

NeuTec Pharma plc
Preliminary Statement
Year Ended 30 June 2005

Preliminary Results for the Year Ended 30 June 2005

Monday 10 October 2005

NeuTec Pharma plc, the biopharmaceutical company exploiting the value of combination therapy in drug resistant infection and cancer, today announces its preliminary results for the year ended 30 June 2005.

NeuTec has taken genetically recombinant antibody (“grab”) based therapeutic products directed towards life threatening infections to a late stage of clinical development. These grabs target hospital-acquired infections such as invasive candidiasis and MRSA, where there is a persistent failure to respond to conventional single drug therapy. Currently there is a validated application for market authorisation for the lead product Mycograb[®], an orphan drug, which has been submitted to the EMEA.

For the year ended 30 June 2005 the Company recorded a loss on ordinary activities before taxation of £3,922,000, compared with a loss in the corresponding period of £3,057,000. The increase in the loss is in line with expectations and is largely due to the increased expense in making an application to the European Regulator, in rolling out a commercialisation programme and in the initiation of new clinical trials (in advanced breast cancer and cryptococcal meningitis). Net cash inflow during the year was £20,652,000 (2004: outflow of £2,885,000) and cash balances at the year end were £28.6 million (2004: £7.9 million). The increase in cash balances reflects the receipt of £24,543,000 in August 2004, being the net proceeds from the successful Placing and Open Offer.

Key Points

- Mycograb[®], which binds to heat shock protein 90 (“hsp90”):
 - application has been made to the EMEA for market authorisation in the treatment of invasive candidiasis. The Common Technical Document has been validated and a list of questions has been received from the Regulator. The Company is currently preparing its response to these questions and is intending to reply within the expected timetable;
 - thirteen patients have been recruited in a multi-centre phase Ib open-label study to evaluate the safety and efficacy of Mycograb[®] administered in combination with Docetaxel in metastatic or recurrent breast cancer patients; and
 - a successful application to the FDA for an Investigational New Drug (“IND”) has been achieved for a phase III study to assess the efficacy and safety of Mycograb[®] as adjunctive therapy for cryptococcal meningitis in patients with AIDS.
- Commercialisation programme for the sale of Mycograb[®] in Europe:
 - appointment of managerial level for European sales team;
 - initiation of a compassionate use programme;
 - manufacturing strategy in place to pursue regulatory approval and reduce cost of goods;
 - leases entered into for European sales hub and new laboratory in the Manchester Science Park; and
 - marketing strategy for conference and publication programmes to maximise product visibility.
- Aurograb[®], which targets methicillin resistant *Staphylococcus aureus* (“MRSA”), the hospital ‘superbug’:
 - 121 patients have been enrolled in the phase III multi-centre, double-blind, placebo-controlled clinical trial. The study involves the recruitment of 150 evaluable patients with deep-seated staphylococcal infections.

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Summary

Anthony Martin, Chairman, commented:

“NeuTec Pharma has continued to explore the potential clinical indications for its lead product, Mycograb®: a validated application to the EMEA was made in March 2005 for the treatment of invasive candidiasis, a successful IND application has been made for the treatment of cryptococcal meningitis and recruitment is progressing well in a phase Ib breast cancer study. Additionally, our phase III clinical study using Aurograb® in MRSA patients is nearing completion of patient recruitment.”

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Chairman's Statement and Operating Review

In July 2004 I was pleased to announce the successful achievement of clinical end points from a multinational confirmatory trial involving our lead product, the orphan drug Mycograb[®], in patients with invasive candidiasis. The data from that trial has been used as a basis for an application for market authorisation in Europe and additional trials have recently commenced using Mycograb[®] to broaden its clinical indications and realise the full value of the drug. There have been a number of other notable achievements during the year under review which are elaborated on below.

Mycograb[®]

Mycograb[®] is a genetically recombinant antibody ("grab") designed for the treatment of invasive or deep-seated candidiasis, which binds to the immunodominant yeast antigen, heat shock protein 90 ("hsp90"). It was originally identified by clinical observations correlating a rising antibody response to hsp90 in surviving patients. Mycograb[®] has intrinsic antifungal activity and demonstrates synergy in combination with a number of other drugs in both *in vitro* and *in vivo* studies.

i) Invasive Candidiasis

The confirmatory study involved 139 patients in 10 European countries and the USA, approximately half of whom received Mycograb[®] plus liposomal amphotericin B (the "test group") and half placebo plus liposomal amphotericin B (the "placebo group"). Amphotericin B is the drug of choice for the treatment of deep-seated candidiasis, but mortality is still as high as 38%.

The primary test of efficacy was based on comparison of the frequency with which patients in the test group showed a complete clinical and mycological response by Day 10 compared to frequency in the placebo group. This showed a highly statistically significant difference (P value < 0.001) between the two groups; those receiving Mycograb[®] showing a complete overall (clinical and mycological) response in 84% of cases compared to 48% in the placebo-treated group. The frequency of deaths due to the candidal infection under treatment was as high as 18% in the placebo group but fell to 4% in the group receiving Mycograb[®], this difference being statistically significant (P value < 0.025).

As a further, laboratory-based test of efficacy, the speed with which culture-confirmed eradication of the fungus was achieved was compared between the two groups. The rate of culture-confirmed eradication of the infection showed a highly statistically significant difference between the two groups (P value < 0.001), the median time to last positive culture being 3 days for the test group, compared to 23 days for the placebo group (Kaplan-Meier).

A candidaemia sub-group analysis of the most severely ill patients with positive blood cultures has been carried out. The number of such patients in the test group with negative cultures and clinical response at day 10 was 30 out of 34 (88%) compared with 15 out of 33 (45%) in the placebo group, this difference being highly statistically significant (P value < 0.0002). This further confirms the activity of the drug.

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An application for market authorisation was made to the European Medicines Evaluation Agency (“EMA”) in March 2005 through delivery and validation of the Common Technical Document. As is customary with such an application two rapporteurs were appointed by the EMA and questions were issued to NeuTec at Day 120. The Company is in the process of replying to these questions, the time limit for this response being six months from the date of issue.

Our response to the Regulator’s questions includes an additional voluntary phase I pharmacokinetic study in healthy volunteers to further characterise the pharmacokinetics and safety profile of the drug. Early recruitment identified an individual who developed lumbar pain, with associated vomiting, after administration of Mycograb® and the reaction was more severe than expected. The patient made a full recovery having taken Codeine, though the Company felt it proper to report the matter to the appropriate regulatory and ethical bodies. A similar, but less severe, reaction was seen in two patients given the full dose of Mycograb® in the confirmatory study. We do not believe this event compromises our ability to get the drug approved and it should be stressed that Mycograb® addresses serious life-threatening illnesses. In all the affected patients the issue resolved with no sequelae.

ii) Carcinoma of the Breast

Hsp90 has been identified as a tumour marker which appears on the outside of certain cancer cells (as with fungi) and is needed for cancer cell survival. The growth of cancer cells is particularly sensitive to the effects of hsp90’s inhibition and this anti-cancer activity has been seen in a series of *in vitro* studies looking at the killing of human cancer cell lines. Dose-limiting toxicity, however, is a major hurdle in the development of chemical hsp90 inhibitors. Mycograb® differs from all other hsp90 inhibitors in having a unique site of action which is not dependent on nucleotide displacement.

In September 2005 NeuTec commenced a phase Ib, pharmacokinetic, multi-centre, open label study to evaluate the safety and efficacy of Mycograb® administered in combination with Docetaxel in metastatic or recurrent breast cancer patients. The study is taking place in three centres based in Serbia and Poland and will involve approximately 20 patients who may have received prior cytotoxic treatment as adjuvant therapy and have a measurable lesion. Patients will be administered with six cycles of treatment, three weeks apart. Thirteen patients have now been recruited into the study whose primary objective is to observe the safety and tolerability of Mycograb® administered in combination with current gold standard therapy. The secondary objective of the study is to monitor the response rate of the target tumours and overall survival and progression-free survival through 7 months post treatment.

iii) Cryptococcus neoformans

Cryptococcus neoformans (“*C. neoformans*”) is one of the most common central nervous system pathogens worldwide and this is a direct consequence of the AIDS epidemic. Globally, it is estimated that 25-30% of persons with AIDS will die as a result of cryptococcal meningitis. Progress in antifungal drug treatment for cryptococcal meningitis has been slow and although amphotericin B was introduced in the late 1950s, it remains the cornerstone of therapy. *In vitro* data has confirmed activity and synergy with Mycograb® and amphotericin B and 5-flucytosine against *C. neoformans*.

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NeuTec has recently been successful in an Investigational New Drug (“IND”) application to the US Food and Drugs Agency (“FDA”) and will shortly be commencing a multi-centre, double-blind, placebo-controlled phase III study to assess the efficacy and safety of Mycograb® as adjunctive therapy for cryptococcal meningitis in patients with AIDS. The trial will take place in the US as well as South Africa and South America.

Aurograb®

Aurograb® targets methicillin resistant *Staphylococcus aureus* (“MRSA”), the hospital ‘superbug’. A phase III multi-centre, double-blind, placebo-controlled study was commenced in May 2004 to determine the safety and efficacy of Aurograb® in patients with deep-seated staphylococcal infections. The study is taking place in six European countries and involves the recruitment of 150 evaluable hospitalised patients. Aurograb® is administered intravenously for up to seven days in combination with vancomycin, the gold standard therapy for deep-seated staphylococcal infections.

Patient recruitment has been constant and we remain confident that patient recruitment will be completed by the calendar year end, or shortly thereafter. Following a three-month last patient close-out and the confirmation of the clinical database, we expect to announce trial results towards the end of the current financial year.

Commercial Programme

Sales strategy. A Head of Product Development was appointed almost a year ago and a small team of regional sales managers was appointed in July 2005, with each member of the team possessing many years of hospital-based antifungal sales experience. It remains the Company’s strategy to further develop this function in anticipation of the roll-out of a European-wide sales plan in 2006 for Mycograb® focusing on five key high value countries and country groupings. Distribution and marketing agreements will be signed with local organisations in smaller jurisdictions, within and outside the European Union.

Named patient programme. A compassionate use programme was instigated early in 2005. A small number of patients have benefited from inclusion within this programme and it is planned to focus additional efforts in this area towards the calendar year end.

Manufacturing. Contracts for the manufacture of Mycograb® were completed with two contract manufacturing organisations (“CMO’s”) during the year. The application for market authorisation in Europe was supported by the data produced over the last five years, during various production batches, by the Company’s original CMO, BioReliance GmbH. A supplementary application for the use of supplies from a second manufacturer will be made in due course. A key goal going forward will be to significantly reduce the cost of goods.

New premises. Leases have been signed in recent months on three units in the Manchester Science Park. One unit will act as the European sales hub and the other units are presently being converted with the intention of becoming a GLP laboratory facility.

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Conferences/Publications. The Company has attended and presented at a number of industry conferences during the year. These included the European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) and the International Symposium on Intensive Care and Emergency Medicine (ISICEM) 2005 conferences. A worldwide programme has been prepared to ensure product visibility at the major 2005/6 conferences and congresses. A programme for the publication of trial results has been prepared to gain maximum publicity at the appropriate stages of the Company's drug development and commercial plans.

Intellectual Property

The Company has continued to strengthen its Intellectual Property portfolio. Since March 2005, for example, three new patents have been granted in the USA, New Zealand and Europe and a further four new International and European patent applications have been filed against cancer, *Clostridium difficile* and fungal infections.

Fund raising and Financial Results

In July 2004 *NeuTec* raised £24,543,000 (net of issue costs) from a successful Placing and Open Offer. This cash inflow has provided the Company with a strong balance sheet to support future clinical trials and commercialisation plans.

For the year ended 30 June 2005 the Company recorded a loss on ordinary activities before taxation of £3,922,000, compared with a loss in the corresponding period of £3,057,000, reflecting continuing investment in its clinical trials, commercial and R&D programmes. Net cash inflow during the year was £20,652,000 (2004: *outflow of £2,885,000*) and cash balances at the year end were £28.6 million (2004: *£7.9 million*). The Company continues to be managed on a tight fiscal control basis.

Prospects

NeuTec Pharma is a well financed biopharmaceutical company with promising late stage compounds addressing several significant and life-threatening indications. During the year we have expanded the potential clinical indications for our lead product, Mycograb®: a validated application has been made to the EMEA for the treatment of invasive candidiasis, a successful IND application has been made for the treatment of cryptococcal meningitis and recruitment is progressing well in a phase Ib breast cancer study. Additionally, our phase III study using Aurograb® in MRSA patients is nearing completion of patient recruitment. Having laid the foundation for the commercial realisation of Mycograb®, we look to the future with continued confidence.

Anthony Martin Ph.D.

Chairman

10 October 2005

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Profit and loss account

	<i>Note</i>	Year ended 30 June 2005 £'000	Year ended 30 June 2004 £'000
Administrative expenses (including research and development costs)		(5,287)	(3,428)
Operating loss		<u>(5,287)</u>	<u>(3,428)</u>
Other interest receivable and similar income		1,365	371
Loss on ordinary activities before taxation		<u>(3,922)</u>	<u>(3,057)</u>
Tax on loss on ordinary activities		325	143
Loss on ordinary activities after taxation		<u>(3,597)</u>	<u>(2,914)</u>
Retained loss for the year		<u>(3,597)</u>	<u>(2,914)</u>
Loss per ordinary share			
Basic and diluted	2	<u>(13.2 pence)</u>	<u>(12.9 pence)</u>

All amounts relate to continuing activities.

There are no recognised gains or losses other than the loss attributable to the shareholders of £3,597,000 (2004: a loss of £2,914,000) in the year and therefore no statement of total recognised gains and losses has been presented.

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Balance sheet

	As at 30 June 2005 £'000	As at 30 June 2004 £'000
Fixed assets		
Tangible assets	308	199
Current assets		
Debtors	592	269
Cash at bank and in hand	28,573	7,921
	<u>29,165</u>	<u>8,190</u>
Creditors: amounts falling due within one year	(1,789)	(1,671)
	<u>27,376</u>	<u>6,519</u>
Net current assets		
	<u>27,684</u>	<u>6,718</u>
Total assets less current liabilities		
	<u>27,684</u>	<u>6,718</u>
Capital and reserves		
Called up share capital	7,265	5,935
Share premium account	33,770	10,537
Profit and loss account	(13,350)	(9,753)
Investment in own shares	(1)	(1)
	<u>27,684</u>	<u>6,718</u>
Equity shareholders' funds		
	<u>27,684</u>	<u>6,718</u>

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Cash flow statement

	Year ended 30 June 2005 £'000	Year ended 30 June 2004 £'000
Operating loss	(5,287)	(3,428)
Depreciation charges	57	40
(Increase)/Decrease in debtors	(79)	54
Increase in creditors	118	34
	<hr/>	<hr/>
Net cash outflow from operating activities	(5,191)	(3,300)
Returns on investment and servicing of finance		
Interest received	978	285
Taxation		
Taxation repayment received	468	161
Capital expenditure		
Payments to acquire tangible fixed assets	(166)	(79)
	<hr/>	<hr/>
Cash outflow before financing	(3,911)	(2,933)
Financing		
Issue of ordinary share capital	25,871	48
Expenses paid in connection with share issue	(1,308)	-
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Increase/(Decrease) in cash in the year	20,652	(2,885)
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Reconciliation of net cash flow to movement in net funds

	2005 £'000	2004 £'000
Net funds at the start of the year	7,921	10,806
Increase/(Decrease) in cash in the year	20,652	(2,885)
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Net funds at the end of the year	28,573	7,921
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Reconciliation of movements in shareholders' funds

	Year ended 30 June 2005 £000	Year ended 30 June 2004 £000
Loss for the financial year	(3,597)	(2,914)
New share capital subscribed (net of issue costs)	24,563	48
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Net addition to/(reduction in) shareholders' funds	20,966	(2,866)
Opening shareholders' funds	6,718	9,584
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Closing shareholders' funds	27,684	6,718
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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 2004 and 30 June 2005 (but is derived from those accounts). Statutory accounts for 2004 have been delivered to the registrar of companies and those for 2005 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 Loss per share

The basic loss per share of 13.2 pence (*30 June 2004: 12.9 pence*) is calculated by reference to the loss for the year of £3,597,000 (*30 June 2004: £2,914,000*) and to a weighted average of 27,149,266 (*30 June 2004: 22,504,295*) ordinary shares in issue during the year.

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.

3 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 at 12 noon on 11 November 2005 at the Royal College of Pathologists, 2 Carlton House Terrace, London SW1Y 5AF.