordinary 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 FRS 14.

**4 Annual Report and Financial statements**

Copies of the Company's Annual Report and financial statements will be sent to shareholders in due course and may be obtained from the registered office at NeuTec Pharma plc, Clinical Sciences Building, Central Manchester Healthcare Trust, Oxford Road, Manchester, M13 9WL. The Annual General Meeting will be held on 16 August 2004 at Broadwalk House, 5 Appold Street, London EC2A 2HA.