

NeuTec Pharma plc

NeuTec Pharma plc Interim Results

27 March, 2006 – Manchester, UK: NeuTec Pharma plc, the biopharmaceutical company targeting drug-resistant infections, today announces its financial results for the six months ended 31 December 2005.

Financial Results

During the period to 31 December 2005, the Company recorded a loss before taxation of £2,934,000 (31 December 2004: £1,643,000), reflecting one-off costs associated with Mycograb® for regulatory support and other items connected with its application for market approval and additional manufacturing costs. Cash outflow during the period was £2,589,000 (2004: outflow of £2,061,000) and cash balances at the period end were £26.0 million (31 December 2004: £30.4 million).

Key Points

Mycograb® progress:

- Mycograb®, which binds to the immunodominant antigen, heat shock protein 90 (“hsp90”), was the subject of a Common Technical Document (“CTD”) submitted to the EMEA in March 2005. A full dataset has recently been submitted in response to the EMEA’s detailed dossier of questions received at day 120 in the process. A number of GCP and GMP inspections were carried out by the Regulator and additional toxicological and pharmacokinetic data was prepared by the Company, including a phase I study successfully carried out in healthy volunteers. The Company is awaiting a response from the EMEA. Progress to date remains consistent with a market launch by the end of 2006;
- Patient recruitment was completed in a phase Ib study to evaluate the safety and efficacy of Mycograb® in combination with Docetaxel in metastatic or recurrent breast cancer patients;
- Regulatory and ethical approval has been obtained for a double-blind, placebo-controlled, multi-centre phase III study using Mycograb® in combination with generic amphotericin B and 5-flucytosine against *Cryptococcus neoformans*. Hospitals in the US, South Africa and South America have agreed to take part in the study which will commence in the coming weeks.

Aurograb®, which targets methicillin-resistant *Staphylococcus aureus* (“MRSA”), the hospital ‘superbug’ has recruited 150 patients in its European phase III clinical trial. The completion of patient enrolment is expected in the near future.

Anthony Martin, Chairman, commented:

“As highlighted earlier this month by the Task Force set up by the Infectious Diseases Society of America, there is a desperate need for new drugs to treat life-threatening infections. NeuTec is

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aggressively trying to fill this void by producing a new class of antibody-based therapeutics which can be taken in combination therapy. Bad bugs need clever drugs.”

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

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Chairman's Statement

Further progress has been achieved in a number of key areas in the six months since the Company last presented an overview of developments. In particular, Mycograb[®] has reached an advanced stage in its application to the European regulator for market authorisation in the treatment of invasive candidiasis and is progressing well in clinical trials to assess its safety and efficacy in combination therapy targeted against advanced carcinoma of the breast.

Mycograb[®]

The Company's lead product, Mycograb[®], is a genetically recombinant antibody ("grab") which binds to the immunodominant antigen, heat shock protein 90 ("hsp90"). The drug is based on a naturally-occurring human antibody response against hsp90, which facilitates the body in defending itself against life threatening infections. Hsp90 was recently highlighted in a leading journal as enabling pathogenic fungi to rapidly develop drug resistance whereas exposure to an hsp90 inhibitor, such as Mycograb[®], can enhance the effect of other anti-fungal agents and preclude or delay the onset of drug resistance or even reverse drug resistance. Also, earlier this month, Mycograb[®] was described as the only antifungal under development with a novel mechanism of action by a Task Force of the Infectious Diseases Society of America.

The evidence supporting the potential clinical and commercial value of Mycograb[®] in different clinical indications has continued to mount during the period under review. Mycograb[®] has made notable advances in each of the three clinical areas where its worth as an adjunct in combination with current best therapy is being assessed:

a) Invasive candidiasis

Following the impressive data from the confirmatory study for the treatment of invasive candidiasis reported upon in 2004, the Company prepared a Common Technical Document and filed an application for market authorization in March 2005. A number of GCP and GMP inspections were carried out by the Regulator in 2005 and at Day 120 in the process, the EMEA posed a number of questions to NeuTec. Detailed answers, often in the form of additional analyses, have been prepared and returned to the EMEA in respect of all questions received. The Company is currently awaiting the response to these answers.

In responding to the Regulator's questions, the drug's safety dataset has been significantly expanded: additional toxicological and pharmacokinetic data has been prepared and an additional voluntary phase I study was successfully carried out. Escalating doses of Mycograb[®] were given to allow for the definition of its safety profile, dose-proportionality, volumes of distribution, time dependent kinetics and method of elimination. This newly expanded dataset has facilitated a clearer label and a more defined set of application guidelines for the drug.

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Progress with the Company's application for market approval remains within the EMEA's prescribed timelines and is consistent with a timetable that includes a regulatory decision before the year end.

Mycograb[®] has Orphan Drug Status in both Europe and the US in the treatment of invasive candidiasis. An editorial comment in *Clinical Infectious Diseases* (November 2005) concluded that earlier analyses have likely underestimated the true incidence of candidemia because of deficient diagnostic testing. The commentary went on to suggest that the attributable mortality rate associated with candidemia in a case control study in the US was estimated to be 49% and that hospital charges attributable to invasive candidiasis were \$33,604 - \$45,602 for adults and \$65,058 - \$119,474 for paediatrics per episode.

b) Carcinoma of the breast

The Company completed patient recruitment in its 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 in late 2005.

The primary objective of the study is to observe the safety and tolerability of Mycograb[®] in combination with Docetaxel when administered at twice the dosage used in the treatment of invasive candidiasis (ie at 2 mg per kg of body weight). The secondary objective is to monitor the response rate of the target tumours and overall survival and progression-free survival through seven months post treatment.

A total of 21 patients were recruited into the study and of these 7 patients have been withdrawn for the following reasons: withdrawal of patient consent (one patient), principal investigator decision (one patient), Docetaxel toxicity (three patients) and cancer progression (two patients). All 14 on-going patients have now received the full course of six cycles of treatment, three weeks apart, and all 20 surviving patients continue to be monitored on a regular basis.

Hsp90 has continued to attract significant industry and scientific attention as a prime target for combinatorial therapy against certain cancers. A presentation by the Company at the International Symposium on Targeted Anticancer Therapies (TAT) in March 2006 was well received and underlined the activity of the drug against a range of cancer cells in the laboratory.

c) Cryptococcal meningitis

Cryptococcus neoformans ("C. neoformans") is the most common form of fungal meningitis and is prevalent in patients with AIDS. It carries a mortality rate of up to 20%. NeuTec is about to commence a phase III study using Mycograb[®] in combination with current best therapy (generic amphotericin B and 5-flucytosine) against *C. neoformans*.

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The trial will involve approximately 150 patients in a double-blind, placebo-controlled, multi-centre study. Regulatory and ethical approval has recently been obtained in South Africa and this follows a successful Investigational New Drug (“IND”) application to the US Food and Drugs Agency (“FDA”). Hospitals in the United States, South Africa and South America have agreed to participate in the study and contracts with investigators are close to finalization.

The results from this trial will be used to assess the efficacy of Mycograb[®] against a further life threatening indication, will widen the safety database, particularly in a non-intensive care unit-based patient environment, and will explore the drug in combination with conventional amphotericin B (as used in the Japanese market in the treatment of systemic candidiasis) rather than liposomal amphotericin B (as used in the US and European markets for the treatment of invasive candidiasis).

Developmental programme

A total of eight patients have been included in the Company’s compassionate use programme in England, Scotland, Belgium and the Netherlands, the majority having failed on mono-therapy with other drugs. As a result, Mycograb[®] has now been given in combination with conventional amphotericin B and Caspofungin as well as with liposomal amphotericin B. It has also been given successfully in the treatment of two children with invasive candidiasis. Significantly, this data has extended the patient safety database. The Company expects to commit further resource to this programme in the coming months.

Advisory group meetings have taken place which include a number of investigators who participated in the confirmatory study into invasive candidiasis and other experts in this area. A detailed programme for attending and presenting at major industry conferences and congresses is being followed, and this includes participation at the 2006 Meetings of the International Symposium on Intensive Care and Emergency Medicine (ISICEM) in Brussels, the European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) in Nice and the International Society for Human and Animal Mycology (ISHAM) Congress in Paris.

These meetings form part of a wide-ranging programme for the identification and targeting of leading specialists and renowned clinicians in the treatment of severe fungal infection. They will extend the awareness of Mycograb[®] and its novel mechanism of action. This programme has been supplemented by the first technical publication of the mechanism of action entitled “Fungal heat-shock proteins in human disease”, published in FEMS (the *Federation of European Microbiological Societies*) in January 2006.

In order to comply with regulatory requirements regarding marketed drugs, the Company has been working with its principal Contract Manufacturing Organisation to implement a full Process Validation Programme during the summer. Three batches of Mycograb[®] were delivered during the period under review and contracts have been signed to secure a further 11 batches of drug in four campaigns over the next 18 months.

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Aurograb[®]

Aurograb[®], which targets Methicillin Resistant *Staphylococcus aureus*, MRSA, is nearing the completion of patient recruitment in a double-blind placebo-controlled phase III study in six European countries. Recent national statistics published for England and Wales has identified that the number of death certificates mentioning *Staphylococcus aureus* has risen in each year from 1993 to 2004, from just over 400 in 1993 to a total in excess of 1,600 in 2004. An increase in the number of death certificates specifying MRSA accounted for all of this increase in deaths.

Recruitment has picked up again in recent weeks following a dip during the Christmas and New Year periods, and a total of 150 patients have now been included in the trial in 24 hospitals. The study will involve the recruitment of 160 – 170 patients to achieve 150 evaluable hospitalized patients with deep-seated staphylococcal infections treated with Aurograb[®] in combination with Vancomycin, the gold standard antibiotic treatment for MRSA.

Financial Results

The loss before taxation for the half year amounted to £2,934,000, compared with a loss in the corresponding period last year of £1,643,000. The increase in the loss is principally due to costs of almost £800,000 for regulatory support and additional one-off costs associated with the application for market authorisation, and manufacturing costs of almost £700,000 incurred during the period.

The limited named patient supply of Mycograb[®] has led to the Company recognizing its first trading revenues in the period under review. Cash outflow before financing amounted to £2,589,000 compared with £2,061,000 (excluding the net inflow from fund raising) in the six months to 31 December 2004. Cash balances at the period end amounted to £26,027,000 (31 December 2004: £30,403,000). Our financial projections indicate that the Company's cash balances are adequate to meet our plans going forward.

Outlook

During the six months under review we have responded to the European Regulator's thorough and systematic list of questions which followed their review of the Common Technical Document presented to them in March 2005. The licence application continues in line with the EMEA's outline process and timetable and we await the outcome to the Company's latest submission of supplementary data. The roll out of our commercialisation strategy remains consistent with a market launch in 2006.

NeuTec Pharma remains sufficiently well funded to meet our future plans, our intellectual property portfolio is robust and other areas of the business continue to develop at a satisfactory rate. We are encouraged by the early indications from the breast cancer trial commenced in September 2005, we are close to commencing a phase III trial in cryptococcus and we are nearing completion of patient recruitment into the phase III study of Aurograb[®] in MRSA.

Anthony Martin Ph.D
Chairman

27 March 2006

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Profit and loss account

	<i>Note</i>	(Unaudited) Six months ended 31 December 2005 £'000	(Unaudited) Six months ended 31 December 2004 £'000	(Audited) Year ended 30 June 2005 £'000
Turnover		11	-	-
Cost of sales		(1)	-	-
Gross profit		<u>10</u>	<u>-</u>	<u>-</u>
Research, development and administrative expenses		(3,605)	(2,271)	(5,287)
Total operating loss		<u>(3,595)</u>	<u>(2,271)</u>	<u>(5,287)</u>
Interest receivable and similar income		661	629	1,365
Loss on ordinary activities before taxation		<u>(2,934)</u>	<u>(1,643)</u>	<u>(3,922)</u>
Taxation on loss on ordinary activities	2	-	325	325
Loss on ordinary activities after taxation		<u>(2,934)</u>	<u>(1,318)</u>	<u>(3,597)</u>
Loss per ordinary share		<u><u>10.5 pence</u></u>	<u><u>5.0 pence</u></u>	<u><u>13.2 pence</u></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.

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Balance sheet

	(Unaudited) As at 31 December 2005 £'000	(Unaudited) As at 31 December 2004 £'000	(Audited) As at 30 June 2005 £'000
Fixed assets			
Tangible assets	414	324	308
	<hr/>	<hr/>	<hr/>
Current assets			
Debtors	775	610	592
Cash at bank and in hand	26,027	30,403	28,573
	<hr/>	<hr/>	<hr/>
	26,802	31,013	29,165
Creditors: amounts falling due within one year	(2,423)	(1,394)	(1,789)
	<hr/>	<hr/>	<hr/>
Net current assets	24,379	29,619	27,376
	<hr/>	<hr/>	<hr/>
Net assets	24,793	29,943	27,684
	<hr/> <hr/>	<hr/> <hr/>	<hr/> <hr/>
Capital and reserves			
Called up share capital	7,265	7,254	7,265
Share premium account	33,813	33,761	33,770
Profit and loss account	(16,284)	(11,071)	(13,350)
Investment in own shares	(1)	(1)	(1)
	<hr/>	<hr/>	<hr/>
Equity shareholders' funds	24,793	29,943	27,684
	<hr/> <hr/>	<hr/> <hr/>	<hr/> <hr/>

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Reconciliation of movements in shareholders' funds

	(Unaudited) Six months ended 31 December 2005 £'000	(Unaudited) Six months ended 31 December 2004 £'000	(Audited) Year ended 30 June 2005 £'000
Loss for the period/year	(2,934)	(1,318)	(3,597)
Movement in share premium account	43	23,224	23,233
New share capital subscribed	-	1,319	1,330
Net (reduction)/increase in shareholders' funds	(2,891)	23,225	20,966
Opening shareholders' funds	27,684	6,718	6,718
Closing shareholders' funds	24,793	29,943	27,684

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Cash flow statement

		(Unaudited) Six months ended 31 December 2005 £'000	(Unaudited) Six months ended 31 December 2004 £'000	(Audited) Year ended 30 June 2005 £'000
Net cash outflow from operating activities	4	(3,151)	(2,595)	(5,191)
Returns on investment and servicing of finance				
Interest received and similar income		705	542	978
Total returns on investments and servicing of finance		705	542	978
Taxation received		-	143	468
Capital expenditure				
Purchase of tangible fixed assets		(143)	(151)	(166)
Cash outflow before financing		(2,589)	(2,061)	(3,911)
Financing				
Issue of ordinary share capital (net of issue costs)		43	24,543	24,563
(Decrease)/Increase in cash in the period/year	5	(2,546)	22,482	20,652

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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 2005 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 2005 was approved by the Board on 27 March 2006.

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 was 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.

3 Loss per share

	(Unaudited) Six months ended 31 December 2005 Pence	(Unaudited) Six months ended 31 December 2004 Pence	(Audited) Year ended 30 June 2005 Pence
Loss per ordinary share:			
Basic	10.5	5.0	13.2
Diluted	10.5	5.0	13.2

Loss per ordinary share is based on the Company's loss for the financial period of £2,934,000 (31 December 2004: £1,318,000; 30 June 2004: £3,597,000).

The weighted average number of shares used in the basic calculation is 27,901,848 (31 December 2004: 26,540,325 ; 30 June 2005: 27,149,266).

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 22.

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Notes (continued)

4	Reconciliation of operating loss to net cash outflow from operating activities		
	(Unaudited) Six months ended 31 December 2005 £'000	(Unaudited) Six months ended 31 December 2004 £'000	(Audited) Year ended 30 June 2005 £'000
Total operating loss	(3,595)	(2,271)	(5,287)
Depreciation and amortisation Charges	37	26	57
Increase in debtors	(227)	(72)	(79)
Increase/(Decrease) in creditors	634	(278)	118
	<hr/>	<hr/>	<hr/>
Net cash outflow from Operating activities	(3,151)	(2,595)	(5,191)
	<hr/> <hr/>	<hr/> <hr/>	<hr/> <hr/>
5	Reconciliation of net cash flow to movement in net funds		
	(Unaudited) Six months ended 31 December 2005 £'000	(Unaudited) Six months ended 31 December 2004 £'000	(Audited) Year ended 30 June 2005 £'000
(Decrease)/Increase in cash and cash equivalents in the period/year	(2,546)	22,482	20,652
	<hr/>	<hr/>	<hr/>
Movement in net funds resulting from cash flows	(2,546)	22,482	20,652
Net funds at the start of the period/year	28,573	7,921	7,921
	<hr/>	<hr/>	<hr/>
Net funds at the end of the period/year	26,027	30,403	28,573
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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. The directors are responsible for preparing the interim report in accordance with the AIM Rules which require that the interim report must be presented and prepared in a form consistent with that which will be adopted in the company's annual accounts having regard to the accounting standards applicable to such annual accounts.

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 for use in the United Kingdom. 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 2005.

KPMG Audit Plc
Chartered Accountants
Manchester
27 March 2006