

## NeuTec Pharma plc

### Interim Results for the Six Months Ended 31 December 2003

**11 March, 2004 – Manchester, UK:** NeuTec Pharma plc, the biopharmaceutical company targeting drug-resistant infections, today announces its financial results for the six months ended 31 December 2003.

NeuTec is developing a portfolio of antibody-based therapeutic products designed to treat life-threatening infections, particularly hospital-acquired infections such as MRSA, which are increasingly resistant to conventional antibiotics.

#### Results

During the six month period to 31 December 2003, the Company recorded a loss before and after taxation of £1,189,000 (31 December 2002: £977,000). The loss is in line with our expectations and reflects the expansion of the clinical trials programme.

#### Key Points

Mycograb<sup>®</sup>, targeting invasive yeast infections, which can affect virtually any part of the body:

- Completed recruitment into its 160 patient phase II clinical trial in January 2004
- Trial results expected in Q3 2004 following 3 month follow up period
- Positive dialogue with EMEA regarding application for market authorisation

Aurograb<sup>®</sup>, which targets methicillin-resistant *Staphylococcus aureus* (“MRSA”), the hospital ‘superbug’:

- 250 patient pan European phase III clinical trial to start imminently
- Phase IIb showed drug to be well tolerated and demonstrated a profile that supports likely activity against MRSA in man.

Anthony Martin, Chairman, commented:

*“NeuTec continues to make excellent progress with both our lead drugs advancing through the clinic and showing an encouraging safety and efficacy profile to date. We have made significant progress since listing two years ago on one of the lowest cash burns in the UK biotechnology industry. We look forward to publishing the results of the Mycograb trial in Q3 2004 and to commencing our phase III Aurograb trial in the coming weeks.”*

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Further information on NeuTec Pharma plc can be found at [www.neutecpharma.com](http://www.neutecpharma.com).

## **Chairman's Statement**

I am pleased to report further progress in our clinical trials programme during the last six months. The Company has achieved further key targets within the expected timescale and these have been achieved with lower than projected cash outflow. The second half of the financial year will see NeuTec Pharma's strategy focus increasingly upon the commercialisation of our products.

### **Clinical Trials - Mycograb®**

In January 2004 the Company announced the completion of recruitment into its double-blind placebo-controlled phase II clinical trial for assessing the safety and efficacy of its lead product, Mycograb®. Mycograb® has Orphan Drug Status in both the EU and US and targets invasive fungal infections which can affect virtually any part of the body.

The study involved 160 patients at 38 centres in 10 European countries and 3 sites in the US. There is a 3 month follow up on each patient so it is anticipated that trial results will be available in Q3 2004. Earlier discussions with the Scientific Advice Working Group ("SAWG") of the European Medicines Evaluation Agency ("EMA"), indicated that the trial results, if satisfactory, may be used to support an application for market authorization for Mycograb® in combination with amphotericin B for the treatment of invasive candidiasis in immunocompetent intensive care patients.

Invasive Candidiasis, a fungal infection that occurs when *Candida* causes bloodstream infections and then spreads throughout the body, affects approximately 22,000 people per year in the USA, making it the fourth most common blood stream infection among hospitalised patients. The mortality rate can be up to 50% of sufferers.

### **Clinical Trials - Aurograb®**

Aurograb®, which targets MRSA, the hospital "superbug", is progressing well towards recruitment into a double-blind placebo-controlled phase III clinical trial. The study will be carried out in 31 centres in 6 European countries and will involve the recruitment of approximately 250 adult hospitalised patients with deep-seated staphylococcal infections.

The latest trial follows an earlier phase IIb study which was completed in June 2003 and found the drug to be well tolerated and demonstrated a profile that supports likely activity against MRSA in man. Aurograb® 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 in strains with partial or complete resistance to vancomycin or linezolid. The phase III trial will compare the effects of Aurograb® in combination with vancomycin versus vancomycin alone in the treatment of MRSA infection.

Methicillin Resistant *Staphylococcus aureus*, MRSA, is regarded as the hospital 'superbug' by virtue of its ability to spread and cause outbreaks with a high mortality rate of up to 60%. Fatal and non-fatal cases have risen 15-fold in the last decade. Deaths have increased from 51 in 1993 to 800 in 2003 in the UK, and cases from 210 to 5,309. In America, the cost of sepsis, the infection of blood or other tissues by bacteria, is as high as \$50,000 per patient, resulting in an economic burden of nearly \$17 billion per year, where it is the 8<sup>th</sup> leading cause of death. In the UK it is estimated that the NHS spends around £1 billion per annum on hospital-acquired infections including MRSA.

## **Financial Overview**

The loss before taxation for the half year amounted to £1,189,000, compared with a loss in the corresponding period of £977,000. The increase in the loss is principally due to the expansion of the clinical trials programme which accounted for £718,000 (2002: £366,000).

The Company remains well funded with cash balances in excess of £9.4 million and cash outflow continues to be managed very tightly. During the period the cash outflow amounted to £1,385,000, compared with £120,000 in the corresponding period. This movement was in line with our expectations and can largely be attributed to payments upon milestones made to the Clinical Research Organisations who manage the clinical trials programme and to the outsourced manufacturers of the drugs used in the studies.

## **Corporate**

Dr Robert Nolan was appointed to the Board as a Non-Executive Director in October 2003. Dr Nolan has over 30 years of experience in the pharmaceutical industry and has been Director of Global Licensing at AstraZeneca since 1989. This high profile role encompasses many therapeutic areas, including licensing deals in cancer and infection. Prior to his current role, Dr Nolan spent ten years at ICI Pharmaceuticals, working in Natural Products Research, seeking novel anti-bacterial and anti-cancer agents. Rodney Graves resigned as Non-Executive Director in November 2003.

## **Outlook**

We are highly encouraged by recent progress in our clinical trials programme. We have achieved important goals for both of the lead drugs within our portfolio of products to prevent deaths from antibiotic-resistant and hospital-acquired infections. Both drugs address areas of high unmet clinical need and we retain the full global rights to all of our products, the pipeline being supported by a strong patent position. During the second half of the financial year we will be directing more attention to developing our commercialisation strategy.

**Anthony Martin Ph.D**  
Chairman

11 March 2004

## Profit and loss account

	<i>Note</i>	(Unaudited) Six months ended 31 December 2003 £'000	(Unaudited) Six months ended 31 December 2002 £'000	(Audited) Year ended 30 June 2003 £'000
<b>Turnover</b>		-	-	-
Cost of sales		-	-	-
		-----	-----	-----
<b>Gross profit</b>		-	-	-
Research, development and administrative expenses		(1,381)	(1,230)	(3,415)
		-----	-----	-----
<b>Total operating loss</b>		(1,381)	(1,230)	(3,415)
Interest receivable and similar income		192	253	470
		-----	-----	-----
<b>Loss on ordinary activities before taxation</b>		(1,189)	(977)	(2,945)
Taxation on loss on ordinary activities	2	-	-	161
		-----	-----	-----
<b>Loss on ordinary activities after taxation</b>		(1,189)	(977)	(2,784)
Dividends paid and proposed		-	-	-
		-----	-----	-----
<b>Retained loss for the period/year</b>		(1,189)	(977)	(2,784)
		=====	=====	=====
<b>Loss per ordinary share</b>				
- Basic and diluted	3	5.3 pence	4.3 pence	12.4 pence
		=====	=====	=====

The Company's operating loss arises from continuing operations.

The Company has no recognised gains or losses in these periods/years other than those reported above and therefore no statement of total recognised gains and losses has been presented.

## Balance Sheet

	<b>(Unaudited)</b> As at 31 December 2003 £'000	<b>(Unaudited)</b> As at 31 December 2002 £'000	<b>(Audited)</b> As at 30 June 2003 £'000
<b>Fixed assets</b>			
Tangible assets	216	172	160
Investments	1	1	1
	<hr/> 217	<hr/> 173	<hr/> 161
	<hr/>	<hr/>	<hr/>
<b>Current assets</b>			
Debtors	95	190	255
Cash at bank and in hand	9,421	12,016	10,806
	<hr/> 9,516	<hr/> 12,206	<hr/> 11,061
	<hr/>	<hr/>	<hr/>
<b>Creditors:</b> amounts falling due within one year	(1,330)	(1,002)	(1,637)
	<hr/> 8,186	<hr/> 11,204	<hr/> 9,424
<b>Net current assets</b>	<hr/>	<hr/>	<hr/>
	<hr/>	<hr/>	<hr/>
<b>Net assets</b>	<hr/> 8,403	<hr/> 11,377	<hr/> 9,585
	<hr/>	<hr/>	<hr/>
	<hr/>	<hr/>	<hr/>
<b>Capital and reserves</b>			
Called up share capital	5,915	5,906	5,911
Share premium account	10,516	10,503	10,513
Profit and loss account	(8,028)	(5,032)	(6,839)
	<hr/> 8,403	<hr/> 11,377	<hr/> 9,585
<b>Equity shareholders' funds</b>	<hr/>	<hr/>	<hr/>
	<hr/>	<hr/>	<hr/>

## Reconciliation of movements in shareholders' funds

	(Unaudited) Six months ended 31 December 2003 £'000	(Unaudited) Six months ended 31 December 2002 £'000	(Audited) Year ended 30 June 2003 £'000
<b>Loss for the period/year</b>	(1,189)	(977)	(2,784)
Add back of share related charges	-	283	283
Movement in share premium account	3	-	6
New share capital subscribed (net of issue costs)	4	-	9
<b>Net reduction in shareholders' funds</b>	<u>(1,182)</u>	<u>(694)</u>	<u>(2,486)</u>
Opening shareholders' funds	9,585	12,071	12,071
<b>Closing shareholders' funds</b>	<u>8,403</u>	<u>11,377</u>	<u>9,585</u>

## Cash flow statement

		(Unaudited) Six months ended 31 December 2003 £'000	(Unaudited) Six months ended 31 December 2002 £'000	(Audited) Year ended 30 June 2003 £'000
<b>Net cash outflow from operating activities</b>	<i>Note</i> 4	(1,647)	(540)	(2,067)
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<b>Returns on investment and servicing of finance</b>				
Interest received and similar income		169	253	564
<hr/>				
<b>Total returns on investments and servicing of finance</b>		169	253	564
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<b>Taxation received</b>		161	180	180
<hr/>				
<b>Capital expenditure</b>				
Purchase of tangible fixed assets		(75)	(13)	(16)
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<b>Cash outflow before financing</b>		(1,392)	(120)	(1,339)
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<b>Financing</b>				
Issue of ordinary share capital		7	-	9
<hr/>				
		7	-	9
<hr/>				
<b>Decrease in cash in the period/year</b>	5	(1,385)	(120)	(1,330)
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## Notes

### 1 Basis of preparation

The interim financial statements have been prepared on the basis of the accounting policies set out in the Company's last Annual Report and Accounts.

The comparative figures for the financial year ended 30 June 2003 are not the Company's statutory accounts for that financial year. Those accounts have been reported on by the Company's auditors and delivered to the Registrar of Companies. The report of the auditors was unqualified and did not contain a statement under section 237(2) or (3) of the Companies Act 1985.

The interim report for the six months ended 31 December 2003 was approved by the Board on 11 March 2004.

### 2 Taxation

There is no charge for taxation during the current period as the estimated effective rate of tax for the year is nil%.

### 3 Loss per share

	<b>(Unaudited)</b> <b>Six months</b> <b>ended</b> <b>31 December</b> <b>2003</b> <b>Pence</b>	<b>(Unaudited)</b> <b>Six months</b> <b>ended</b> <b>31 December</b> <b>2002</b> <b>Pence</b>	<b>(Audited)</b> <b>Year ended</b> <b>30 June</b> <b>2003</b> <b>Pence</b>
Loss per ordinary share:			
Basic	<b>5.3</b>	<b>4.3</b>	<b>12.4</b>
Diluted	<b>5.3</b>	<b>4.3</b>	<b>12.4</b>

Loss per ordinary share is based on the Company's loss for the financial period of £1,189,000 (31 December 2002: £977,000; 30 June 2003: £2,784,000).

The weighted average number of shares used in the basic calculation is 22,493,156 (31 December 2002: 22,468,396; 30 June 2003: 22,472,660). 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 diluted loss per ordinary share is identical to that used for the basic loss per ordinary share. This is because the exercise of these options would have the effect of reducing the loss per ordinary share and is therefore not dilutive under the terms of FRS 14.

Notes (continued)

4 **Reconciliation of operating loss to net cash outflow from operating activities**

	(Unaudited) Six months ended 31 December 2003 £'000	(Unaudited) Six months ended 31 December 2002 £'000	(Audited) Year ended 30 June 2003 £'000
Total operating loss	(1,381)	(1,230)	(3,415)
Depreciation and amortisation charges	19	14	29
Share option charges	-	283	283
Decrease in debtors	21	34	36
(Decrease)/Increase in creditors	(306)	359	1,000
Net cash outflow from Operating activities	<u>(1,647)</u>	<u>(540)</u>	<u>(2,067)</u>

5 **Reconciliation of net cash flow to movement in net funds**

	(Unaudited) Six months ended 31 December 2003 £'000	(Unaudited) Six months ended 31 December 2002 £'000	(Audited) Year ended 30 June 2003 £'000
Decrease in cash and cash equivalents in the period/year	(1,385)	(120)	(1,330)
Movement in net funds resulting from cash flows	(1,385)	(120)	(1,330)
Net funds at the start of the period/year	<u>10,806</u>	<u>12,136</u>	<u>12,136</u>
Net funds at the end of the period/year	<u>9,421</u>	<u>12,016</u>	<u>10,806</u>

Independent Review Report by KPMG Audit Plc to *NeuTec* Pharma plc

## **Introduction**

We have been engaged by the company to review the financial information set out on pages 3 to 8 and we have read the other information contained in the interim report and considered whether it contains any apparent misstatements or material inconsistencies with the financial information.

This report is made solely to the company in accordance with the terms of our engagement. Our review has been undertaken so that we might state to the company those matters we are required to state to it in this report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the company for our review work, for this report, or for the conclusions we have reached.

## **Directors' responsibilities**

The interim report, including the financial information contained therein, is the responsibility of, and has been approved by, the directors.

## **Review work performed**

We conducted our review having regard to the guidance contained in Bulletin 1999/4: Review of interim financial information issued by the Auditing Practices Board. A review consists principally of making enquiries of management and applying analytical procedures to the financial information and underlying financial data and, based thereon, assessing whether the accounting policies and presentation have been consistently applied unless otherwise disclosed. A review is substantially less in scope than an audit performed in accordance with Auditing Standards and therefore provides a lower level of assurance than an audit. Accordingly we do not express an audit opinion on the financial information.

## **Review conclusion**

On the basis of our review we are not aware of any material modifications that should be made to the financial information as presented for the six months ended 31 December 2003.

*KPMG Audit Plc*  
Chartered Accountants  
Manchester  
11 March 2004