

Preliminary Results for the Year Ended 30 June 2003

NeuTec Pharma plc, a biopharmaceutical company targeting drug-resistant infections, today announces its preliminary results for the year ended 30 June 2003.

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

Results

For the year ended 30 June 2003 cash outflow was £1,330,000 (2002: £1,572,000, excluding net cash receipts from the Initial Public Offering during 2002). Cash balances at the period end were £10.8 million (2002: £12.1 million). The Company recorded a loss on ordinary activities before taxation of £2,945,000, compared with the loss in the corresponding period of £2,056,000, reflecting the progress achieved in its clinical trials and development programmes.

Key Points

- Mycograb[®], which targets invasive yeast infections:
 - extended the scope of the Phase II clinical trial into a further 9 European countries;
 - successful Investigational New Drug (“IND”) application followed by agreement from the US Food and Drug Administration (“FDA”) to extend the Phase II trials into the USA. Five US centres are active and the first US patient has now been recruited;
 - an interim analysis showed no drug-related significant adverse events and the pharmacokinetic data confirmed the appropriateness of the dosing regimen for candida infections; and
 - additional pre-clinical testing has demonstrated synergy with the echinocandins and the spectrum of drug activity has been extended to moulds and *Cryptococcus neoformans* (a common cause of meningitis in HIV-infected patients).
- Aurograb[®], which targets methicillin resistant *Staphylococcus aureus* (“MRSA”), a hospital ‘superbug’:
 - successfully completed two Phase II clinical studies on Aurograb[®]; and
 - preparing a protocol for regulators aimed at commencing a pan-European double-blind, placebo-controlled, Phase III study.

Intellectual Property:

- strengthened intellectual property portfolio with the addition of ten new patents, including two granted in Japan for Mycograb[®] and new patents in USA and Australia for Aurograb[®]; and
- filed two new patents against *Clostridium difficile*, the cause of antibiotic-associated diarrhoea.

Corporate:

- appointed Dr Robert Nolan to the Board as non-Executive Director. Dr Nolan is Director of Global Licensing with AstraZeneca plc and has been with the company since 1979. (See separate announcement).

Product pipeline:

- the Company's platform technology, FABTEC[®], has continued to be deployed for the discovery of new therapeutic agents and during the year was successful in identifying the key sequences in patients who have recovered from SARS, *Clostridium difficile* and vancomycin-resistant enterococci ("VRE").

Summary

Anthony Martin, Chairman, commented:

"We have made further significant progress during the past year in developing our portfolio of products to prevent deaths from antibiotic-resistant and hospital-acquired infections. We are encouraged by the identification of a wider spectrum of drug activity for Mycograb[®] and this will lead to further clinical evaluation. We are particularly pleased to have commenced patient recruitment in the USA in the last fortnight.

Aurograb[®], which targets MRSA, has successfully completed the two stages of its Phase II clinical trials programme and we are in process of submitting a protocol to regulators to commence full Phase III trials. We look forward to achieving further clinical progress during the current year."

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Chairman's Statement and Operating Review

In our first full year since admission to trading on the Alternative Investment Market of the London Stock Exchange, 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. A series of important clinical milestones have been reached and these have been achieved with lower than expected cash outflow.

Clinical Trials – Mycograb[®]

Our lead product targeting invasive yeast infections has significantly extended the scope of its clinical trials programme.

As reported last year, during mid 2002 the Company procured additional European sites to accelerate its Phase II clinical trials programme and gain earlier European awareness of the product in advance of market authorisation. The trial is currently active in 10 European countries and has recently been extended into five centres in the USA. This followed agreement from the US Food and Drug Administration ("FDA") in March 2003 to extend the trials

into the USA. The drug was granted Orphan Drug Status by the FDA in September 2002. The first US patient was recruited in September 2003.

An interim analysis was carried out in December 2002 on the first 20 evaluable subjects and this revealed there had been no Mycograb[®]-related significant adverse events and the pharmacokinetic data confirmed the appropriateness of the dosing regimen for candida infections.

Additional pre-clinical testing of the drug has demonstrated synergy with the echinocandins and the spectrum of drug activity has been extended to moulds and *Cryptococcus neoformans*, a significant cause of meningitis in patients with HIV infection. Pre-clinical data has also been published in a leading journal (Antimicrobial Agents and Chemotherapy) in July 2003 and has been presented at international meetings in Germany and the Netherlands (European Confederation of Medical Mycology 9th Congress).

Clinical Trials – Aurograb[®]

Aurograb[®] targets methicillin resistant *Staphylococcus aureus* (“MRSA”), the hospital ‘superbug’, and has reached two key milestones during the year:

1) UK Phase II clinical trials in systemically ill patients commenced in August 2002 and an initial dose-ranging Phase IIa study was completed in January 2003. The study reported the first clinical data in eight patients with MRSA sepsis on vancomycin therapy. The data generated did not raise any concerns over the toxicological profile of Aurograb[®]; and

2) A Phase IIb European study was completed in June 2003 in nine patients. This study was designed to look for tolerability and the pharmacokinetic profile of Aurograb[®] given over a five day period. The drug was found to be well tolerated and it demonstrated a profile that suggests 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, it is more effective than either drug used on its own. This activity is also evident with strains showing partial resistance to vancomycin.

During the summer of 2003 a series of meetings with focused groups of physicians has taken place in Hungary, the Czech Republic and Germany leading to Phase III clinical trials protocol agreement. Over 20 hospitals in 6 European countries have now agreed to take part in the Phase III study which is scheduled to commence in the first quarter of 2004.

Research and Development Programme

The Company has continued to develop its research programmes targeted at other serious infections. NeuTec Pharma’s platform technology, FABTEC[□], has been deployed for the discovery of new therapeutic agents and during the year was successful in identifying the key antibody sequences in patients who have recovered from SARS, *Clostridium difficile* and vancomycin-resistant enterococci (“VRE”). 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. The FABTEC[□] technology has recently become available for licensing to third party companies.

Mycograb[®] is based on a naturally-occurring human antibody response against Hsp90, which helps the body defend itself against life-threatening fungal infections. There is increasing scientific evidence that both tumour cells and fungal cells are heavily dependent on Hsp90 for their survival and proliferation in the human host. In the last week the Company has announced its intention to seek development partners for Mycograb[®] in the field of oncology, an area that has hitherto been outside its chosen therapeutic focus.

Intellectual Property

Substantial progress has been made in securing additional patents to protect the Company's intellectual property portfolio. Two new patents have been filed against *Clostridium difficile*, the cause of antibiotic-associated diarrhoea, and ten new patents have been granted, including NeuTec Pharma's first two patents in Japan for Mycograb[®] and the first two patents for Aurograb[®] in the USA and Australia.

Results

For the year ended 30 June 2003 cash outflow was £1,330,000 (2002: £1,572,000, excluding net cash receipts from the Initial Public Offering in February 2002). The Company recorded a loss on ordinary activities before taxation of £2,945,000, compared with a loss in the corresponding period of £2,056,000, reflecting the progress in the clinical trials and development programmes. These figures are stated after interest receivable of £470,000 (2002: £273,000) and before research and development tax credits of £161,000 (2002: £180,000).

The difference between the cash outflow and the loss for the year is due to active cash management, the incidence of non cash items such as a £283,000 (2002: £283,000) UITF 17 charge for share options and timing differences between the incurring of costs and the associated invoicing profile.

Corporate

We are pleased to confirm the appointment of Dr Robert Nolan to the Board as non-Executive Director with immediate effect. Dr Nolan is Director of Global Licensing with AstraZeneca plc and has been with the company since 1979. Mr Rodney Graves will not be seeking re-appointment to the Board as a non-Executive Director at the forthcoming Annual General Meeting. I would like to thank Rodney on behalf of the Company for his contribution since joining the Board in 1997.

Prospects

The Board is encouraged by the many developments achieved during the year. We have made further significant progress during the past year in developing our portfolio of products to prevent deaths from antibiotic-resistant and hospital-acquired infections. We are encouraged by the identification of a wider spectrum of drug activity for Mycograb[®] and this will lead to further clinical evaluation. We are particularly pleased to have commenced patient recruitment in the USA in the last fortnight.

Aurograb[®] has successfully completed the two stages of its Phase II clinical trials and will soon be commencing a pan-European Phase III trial. We look forward to achieving further clinical progress, principally with Mycograb[®] and Aurograb[®], during the coming year.

Anthony Martin Ph.D.

Chairman

14 October 2003

Profit and loss account

		Year ended 30 June 2003 £'000	Year ended 30 June 2002 £'000
Administrative expenses (including research and development costs)		(3,415)	(2,329)
Operating loss		(3,415)	(2,329)
Other interest receivable and similar income		470	273
Loss on ordinary activities before taxation		(2,945)	(2,056)
Tax on loss on ordinary activities		161	180
Loss on ordinary activities after taxation		(2,784)	(1,876)
Retained loss for the year		(2,784)	(1,876)
Loss per ordinary share			
Basic and diluted	3	(11.8 pence)	(10.7 pence)

All amounts relate to continuing activities

There are no recognised gains or losses other than the loss attributable to the shareholders of £2,784,000 (2002: a loss of £1,876,000) in the year and therefore no statement of total recognised gains and losses has been presented.

Balance sheet

	£'000	As at 30 June 2003 £'000	£'000	As at 30 June 2002 £'000
Fixed assets				
Tangible assets		160		173
Investments		1		1
		<u>161</u>		<u>174</u>
Current assets				
Debtors	255		404	
Cash at bank and in hand	10,806		12,136	
		<u>11,061</u>		<u>12,540</u>
Creditors: amounts falling due within one year	(1,637)		(643)	
		<u>9,424</u>		<u>11,897</u>
Net current assets		9,424		11,897
Total assets less current liabilities		<u>9,585</u>		<u>12,071</u>
Capital and reserves				
Called up share capital		5,911		5,906
Share premium account		10,513		10,503
Profit and loss account		(6,839)		(4,338)
Equity shareholders' funds		<u>9,585</u>		<u>12,071</u>

Cash flow statement

	Year ended 30 June 2003 £'000	Year ended 30 June 2002 £'000
Operating loss	(3,415)	(2,329)
Depreciation charges	29	27
Share option charges	283	283
Decrease/(Increase) in debtors	36	(106)
Increase in creditors	1,000	435
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Net cash outflow from operating activities	(2,067)	(1,690)
Returns on investment and servicing of finance		
Interest received	564	167
Taxation		
Taxation repayment received	180	-
Capital expenditure		
Payments to acquire tangible fixed assets	(16)	(49)
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Cash outflow before financing	(1,339)	(1,572)
Financing		
Net proceeds from issue of shares	9	10,060
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(Decrease)/Increase in cash in the year	(1,330)	8,488
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Reconciliation of net cash flow to movement in net funds		
	2003	2002
	£'000	£'000
Net funds at the start of the year	12,136	3,648
Movement in net funds in the year	(1,330)	8,488
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Net funds at the end of the year	10,806	12,136
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Reconciliation of movements in shareholders' funds

	Year ended 30 June 2003 £000	Year ended 30 June 2002 £000
Loss for the financial year	(2,784)	(1,876)
Charge in relation to share related rewards	283	283
New share capital subscribed (net of issue costs)	9	10,060
Movement in share premium account	6	-
Net (reduction in)/addition to shareholders' funds	(2,486)	8,467
Opening shareholders' funds	12,071	3,604
Closing shareholders' funds	9,585	12,071

Notes

1. Nature of Financial Information

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

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 FRS 18 'Accounting policies' and FRS19 'Deferred tax' in these financial statements.

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

3. Loss per share

The basic loss per share of 11.8 pence (30 June 2002: 10.7 pence) is calculated by reference to the loss for the year of £2,784,000 (30 June 2001: £1,876,000) and to a weighted average of 23,629,448 (30 June 2002: 17,568,001) 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 28 November 2003 at the Royal College of Pathologists.