

## Neuren Pharmaceuticals Limited

### Appendix 4D Half-Year Financial Report

**30 June 2005**

Name of entity

Neuren Pharmaceuticals Limited

ARBN

111 496 130

Half-year ended

30 June 2005

1. Neuren Pharmaceuticals Limited ("Neuren" or the "Company") presents this financial report, including the interim financial statements, for the six months ended 30 June 2005.

The interim financial statements have been prepared in accordance with New Zealand FRS-24: *Interim Financial Statements*. As these are the first interim financial statements to be prepared and presented by the Company, comparative information for the previous corresponding interim period has not been presented.

All amounts shown are in NZ\$'000s unless otherwise stated.

The Interim Report should be read in conjunction with the Company's annual report for the year ended 31 December 2004.

#### 2. Results for announcement to the market

	30 June 2005 NZ\$'000	% Change
2.1 Operating revenue	1,195	n/a
2.2 Loss after tax from ordinary activities	(4,021)	n/a
2.3 Net loss from ordinary activities	(4,021)	n/a
2.4 Dividends and franked amount per security	nil	n/a
2.5 Dividend record date	n/a	
2.6 Explanation of results:		
<p>During the period capital raising activities were completed, raising A\$15 million in further share capital, incurring NZ\$1.9 million in IPO costs. The net loss for the period was NZ\$4.0 million, and at 30 June 2005 net assets were NZ\$19.9 million with NZ\$11.0 million cash. These results were in line with the Company's expectations. Research and development of the Company's compounds, for which the capital raised was intended, has continued through the period. A more detailed discussion of the activities undertaken in the period is set out in the Chief Executive's Report contained in the attached Interim Report to shareholders.</p>		

+ See chapter 19 for defined terms.

**3. Net Tangible Assets per Security**

	<u>Current period</u>	<u>Comparative period</u>
Net tangible assets per share	NZ\$ 0.12	n/a

**4. Entities over which control has been gained or lost during the period:**

None.

**5. Details of dividends**

Not applicable.

**6. Details of dividend reinvestment plans**

Not applicable.

**7. Details of associates and joint venture entities**

None.

**8. Accounting standards**

The interim financial statements have been prepared in accordance with New Zealand FRS-24: *Interim Financial Statements*.

**9. Audit dispute or qualification**

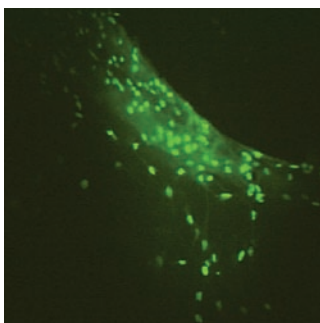
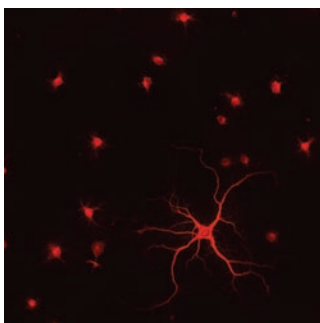
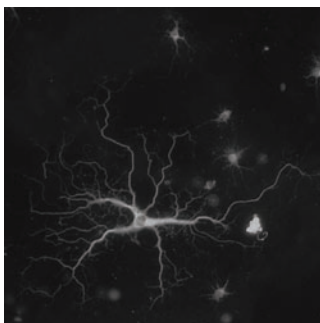
The interim financial statements have been subject to independent review by the Company's auditors. The unqualified review report is included in the attached Interim Report.

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<sup>+</sup> See chapter 19 for defined terms.

# INTERIM REPORT 2005

Neuren Pharmaceuticals Limited  
ARBN 111 496 130



**neuren**  
pharmaceuticals

The Directors submit the financial report of Neuren Pharmaceuticals Limited for the half-year ended 30 June 2005.

### Directors' details

The names of Directors who held office during or since the end of the half-year:

Dr Robin Congreve (Chairman)  
Mr Tom Amos  
Mr David Clarke  
Dr Graeme Howie  
Mr Trevor Scott  
Dr Douglas Wilson

### Review of operations

During the period capital raising activities were completed, raising A\$15 million in further share capital, incurring NZ\$1.9 million in IPO costs. The net loss for the period was NZ\$4.0 million, and at 30 June 2005 net assets were NZ\$19.9 million with NZ\$11.0 million cash. These results were in line with the Company's expectations. Research and development of the Company's compounds, for which the capital raised was intended, has continued through the period. A more detailed discussion of the activities undertaken in the period is set out in the Chief Executive's Report.

### Corporations Act, Australia - Directors' declaration

The Directors of Neuren Pharmaceuticals Limited ("Neuren") declare that:

1. The accompanying financial statements of Neuren and its subsidiaries for the six months ended 30 June 2005 and the notes to those financial statements:
  - a. comply with the accounting standards issued by the Institute of Chartered Accountants of New Zealand; and
  - b. give a true and fair view of the financial position as at 30 June 2005 and of the performance for the six months ended on that date of Neuren and its subsidiaries.
2. In the Directors' opinion there are reasonable grounds to believe that Neuren will be able to pay its debts as and when they become due and payable.

This report is signed and declaration made in accordance with a resolution of the Board of Directors dated 30 August 2005.

On behalf of the Board



Dr Robin Congreve  
Chairman

Dear Shareholders

This first six months since listing on the Australian Stock Exchange have been most satisfying in terms of achievement of the objectives and milestones we set ourselves for the period. As noted in the Annual Report we have strengthened our Board and management capabilities and Neuren continues to be well on track to delivering on all its objectives for the 2005 year.

### **Glypromate® clinical development programme**

Of particular note is the outcome of the pre-IND meeting with the US Food and Drug Administration (FDA) in April 2005. The meeting was primarily to present Neuren's plans for a Phase 2b study of Glypromate® to prevent neurocognitive decline in patients undergoing coronary artery bypass graft (CABG) surgery. As a result and at their recommendation, the FDA will allow Neuren to move straight to a Phase 3 study rather than the planned Phase 2b study, and the Glypromate® clinical development programme will accelerate by two years incurring an estimated \$6 - 8 million less in direct costs.

The Company has had to bring forward a number of activities which would otherwise not have been required for a Phase 2b study in order to satisfy the higher demands of a Phase 3 trial, which will cost an additional \$1.8 million in the coming six months. Although costs are being incurred earlier than planned, the Company believes this opportunity needs to be taken as it not only accelerates Neuren to a Phase 3 trial in 2006 rather than 2008, but also gives us the potential to be first in market. Very few Australasian biotech companies have this opportunity.

The 30 patient Phase 2a trial of Glypromate® to confirm the safety and pharmacokinetics of the drug in patients was initiated in August 2005 and is expected to be completed by the end of this year. Neuren has engaged five hospitals for the small Phase 2a trial in order to pre-test many of the systems and processes that will be required for the larger multi-centre Phase 3 trial. Neuren has appointed Professor Allan Merry, a widely recognised expert on cardiovascular surgery and anaesthetics, as principal investigator for the trial being conducted at Auckland City Hospital, Mercy Hospital (Auckland), Waikato Hospital (Hamilton), Wakefield Hospital (Wellington) and the Alfred Hospital (Melbourne). Neuren is also working with Professor Stanton Newman, head of the Department of Psychiatry and Behavioural Sciences in the Medical School at University College London, an internationally recognised expert on the cognitive aspects of cardiovascular surgery.

The production processes for Glypromate® have now been completed according to international Phase 3 standards for medicines by FDA (USA) and EMEA (Europe) approved contract manufacturers. Neuren has completed audits of the manufacturers and found them to be compliant with applicable regulations and standards.

### **NNZ-2566 development programme**

Neuren executed a Material Transfer Agreement (MTA) with the US Army Walter Reed Army Institute of Research in June 2004 to evaluate NNZ-2566 in Traumatic Brain Injury (TBI). The results of experiments conducted under the MTA showed statistically significant benefits in the Army's model and, in March 2005, Neuren executed a second stage Cooperative Research and Development Agreement (CRADA) with the US Army for co-development of NNZ-2566 for TBI. This will result in a significant reduction in preclinical research costs to be borne by Neuren. The

CRADA represents the second stage of what the Company expects will be a three-stage collaboration including further preclinical development and subsequent clinical trials. Under the CRADA, the Army will continue to conduct experiments in animal models of TBI in order to optimise the dose and schedule for drug administration. In April 2005, the CRADA was expanded to include additional research and experiments for a new biological marker and potential clinical endpoint for TBI.

We have had several enquiries about proposed closures of US military facilities under the Defense Realignment Program, and one of the facilities on the list has caused some confusion. The Walter Reed Army Medical Center, a hospital in Washington D.C. may be merged with another hospital. This Center is not affiliated with our partner, The Walter Reed Army Institute of Research, in Silver Spring, Maryland, and the Institute is not proposed for closure.

With regard to manufacturing, Neuren entered into an agreement with a contract manufacturer in New Jersey (USA) for the development and validation of the manufacturing process for NNZ-2566. Drug substance suitable for non-clinical pharmacology and toxicology studies has been produced and delivered, and the first batch of cGMP product for a Phase 1 trial will be delivered later this year. cGLP pharmacology and toxicology studies have also been initiated with a US based contract research organisation.

The Company plans to conduct a Phase 1 study of intravenous NNZ-2566 in early 2006. Preparation of the protocol, investigator's brochure, informed consent, ethics application and other required documents for the Phase 1 study is underway.

Neuren has also developed several potential oral formulations of NNZ-2566. Results of recent studies show evidence of good absorption and drug levels in circulation when these oral formulations are given to animals. These encouraging findings confirm Neuren's belief that NNZ-2566 offers excellent potential as an oral drug for chronic conditions. In-house experiments in an animal model of stroke have been initiated to assess the neuroprotective effects of NNZ-2566 given orally. The Company is presently preparing to commence preclinical development of an oral form of NNZ-2566 for chronic indications such as preventing secondary strokes and transient ischemic attacks as well as degenerative diseases such as Alzheimer's and Parkinson's disease dementia.

### **Neural Regeneration Peptides (NRPs) research programme**

Neuren and Metabolic Pharmaceuticals Limited have agreed to collaborate to develop the NRPs for acute and chronic neurological conditions. This collaboration is partly funded by a government grant of \$635,000 from the Australia New Zealand Biotechnology Partnership Fund, providing 25% of the funding needed for the collaboration while Neuren and Metabolic Pharmaceuticals will contribute 25% and 50% of the funding, respectively. Again, this increases the speed of development and reduces the cost to Neuren. Neuren and Metabolic Pharmaceuticals will share equally in intellectual property and commercial outcomes.

The first animal studies involving NRPs reveal exciting results in neurodegenerative animal disease models mimicking Multiple Sclerosis as well as CNS-injury models. Scientific data on the NRPs has been presented for the first time at an international conference and the first manuscript has been submitted for publication.

### **Diketopiperazines (DKP) and Macrocyclic research programmes**

NNZ-2591, one of the patented analogues in the DKP family of compounds, has exhibited potent neuroprotective effects in animal models of stroke and Parkinson's disease. These results are presently being confirmed. If positive, Neuren intends to nominate NNZ-2591 as a development candidate and to initiate the pharmacology/toxicology and chemistry-related activities necessary to advance this candidate into the next phase of preclinical development.

### **Growth and Metabolism research programmes**

A promising partial agonist of Growth Hormone (GH) has been synthesised; this compound has been designed to have beneficial effects of GH on metabolism without the unwanted side effects often seen in adults receiving GH. Promising in vivo data has been obtained and is now being confirmed. Neuren plans to out-licence this technology or seek a partner for development of this molecule before initiating any clinical development activities.

Neuren is also developing an antagonist that targets a mediator of GH activity that appears to be responsible for the proliferation and malignant behaviour of some breast cancers. The antagonist will be used to confirm proof of principle. If this is obtained, the Company will optimise one or more approaches to confirm their effect in established animal models. Neuren would most likely seek to out-license this product while it is in preclinical development.

### **Financial Position**

The financial results presented in this report are consistent with the Company's expectations for the period as described in the IPO documents, with closing cash at 30 June 2005 of \$11 million.

The Company continues to perform contract research for Pfizer, however given their worldwide cost-cutting announced earlier this year, Neuren expects that Pfizer may reduce its outsourced research. Neuren is increasingly becoming more focussed on clinical development rather than basic research, and especially third party contract research, with the Company now actively seeking to further expand its resources from basic research into clinical and product development, and commercialisation. Any decrease in contract revenue is expected to be mitigated to some degree by increased revenue as a result of grant applications the Company currently has underway.

I would like to thank shareholders for their continuing interest in Neuren and look forward to reporting the achievement of further milestones in the near future.



Mr David Clarke  
Chief Executive Officer

## Interim Statement of Financial Performance (Unaudited)

Company and Group	Six months Jun 2005 NZ\$'000	Year ended Dec 2004 NZ\$'000
Total operating revenue from continuing activities	1,195	2,598
Total operating expenses from continuing activities	(5,197)	(8,767)
<b>Operating deficit before taxation</b>	(4,002)	(6,169)
Income tax	(19)	-
<b>Net deficit after taxation</b>	\$ (4,021)	\$ (6,169)
<b>Basic and diluted net deficit per share</b>	\$(0.04)	\$(0.15)

## Interim Statement of Movements in Equity (Unaudited)

Company and Group	Paid-in Capital		Accumulated Deficit	Total	Recognised Revenues and Expenses
	Shares 000's	NZ\$'000	NZ\$'000	NZ\$'000	NZ\$'000
Shareholders' equity as at 1 January 2004	840	\$ 8	\$ (5,525)	\$ (5,517)	
Shares issued on conversion of preference shares	5,079	7,365		7,365	
Shares issued on acquisition of NeuronZ Limited's business	16,277	11,453		11,453	
Shares issued for cash	2,332	2,332		2,332	
Share split	37,972	-		-	
Net deficit			(6,169)	(6,169)	(6,169)
Total recognised revenues and expenses					\$ (6,169)
Shareholders' equity as at 31 December 2004	62,500	\$ 21,158	\$ (11,694)	\$ 9,464	
Shares issued in initial public offering ("IPO")	37,500	16,309		16,309	
IPO costs expensed		(1,882)		(1,882)	
Net deficit			(4,021)	(4,021)	(4,021)
Total recognised revenues and expenses					\$ (4,021)
Shareholders' equity as at 30 June 2005	100,000	\$ 35,585	\$ (15,715)	\$ 19,870	

The accompanying notes form part of this financial report.



## Interim Statement of Financial Position (Unaudited)

Company and Group	As at Jun 2005 NZ\$'000	As at Dec 2004 NZ\$'000
<b>ASSETS</b>		
<b>Current Assets:</b>		
Cash and cash equivalents	11,004	343
Receivables	695	1,066
Other current assets	291	913
<b>Total current assets</b>	11,990	2,322
<b>Non-current assets:</b>		
Property, plant and equipment	53	72
Intangible assets	11,201	11,616
<b>Total non-current assets</b>	11,254	11,688
<b>TOTAL ASSETS</b>	\$ 23,244	\$ 14,010
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable and accrued liabilities	3,374	4,546
<b>Total current liabilities</b>	3,374	4,546
<b>SHAREHOLDERS' EQUITY</b>		
Share capital	35,585	21,158
Accumulated deficit	(15,715)	(11,694)
<b>Total shareholders' equity</b>	19,870	9,464
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	\$ 23,244	\$ 14,010

The accompanying notes form part of this financial report.

## Interim Statement of Cash Flows (Unaudited)

Company and Group	Six months Jun 2005 NZ\$'000	Year ended Dec 2004 NZ\$'000
<b>Cash flows from operating activities:</b>		
Receipts from customers	504	1,587
Receipts from grants	529	867
Interest received	343	10
GST refunded	158	117
Payments to employees	(889)	(1,611)
Income taxes (paid) refunded	(24)	150
Payments to other suppliers	(4,673)	(5,105)
<b>Net cash used in operating activities</b>	<b>(4,052)</b>	<b>(3,985)</b>
<b>Cash flows from investing activities:</b>		
Purchase of plant and equipment	(4)	(20)
Cash acquired on acquisition of the business of NeuronZ Limited	-	116
Proceeds from disposal of property, plant and equipment	-	543
<b>Net cash (used in) from investing activities</b>	<b>(4)</b>	<b>639</b>
<b>Cash flows from financing activities:</b>		
Proceeds from the issue of shares	16,309	2,332
Payments for share issue expenses	(1,524)	-
<b>Net cash from financing activities</b>	<b>14,785</b>	<b>2,332</b>
<b>Net increase (decrease) in cash held</b>	<b>10,729</b>	<b>(1,014)</b>
Effect of exchange rate changes on cash balances	(68)	(43)
Cash at the beginning of the period	343	1,400
<b>Cash at the end of the period</b>	<b>\$ 11,004</b>	<b>\$ 343</b>
<b>Reconciliation with net deficit:</b>		
Net deficit	\$ (4,021)	\$ (6,169)
Non-cash items requiring adjustment:		
Depreciation and amortisation	438	1,115
Foreign exchange loss	144	43
Preference share dividend	-	126
Movements in working capital	(613)	999
Items classified as investing activities	-	(99)
<b>Net cash used in operating activities</b>	<b>\$ (4,052)</b>	<b>\$ (3,985)</b>

The accompanying notes form part of this financial report.

# Notes to the Interim Financial Statements

Six months ended 30 June 2005 (Unaudited)

## 1. Nature of business

Neuren Pharmaceuticals Limited (ASX: NEU) is a publicly listed biopharmaceutical company focusing on the development of therapeutics for conditions associated with brain injury and neurodegeneration, including acute indications such as cognitive impairment resulting from cardiac surgery, traumatic brain injury and stroke, as well as chronic conditions such as Alzheimer's and Parkinson's diseases. In addition, the Company is engaged in research and development in metabolic disorders such as obesity, growth disturbances and cancers related to the functions of growth hormone. Neuren has operations in New Zealand, Australia and the USA. These interim financial statements are for the Company and the Group (comprising the Company and its subsidiaries). At 30 June 2005 the subsidiary companies had no material operations.

The interim financial statements are for the six months ended 30 June 2005. They have been prepared in accordance with New Zealand FRS-24: *Interim Financial Statements* and should be read in conjunction with the Company's annual report for the year ended 31 December 2004.

The accounting policies used are consistent with those used to prepare the financial statements contained in the annual report for the year ended 31 December 2004. There have been no changes in accounting policies during the interim period.

As these are the first interim financial statements to be prepared and presented by the Company, comparative information for the previous corresponding interim period has not been presented.

## 2. Continuing ordinary activities

Operating deficit before taxation includes:

<b>Company and Group</b>	<b>Six months Jun 2005 NZ\$'000</b>	<b>Year ended Dec 2004 NZ\$'000</b>
Contract research revenue	245	1,643
Grant revenue	606	945
Interest revenue	343	10
Amortisation of intangible assets	(415)	(830)
Research and development costs	(3,501)	(5,567)

## 3. Share capital

On 31 January 2005, the Company accepted share subscriptions under its IPO amounting to A\$15 million for 37,500,000 new ordinary shares, and on 3 February 2005 was admitted to the Official List of the Australian Stock Exchange Limited.

Costs of \$1,882,000 incurred in relation to the IPO have been offset against capital raised.

#### 4. Contingent liabilities

There are no contingent liabilities as at 30 June 2005 (31 December 2004: nil).

#### 5. Adoption of International Financial Reporting Standards ("IFRS")

The Company and Group will be required to present its financial statements in accordance with New Zealand equivalent IFRS ("NZ IFRS") for the financial year commencing 1 January 2007. On adoption of NZ IFRS, comparative information will be restated using NZ IFRS. No final decision has been made as to whether the Company and Group will early adopt NZ IFRS.

The Company has yet to assess the impact to its financial statements of adopting NZ IFRS, however changes in accounting policies are likely to arise with respect to:

- Recognition and classification of Financial Instruments under NZ IAS 32 and 39: financial instruments will be required to be classified and measured in accordance with that classification. While the Company does not currently utilise derivative financial instruments, the classification and measurement process may impact other financial instruments.
- Share and option based payments under NZ IFRS 2: the Company will be required to determine and recognise the fair value of options and other forms of equity based remuneration.
- Income Taxes under NZ IAS 12: the Company will be required to adopt a balance sheet approach under which temporary differences are identified for each asset or liability rather than the effects of the timing and permanent differences between taxable income and accounting profit.
- Asset impairment testing under NZ IAS 36: the Company will be required to annually review tangible and intangible assets for impairment with such review being based on the fair value of, or discounted cash flows generated by, each asset rather than undiscounted cash flows.

The differences between current NZ GAAP and NZ IFRS identified above may have a significant effect on the presented financial position and performance. The areas identified above should not be taken as an exhaustive list of all the differences between NZ GAAP and NZ IFRS. None of the potential impacts of the adoption of NZ IFRS on the financial performance and financial position, including systems upgrades and other implementation costs, have been quantified yet.

#### 6. Subsequent events

There are no events subsequent to 30 June 2005 to report for the Company or its subsidiaries as at 30 August 2005.

## Accountants' Report

### To the shareholders of Neuren Pharmaceuticals Limited

We have reviewed the interim consolidated financial statements. The interim consolidated financial statements provide information about the past consolidated financial performance and consolidated cash flows of the Group for the period ended 30 June 2005 and its consolidated financial position as at that date. This information is stated in accordance with the accounting policies set out on pages 13 to 15 of the most recent Annual Report.

#### Directors' responsibilities

The Company's Directors are responsible for the preparation and presentation of the interim financial statements that present fairly the consolidated financial position of the Group as at 30 June 2005 and its consolidated financial performance and consolidated cash flows for the period ended on that date.

#### Accountants' responsibilities

We are responsible for reviewing the interim consolidated financial statements presented by Management and the Directors in order to report whether, in our opinion and on the basis of the procedures performed by us, anything has come to our attention that would indicate that the interim consolidated financial statements do not present fairly the matters to which they relate.

#### Basis of opinion

A review is limited primarily to enquiries of Group personnel and analytical review procedures applied to financial data and thus provides less assurance than an audit. We have not performed an audit on the interim financial statements and, accordingly, we do not express an audit opinion.

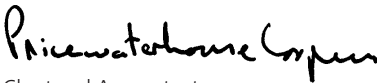
We have reviewed the interim financial statements of the Group for the period ended 30 June 2005 in accordance with the Review Engagement Standards issued by the Institute of Chartered Accountants of New Zealand.

We have no relationship with or interests in the Company or any of its subsidiaries other than in our capacity as accountants conducting this review, auditors of the annual financial statements and providers of taxation services.

#### Review opinion

Based on our review, nothing has come to our attention that causes us to believe that the interim consolidated financial statements do not present fairly the consolidated financial position of the Group as at 30 June 2005 and its consolidated financial performance and consolidated cash flows for the period ended on that date.

Our review was completed on 30 August 2005 and our review opinion is expressed as at that date.



Chartered Accountants  
Auckland

**Company**

Neuren Pharmaceuticals Limited  
ARBN 111 496 130

**Corporate Head Office**

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**Directors**

Dr Robin Congreve  
Mr Tom Amos  
Mr David Clarke  
Dr Graeme Howie  
Mr Trevor Scott  
Dr Douglas Wilson

**Company Secretary**

Mr Robert Waring

**Auditors**

PricewaterhouseCoopers  
188 Quay Street  
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Auckland, New Zealand

**Share Registry**

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**Stock Exchange Listing**

Australian Stock Exchange Limited  
ASX Code: NEU

**Website**

[www.neurenpharma.com](http://www.neurenpharma.com)

**INTERIM REPORT 2005**

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