

NeuTec Pharma plc
Interim Results for the Six Months Ended 31 December 2004

14 March, 2005 – Manchester, UK: NeuTec Pharma plc, the biopharmaceutical company targeting drug-resistant infections, today announces its financial results for the six months ended 31 December 2004.

NeuTec is developing a portfolio of antibody-based therapeutic products designed to treat life-threatening infections. The first of these, Mycograb[®], has successfully finished a Confirmatory Study in the treatment of disseminated candidiasis. The application process for Market Authorisation in Europe has commenced.

Financial Results

During the six month period to 31 December 2004, the Company recorded a loss before taxation of £1,643,000 (31 December 2003: £1,189,000). The increase in the loss reflects the commencement of commercial scale manufacturing of the lead product, Mycograb[®]. The cash balance at the period end was £30,403,000, an increase of £20,982,000 since 31 December 2003, principally due to the receipt of £24,543,000 (net of issue costs) resulting from a successful Placing and Open Offer in July 2004.

Key Points

Mycograb[®], targeting invasive yeast infections, which can affect almost any part of the body:

- Reported the successful completion of a Confirmatory trial in July 2004
- Convincing statistical significance reported for both primary and secondary endpoints
- Significant reduction in *Candida*-attributable mortality
- Process of application for market authorisation in Europe commenced with delivery of the Common Technical Document to EMEA
- Progress to date consistent with market launch in 2006

Other Mycograb[®] developments:

- Commercial scale manufacturing contracts signed with, and technology transfer completed to, second larger scale CMO
- Contracts signed for future clinical studies in both *Cryptococcus neoformans* (in US, South America and South Africa) and in Carcinoma of the breast (Europe)
- Programme underway for presenting at International Conferences and Congresses
- Key European Countries identified for product launch pending market approval
- Appointment of Mr Alan Cooke as Head of Product Development
- Programme for a Named Patient Supply instigated

Aurograb[®], which targets methicillin-resistant *Staphylococcus aureus* (“MRSA”), the hospital ‘superbug’:

- Phase III clinical trial progressing with completion of patient enrolment expected in 2005

Intellectual Property

- Continued strengthening of IP position via filing and granting of new patents

Anthony Martin, Chairman, commented:

“NeuTec continues to make excellent progress in transforming the Company into a successful biopharmaceutical business. Mycograb[®] has clearly demonstrated an impressive safety and efficacy profile and we remain confident of the drug’s commercial prospects. The Company is now well funded and continues to make good progress with a low cash burn. Our phase III Aurograb trial for MRSA is progressing on schedule and we expect to complete recruitment in 2005.”

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Further information on *NeuTec Pharma plc* can be found at www.neutecpharma.com.

Chairman's Statement

Substantial progress has been made in the first half of the financial year. The Company successfully raised £24.5 million in August 2004. We have moved our lead product further towards commercialisation and have secured an additional contract manufacturer as well as strengthened our management team. We have also made a number of advancements in other parts of the business through our clinical trials programme.

Mycograb®

Mycograb®, the Company's lead product, is based on a naturally-occurring human antibody response against hsp90, which helps the body defend itself against life threatening fungal infections. Invasive candidiasis, a fungal infection that occurs when *Candida* causes deep-seated infections and then spreads throughout the body, is the fourth most common blood stream infection among hospitalised patients. The mortality rate due to this infection has been reported as 10-19% on existing therapies.

- Clinical Trials

In July 2004 the Company reported the successful completion of a multi-national, double-blind, placebo-controlled trial to combat life-threatening fungal infection due to various species of the yeast *Candida*. The Confirmatory study involved 139 patients at 26 centres in 10 European countries and 2 sites in the US and demonstrated convincing statistical significance ($P < 0.001$) both for the primary composite endpoint (clinical and culture-confirmed resolution of infection by day 10) and in separate evaluations of the two components of the combined endpoint.

A second clinically important endpoint used was *Candida*-attributable mortality at the four week follow-up visit (Day 33), and again there was a statistically significant difference between the treatment arms ($P = 0.025$). As an additional culture-based endpoint, speed of culture-confirmed resolution of the infection was examined and this was over twice as fast in the Mycograb-treated group compared with placebo.

As a result of the above findings, *NeuTec* announced its intention to apply for market authorisation in Europe for Mycograb® in the treatment of invasive candidiasis in combination with amphotericin-B. *NeuTec* has begun the process of applying for market authorisation in Europe by delivering a Common Technical Document ("CTD") to the European Medicines Evaluation Agency ("EMA"). Progress to date is consistent with a timetable for the market launch of Mycograb® in 2006.

- Programme for Compassionate Use

The Company has instigated a limited Named Patient Supply of Mycograb® using a UK based registered and licensed drug distributor who will provide initial distribution into the UK and Europe.

- Manufacturing

In November 2004 *NeuTec* signed a contract with CMC Biopharmaceuticals (“CMC”), a Contract Manufacturing Organisation based in Denmark specialising in *E.coli* fermentation. CMC are a full service provider who will provide process development, manufacturing, analytical and quality control services to *NeuTec*. The technology transfer process has completed successfully and scale up of production into a larger scale fermentation suite is currently taking place.

Additionally, a contract was signed last month with BioReliance Manufacturing GmbH, our existing manufacturer, for the production of additional stocks of Mycograb[®] for use in future clinical trials or for commercial sale.

- Commercial Programme

Mr Alan Cooke was appointed as Head of Product Development in October 2004. Previously, Alan spent 10 years involved in initiating the European sales of the first liposomal amphotericin-B in Europe.

NeuTec's market analysis has identified the key European centres for early product launch pending market approval. The Company believes its strategy of directly selling the product in Europe will maximise shareholder value from this product.

The Company is preparing to present at a series of Industry Meetings and Congresses in 2005. Members of the Mycograb[®] Study Group will be presenting on behalf of *NeuTec* at the International Society of Intensive Care and Emergency Medicine (“ISICEM”) Conference in Brussels at the end of March and at the European Congress of Clinical Microbiology and Infectious Diseases (“ECCMID”) in Copenhagen in April 2005.

- New indication: Cryptococcal Meningitis

A contract was signed in December 2004 with a division of Ingenix Pharmaceutical Services (UK) Limited for a phase III randomized, double-blind, and placebo controlled study to evaluate the safety and efficacy of Mycograb[®] to be employed as an add-on therapy to recommended induction treatment of cryptococcal meningitis. This study will take place in US and South America and a further study will commence in AIDS patients in South Africa. All of these trials are dependent upon obtaining regulatory and ethical approval.

The results from these studies will broaden the patient database, with respect to safety, to a non-intensive care unit-based patient population and at the same time explore an additional indication for the drug in combination with conventional rather than liposomal amphotericin B.

Cryptococcus neoformans has a high mortality rate: in the US, for example, mortality from this infection has recently been reported as varying from 11% to 21%. *In vitro* testing has demonstrated synergy between amphotericin-B and Mycograb[®] against this fungal infection. The Company recently published a paper in Diagnostic Microbiology and Infectious Disease 51 (2005) entitled “Evaluation of Mycograb[®], amphotericin-B, caspofungin, and fluconazole in combination against *Cryptococcus neoformans* by checkerboard and time-kill methodologies.”

- New indication: Cancer

A contract was signed in February 2005 with Pharm-Olam International Limited for a pharmacokinetic open-label study evaluating the safety and efficacy of Mycograb[®] administered intravenously in combination with a Taxotere (docetaxel). The study will involve approximately 20 patients with advanced carcinoma of the breast (phase Ib) and will take place in two European countries pending regulatory and ethical approval.

Aurograb[®]

Aurograb[®], which targets MRSA, is progressing through a double-blind placebo-controlled phase III clinical trial. The study commenced in May 2004 and involves the recruitment of 150 evaluable hospitalised patients with deep-seated staphylococcal infections. To date 74 patients have been recruited in 19 centres in 5 European countries. Following recent regulatory approval, a number of French centres are about to be initiated, increasing the number of active countries in the trial to six. There is a high incidence of MRSA in France and given current recruitment rates in the existing active centres we anticipate the completion of patient enrolment in 2005.

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. Recently, the UK’s Office for National Statistics figures revealed the number of deaths linked to MRSA doubled in the four years between 1999 and 2003, to 955. From April to September 2004, 3,519 NHS patients were infected with MRSA. It is estimated that the NHS spends around £1 billion per annum on hospital-acquired infections including MRSA.

Financial Results

The loss before taxation for the half year amounted to £1,643,000, compared with a loss in the corresponding period of £1,189,000. The increase in the loss is principally due to the commencement of commercial scale manufacturing of Mycograb[®], which accounted for £696,000 (2003: £nil).

Encouraged by the clinical data on Mycograb[®] and the near term opportunities available to create significant shareholder value, *NeuTec* successfully raised additional equity funds of £24.5 million (net of expenses) through a Placing and Open Offer in July 2004. As a result, the Company is well funded with cash balances at 31 December 2004 amounting to £30.4 million. Cash outflow continues to be managed very tightly and during the period under review the cash outflow (excluding the effect of the equity fund raising) amounted to £2,060,000, compared with £1,392,000 in the corresponding period. This movement was in line with our expectations.

Intellectual Property

During the period under review *NeuTec* has continued to strengthen its intellectual property rights portfolio. For example, the first patent has been granted in Europe on FABTEC[®], the Company's proprietary technology platform, and further patents have been granted against the hsp90 homologue in bacteria.

Outlook

We are making good progress in transforming *NeuTec* Pharma into a successful bio-pharmaceutical business in a specialist niche area using antibody based drugs. In the short to medium term we are seeking to increase the value of Mycograb[®] by demonstrating its clinical efficacy in other medical conditions whilst preparing for its market launch in 2006 in Europe for the treatment of invasive candidiasis. Additionally, we are working to complete the phase III study for Aurograb[®] in MRSA. With a pipeline of promising drugs and a healthy balance sheet, we look to the future with confidence.

Anthony Martin Ph.D
Chairman

14 March 2005

Profit and loss account

		(Unaudited) Six months ended 31 December 2004 £'000	(Unaudited) Six months ended 31 December 2003 £'000	(Audited) Year ended 30 June 2004 £'000
Turnover		-	-	-
Cost of sales		-	-	-
Gross profit		<u>-</u>	<u>-</u>	<u>-</u>
Research, development and administrative expenses		(2,271)	(1,381)	(3,428)
Total operating loss		<u>(2,271)</u>	<u>(1,381)</u>	<u>(3,428)</u>
Interest receivable and similar income		629	192	371
Loss on ordinary activities before taxation		<u>(1,643)</u>	<u>(1,189)</u>	<u>(3,057)</u>
Taxation on loss on ordinary activities	2	325	-	143
Loss on ordinary activities after taxation		<u>(1,318)</u>	<u>(1,189)</u>	<u>(2,914)</u>
Dividends paid and proposed		-	-	-
Retained loss for the period/year		<u>(1,318)</u>	<u>(1,189)</u>	<u>(2,914)</u>
Loss per ordinary share		<u>5.0 pence</u>	<u>5.3 pence</u>	<u>12.9 pence</u>
- Basic and diluted	3			

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

	(Unaudited) As at 31 December 2004 £'000	(Unaudited) As at 31 December 2003 £'000	(Audited) As at 30 June 2004 £'000
Fixed assets			
Tangible assets	324	216	199
	<hr/>	<hr/>	<hr/>
Current assets			
Debtors	610	95	269
Cash at bank and in hand	30,403	9,421	7,921
	<hr/>	<hr/>	<hr/>
	31,013	9,516	8,190
Creditors: amounts falling due within one year	(1,394)	(1,330)	(1,671)
	<hr/>	<hr/>	<hr/>
Net current assets	29,619	8,186	6,519
	<hr/>	<hr/>	<hr/>
Net assets	29,943	8,402	6,718
	<hr/> <hr/>	<hr/> <hr/>	<hr/> <hr/>
Capital and reserves			
Called up share capital	7,254	5,915	5,935
Share premium account	33,761	10,516	10,537
Profit and loss account	(11,071)	(8,028)	(9,753)
Investment in own shares	(1)	(1)	(1)
	<hr/>	<hr/>	<hr/>
Equity shareholders' funds	29,943	8,402	6,718
	<hr/> <hr/>	<hr/> <hr/>	<hr/> <hr/>

Reconciliation of movements in shareholders' funds

	(Unaudited) Six months ended 31 December 2004 £'000	(Unaudited) Six months ended 31 December 2003 £'000	(Audited) Year ended 30 June 2004 £'000
Loss for the period/year	(1,318)	(1,189)	(2,914)
Movement in share premium account	23,224	3	-
New share capital subscribed	1,319	4	48
Net increase/(reduction) in shareholders' funds	<u>23,225</u>	<u>(1,182)</u>	<u>(2,866)</u>
Opening shareholders' funds	6,718	9,585	9,584
Closing shareholders' funds	<u>29,943</u>	<u>8,403</u>	<u>6,718</u>

Cash flow statement

		(Unaudited) Six months ended 31 December 2004 £'000	(Unaudited) Six months ended 31 December 2003 £'000	(Audited) Year ended 30 June 2004 £'000
Net cash outflow from operating activities	4	(2,595)	(1,647)	(3,300)
Returns on investment and servicing of finance				
Interest received and similar income		542	169	285
Total returns on investments and servicing of finance		542	169	285
Taxation received		143	161	161
Capital expenditure				
Purchase of tangible fixed assets		(151)	(75)	(79)
Cash outflow before financing		(2,061)	(1,392)	(2,933)
Financing				
Issue of ordinary share capital (net of issue costs)		24,543	7	48
		24,543	7	48
Increase/(Decrease) in cash in the period/year	5	22,482	(1,385)	(2,885)

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 2004 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 2004 was approved by the Board on 14 March 2005.

2 **Taxation**

There is no charge for taxation during the current period as the estimated effective rate of tax for the year is nil%. A taxation credit of £325,000 has been recognised in the profit and loss account for the six months ended 31 December 2004 in respect of the payment of Research and Tax Credits from the Inland Revenue which was received in January 2005.

3 **Loss per share**

	(Unaudited) Six months ended 31 December 2004 Pence	(Unaudited) Six months ended 31 December 2003 Pence	(Audited) Year ended 30 June 2004 Pence
Loss per ordinary share:			
Basic	5.0	5.3	12.9
Diluted	5.0	5.3	12.9
	=====	=====	=====

Loss per ordinary share is based on the Company's loss for the financial period of £1,318,000 (*31 December 2003: £1,189,000; 30 June 2004: £2,914,000*).

The weighted average number of shares used in the basic calculation is 26,540,325 (*31 December 2003: 22,493,156 ; 30 June 2004: 22,504,295*). The weighted average number of shares reflects the allotment of new equity on 16 August 2004 following the Placing and Open Offer dated 23 July 2004.

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 2004 £'000	(Unaudited) Six months ended 31 December 2003 £'000	(Audited) Year ended 30 June 2004 £'000
Total operating loss	(2,271)	(1,381)	(3,428)
Depreciation and amortisation charges	26	19	40
(Increase)/Decrease in debtors	(72)	21	54
(Decrease)/Increase in creditors	(278)	(306)	34
Net cash outflow from Operating activities	<u>(2,595)</u>	<u>(1,647)</u>	<u>(3,300)</u>

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

	(Unaudited) Six months ended 31 December 2004 £'000	(Unaudited) Six months ended 31 December 2003 £'000	(Audited) Year ended 30 June 2004 £'000
Increase/(Decrease) in cash and cash equivalents in the period/year	22,482	(1,385)	(2,885)
Movement in net funds resulting from cash flows	<u>22,482</u>	<u>(1,385)</u>	<u>(2,885)</u>
Net funds at the start of the period/year	7,921	10,806	10,806
Net funds at the end of the period/year	<u>30,403</u>	<u>9,421</u>	<u>7,921</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 5 to 10 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 2004.

KPMG Audit Plc
Chartered Accountants
Manchester
14 March 2005