

### **Neuren Pharmaceuticals**

Institutional Placement Raising \$6.36 million November 2005



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- 1. Company Overview
- 2. Lead Products Glypromate® and NNZ 2566
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### Corporate overview

### **Corporate Snapshot**

Neuren is a drug development company targeting brain repair& rescue, metabolism and cancer

Neuren's lead products protect against brain damage

Glypromate® has been accelerated into Phase-3 clinical trials following a productive meeting with FDA

ASX code:	NEU
Share price:	\$0.60
Market cap:	\$60m
Cash:	\$9.1m (as at 1 October 2005)
Shares on issue:	100.0m (of which 62.5m are in escrow)
	20.5m options

**Recent Accolades:** 

- > BRW Top Ten Stocks Under \$1.00
- > Awarded NZ 2005 Biotechnology company of the year
- > CSO inaugurated into US Institute of Medicine

#### Repairing brain damage from aging and injury

#### Register

Neuronz Ltd:	12.4%
NZ Seed Fund Management Ltd:	11.4%
Macquarie Bank Tech Funds:	9.6%
Pfizer Inc:	8.1%
K One W One:	6.7%
Top Twenty:	74.5%

#### Share Price Performance Since IPO



neuren

### Investment highlights

Stage of Development Poised for Major Milestones

Excellent Commercialisation Prospects

- Glypromate® accelerated to Phase 3 in CY2006
  - Multi-site international and domestic trials
- NNZ 2566 is entering Phase 1 in 1H CY2006 & Phase 2 in 2H CY2006
  - Conducting in collaboration with the US Department of Defence
- Major milestones that are expected to lead to significant rerating of stock:
  - Poised to become one of very few Australian companies conducted a Phase 3 trial under FDA jurisdiction
- Option to secure licensing deal for Lead Products (Glypromate® and NNZ 2566 IV) in 2008
  - Pivotal Phase 3 efficacy trial completed for Glypromate®
- Opportunity to out-license three product lines in near term (from Q1 2007)
  - Already received approaches from Pharma with respect to NRPs, DKPs and NNZ 2566 Oral
  - Requirements for licensing deal understood
- Attractive margins and cost of goods



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### **Investment highlights**

Uniquely positioned to fund its	
own Phase 3 Study	

Significant Market Opportunities

Excellent Management Team

Breadth and quality of portfolio

- Very few Australian companies are in Phase 3 trials: Typically prohibitively expensive
- Neuren in close consultation with the US FDA are structuring a very cost effective Phase 3 trial (first pivotal study = A\$10m)
- Plus time and money savings from acceleration in to Phase 3
- Products address multi-billion markets with unmet needs
- Limited competition
- Extensive international experience in drug development and commercialisation (100+ years; Filed 100 INDs )
- Top calibre international partners: Pfizer, US Department of Defence
- Six Family of products
- Strategic Choice: Pipeline, Development Cost, Out-licence

Attractively Priced

14% discount to 5-day VWAP

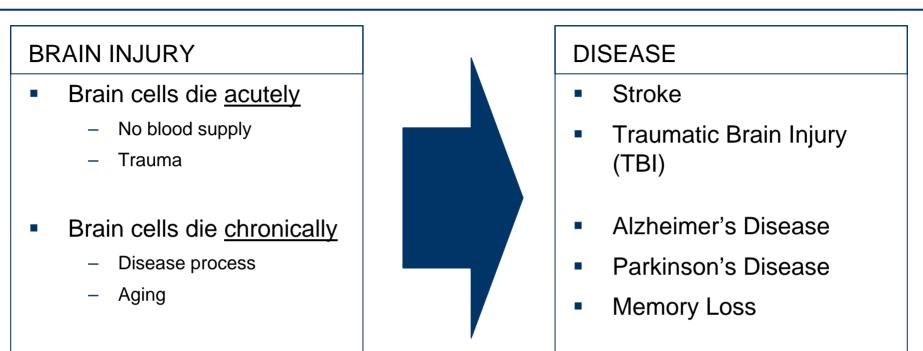


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# Repairing brain damage from aging and injury



- Nervous tissue in the brain has very poor regenerative capacity
- Most neuronal damage is the result of eventual cell death that occurs over the hours or days following the initial injury

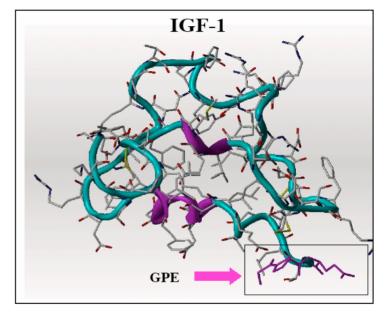
### Provides a window of time for rescue

Neuren's products take the brain's natural repair agents and improve them to minimise post-injury neuronal cell death



# Lead Products: Glypromate® and NNZ-2566

- Neural repair agents face several challenges, including:
  - Blood-brain barrier prevents many molecules reaching the brain
  - Most brain injuries, such as stroke, are unscheduled
  - Several mechanisms by which cell death occurs
- Neuren's two lead compounds address these challenges:
  - 1. Glypromate®
  - 2. NNZ-2566



- Glypromate® is derived from a naturally occurring peptide that is generated by the human brain. Glypromate® has the following significant neuroprotection characteristics:
  - Crosses the blood brain barrier
  - Long therapeutic window (highly effective when administered 7 11 hours after primary injury)
  - Highly effective in six different animal models



# Lead Products: Glypromate® and NNZ-2566

- NNZ-2566 is a modified version of Glypromate® with additional attractive characteristics including:
  - 1. Longer Acting: Better treatment window
  - 2. Oral bioavailability: Critical for chronic indications including Parkinson's Disease, Alzheimer's Disease and aged related dementia
- The first indication that NNZ-2566 is being tested for is neuroprotection in patients that have experienced Traumatic Brain Injury (TBI)
- Neuren has negotiated a very attractive development arrangement with the US Department of Defence (Walter Reed Army Institute of Research)
  - Walter Reed Army Institute of Research funds half of the pre-clinical research
  - Neuren retains all future commercial rights to NNZ-2566 outside the US Military (1-2% of the total market)
- Neuren has achieved excellent results to date utilising well-established animal models for TBI
  - NNZ-2566 has delivered up to 70% improvement in behavioral outcome
- Neuren anticipates that NNZ-2566 will also be accelerated into Phase 3



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## Glypromate® - Neuroprotection in CABG Surgery

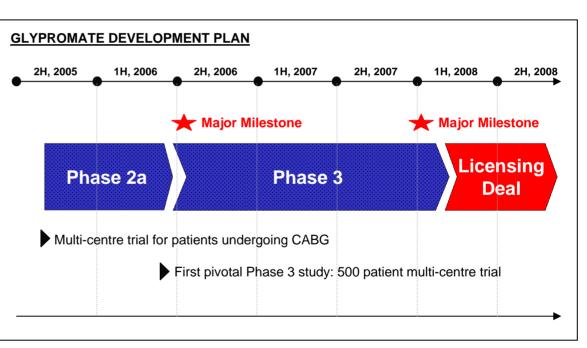
- The first indication that Glypromate® is being tested for is neuroprotection in patients undergoing Coronary Artery Bypass (CABG) Surgery
  - During CABG surgery the heart is stopped and bypassed using a machine
  - When machine is removed and heart re-started tiny clots pass to the brain
  - Up to 70% of patients have a decline in cognitive function following CABG surgery
- CABG surgery was selected by Neuren because of its excellent drug trial characteristics:
  - CABG surgery scheduling is timed and known
  - No ambiguity in diagnosis
  - Base-line cognitive function can be tested
  - Drug can be administered at optimal timing for maximal effect

No drugs currently available - An agent capable of providing neuroprotection for patients undergoing CABG would be rapidly adopted



# Glypromate® – Accelerated into Phase 3

- Successfully completed the preclinical program and Phase 1 clinical study
  - Safe and non-toxic; Well tolerated by humans
- Currently in Phase-2a
  - Multi-centre trial for patients undergoing CABG which will complete in early CY2006
- Pre-investigational new drug meeting with the US FDA enabled Glypromate® directly into Phase-3 clinical testing
- Neuren now poised to commence Phase 3 clinical trial in 2006 (originally planned for 2008)



### Entering significant clinical development phase in next 6 months



### Glypromate® - Cost effective Phase 3 study

- Phase 3 trials are normally prohibitively expensive for Australian companies
- Neuren's first pivotal Phase 3 study has been structured in close consultation with the FDA and is extremely cost effective Phase 3 study in CY2006:
  - 500 patient multi- site trial, completion within 18 months
  - AUD\$10 million for first pivotal Phase 3 study
  - Plus significant time and cost savings from acceleration

### Neuren is extremely well-positioned

- Positions Neuren as one of very few listed ASX-companies conducting Phase 3 trials
- Further, Neuren is uniquely positioned in that it can self-fund the trial maximising its ability to secure lucrative licensing deals
- Acceleration reduces time to market for the drug
- Neuren has option to license Glypromate® out following first pivotal Phase-3 trial



# Glypromate® - Development has been significantly de-risked

- Why do drugs fail?
  - Safety
     Manufacturing
     The reasons that 70% of drugs fail
     Toxicology

Neuren's development program has demonstrated that these factors are not an issue for Glypromate®

- Phase 3 study will generate efficacy data from human patients
  - Glypromate® was significantly neuroprotective in six different animal models
  - Glypromate® has multiple modes of action
  - Neuren is working closely with FDA : Glypromate® is potentially "first in market" (i.e. no drug comparison thereby reducing efficacy development risks)
  - Neuren clinical development programs are conducted within gold star standards: Jain report
  - Neuren's team has extensive experience in taking drugs to market

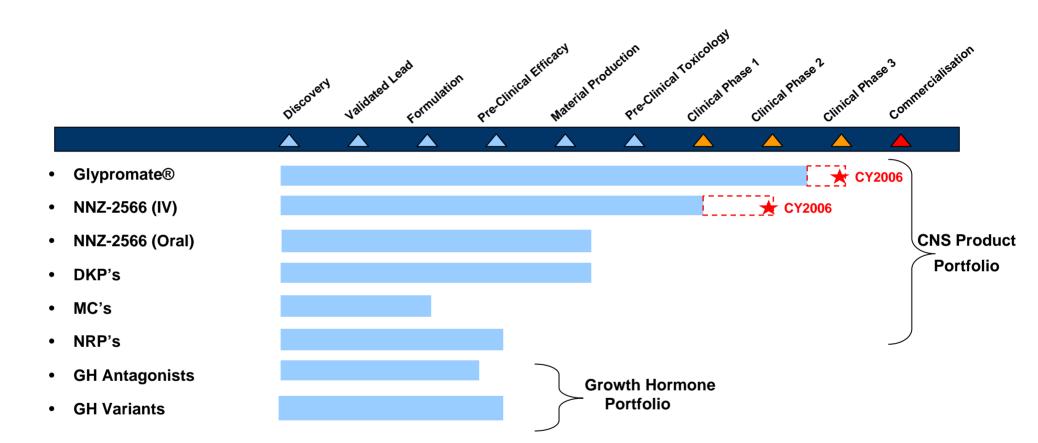
Neuren's team understands and manages drug development risk



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### **Development pipeline**



#### Extensive development portfolio offering several means of delivering value



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### **Commercialisation strategy**

Excellent Commercialisation Prospects

- Option to secure licensing deal for Lead Products (Glypromate® and NNZ 2566 IV) in 2008
  - Lucrative deal has pivotal Phase 3 efficacy trial will have been completed independently for Glypromate®
- Opportunity to out-license three product lines in near term (from 2007)
  - Already received approaches from Pharma
  - Interest in NRPs, DKPs and NNZ 2566 Oral
  - Requirements for licensing deal understood

### **Neuren's Commercialisation Principles**

- Build World-Class Partnerships Early
  - Pfizer, WRAIR, Metabolic Pharmaceuticals
  - Secure best of breed external verification (FDA IND)
- Move Quickly into Clinical Trials
  - Acute indications due to cost of trials (CABG, Traumatic brain injury...) followed by chronic diseases.
  - Glypromate accelerated to Phase 3; other previous TBI trials FDA fast tracked
- Maintain Multiple Products and Parallel Development
- Target large markets with unmet needs

# Significant market opportunities

• Several significant applications for both acute (short-term) and chronic (long-term) indications:

Acute Indications	Chronic Indications
Stroke	<ul> <li>Alzheimer's Disease</li> </ul>
<ul> <li>Coronary Artery Bypass (CABG) Surgery</li> </ul>	<ul> <li>Parkinson's Disease</li> </ul>
<ul> <li>Traumatic Brain Injury</li> </ul>	<ul> <li>Multiple Sclerosis</li> </ul>

• Large and growing markets with unmet needs:

Indication	Cases per year (US)	Market Size US\$	Effective Treatment
Bypass Surgery	400,000	\$2.0b	No
Traumatic Brain Injury	1,000,000	\$1.0b	No
Stroke	800,000	\$3.5b	No
Parkinson's Disease	3,000,000	\$2.0b	Minimal
Alzheimer's Disease	4,500,000	\$2.5b	Minimal
Multiple Sclerosis	800,000	\$2.5b	Minimal



# Key commercial milestones

Glypromate	e®	
Completion of Phase 2a trial report	Q1 CY2006	Pre-clinical toxicology c
Pre-Phase 3 CMC,Tox package Trial	Q1 CY2006	Third-stage with US Dep Defence
Commence Phase 3 Trial	Q3 CY2006	Commence Trial
		Phase 1 res

Major value driver – One of only a very small group of Australian companies to enter Phase 3

NNZ-2566		
Pre-clinical Phase 1	Q4	
toxicology completed	CY2005	
Third-stage contract with US Dep't of Defence	Q1 CY2006	
Commence Phase 1	Q1	
Trial	CY2006	
Phase 1 results	Q2/3 CY2006	
Oral – Chronic models	Q2	
complete	CY 2006	
Commencement of	Q4	
Phase 2a	CY2006	

Other Compounds		
NRP in vivo programme completes	Q3 CY2006	
DKP's – Lead candidate selection	Q2 CY2006	



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- Neuren's Board has extensive experience and expertise in drug development, regulatory approval and commercialisation
- Two of Neuren's Board have major multinational pharmaceutical experience with direct expertise in successfully taking drugs to global markets

Board of Directors			
Dr Robin Congreve (PHD)	Leading NZ international businessman		
<i>Chairman</i>	Partner in Oceania and Eastern Group		
David Clarke (ME, MBA)	Senior positions in healthcare, technology and finance		
Executive Director, CEO	Former CEO, South Auckland Health		
Dr Douglas Wilson, MB, ChB,	Former SVP, World Head Medical and Regulatory		
PHD	Affairs, Boehringer Inglehim		
<i>Non-Executive Director</i>	Participated in bringing 10 new drugs to market in USA		
Dr Graeme Howie, PhD	Former Pfizer New York; Senior exec. Pharmacia		
Non-Executive Director	20+ years big pharma drug development expertise		
Tom Amos, B.Eng	Director, Macquarie Bank (Macquarie Technology		
Non-Executive Director	Ventures)		
Trevor Scott, FCA	Leading NZ businessman		
Non-Executive Director	Chair of Blis and PEBL		



Management and Scientists			
Prof Peter Gluckman (MB, DSc, FRS)	Pediatrician, endocrinologist, Director of Liggins Institute		
cso	Former Dean, University of Auckland Medical School		
	World authority in neuroscience and endocrinology		
Dr Mike Bickerdike (Phd )	Formerly private UK biotech		
Managing Scientist	Clinical and Collaboration/JV experience (Roche)		
Lawrence Glass (BSc, MSc)	25+ years experience in biomedical research and product development		
СВО	Former CEO of a CRO that was a subsidiary of a NYSE public company		
Robyn Murdoch (MBA)	Extensive experience in Clinical Development		
CDO	Formerly Pfizer, Roche, Lilly		
Maggie Scott (MBA)	18 years experience in Clinical Trials		
Head Clinical Operations	Formerly Pfizer, Roche, Novartis, Lilly		
Rob Turnbull (Bcom, CA)	Corporate finance experience in Biotech		
CFO	Formerly with PriceWaterhouseCoopers		
Dr Kathryn Jones (PhD)	Neuroscientist with Masters in Commercial Law		
BD	Extensive IP and project management experience		



### Drugs to market in USA: 100+ years experience, 100 IND's

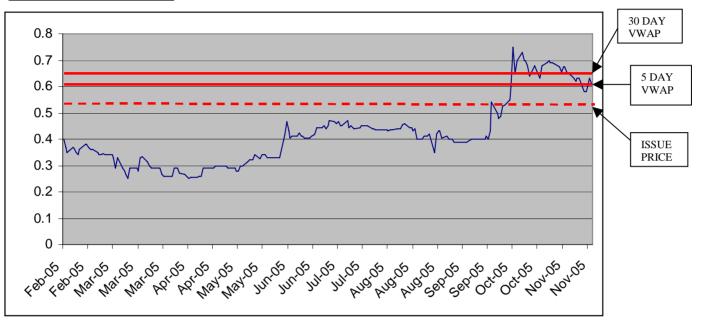
- Atrovent for common cold, Atrovent nasal for allergic rhinitis, Combivent for COPD, Asasantin for TIAs, pameprexole for Parkinson's, Meloxicam as a NSAID for osteoarthritis, Spiriva for COPD, Nevirapine for HIV, Flomax for prostatic hypertophy, Telmisartan for hypertension, and Telmisartan/hydrochlorothiazide combo for hypertension, bolus thrombolytic for AMI, TPA for stroke
- Plus worked on drugs in Hepatitis C, various anti cancer drugs, anti adhesion molecules in stroke and burns, NMDA antagonists in stroke, thrombolytics in stroke, bolus thrombolytics for acute myocardial infarcts, drugs for Alzheimer's and depression, P38 MAP kinase inhibitors for Rheumatoid arthritis, drugs to inhibit nausea and vomiting after intense cytotoxic therapy for cancer, drugs for migraine, ICAM receptor inhibitors for rhinovirus induced common cold, Nonpeptidic HIV protease inhibitors for HIV



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### Placement



#### **Neuren Pricing Graph**

- Offer of 12m shares to raise \$6.36m
- Attractive issue price of \$0.53
  - 12% discount to last close
  - 14% discount to 5 day VWAP
  - 19% discount to 30 day VWAP



### Share Capital Structre

Existing shares on issue	100,000,000	89%
Placement shares	11,990,000	11%
Total shares post capital raising	147,758,765	100%
Market capitalisation @0.53 per share	\$59,254,700	

<u>Use of Funds</u>	A\$000
Glypromate® pre-Phase 3 costs	\$2,300
Accelerated Chronic (NNZ-2566, NNZ-2591)	\$1,000
NNZ-2566 additional product for toxicity study	\$1,000
NNZ-2566 new US Army programme	\$ 700
Working Capital	\$1,000
Costs of the Offer	\$ 360
	\$6,360

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Trading halt	29-30 November
Dispatch of Firm Allocation Offer Letters	1 December
Receipt of Firm Allocation Offer Letters	2 December
Announce Placement to ASX	2 December
Settlement of Placement shares	7 December
Placement shares listed on ASX	8 December

All queries regarding the process should be directed to: Patersons Securities – Nicki Garrett on (02) 8238 6229 or 0410 503 926 Taylor Collison – Craig Ball on (08) 8217 3900 or 0409 121 688



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Stage of Development Poised for Major Milestones Glypromate® accelerated to Phase 3 in CY2006

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Excellent Commercialisation Prospects

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Breadth and quality of portfolio

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Diketopiperazines (DKPs)	<ul> <li>Small molecules that are both neuroprotectant and stimulate neurite growth for neurodegenerative diseases</li> <li>Most advanced compound, NNZ-2591, is currently being tested in animals</li> </ul>
Growth Hormones (GH)	<ul> <li>Growth hormone program is focused on finding molecules for the treatment of cancer (promote or inhibit growth in certain tumour types)</li> <li>Collaborations with Pfizer</li> </ul>
Neural Regeneration Peptides (NRPs)	<ul> <li>Peptides that stimulate neuronal regeneration and may have applications in a variety of neurodenegerative diseases</li> <li>Collaborations with Metabolic Pharmaceuticals</li> </ul>
Liggins Institute	• Under an agreement with the Liggins Institute (University of Auckland) Neuren has an automatic right-to-own any intellectual property generated in the fields of neural repair and rescue, growth and metabolism

Six families of compounds with 72+ patents



## Limited competition

Acute	<ul> <li>No drugs currently on the market</li> <li>Competitors are currently conducting clinical trials for CABG, Traumatic Brain</li></ul>
Neurodegeneration	Injury and Stroke <li>Glypromate® has a superior profile to other products in development</li>
Chronic Neurodegeneration	<ul> <li>Current products offer minimal effectiveness</li> <li>NNZ-2566 oral has shown excellent results to date</li> <li>Other compounds ( DKP,NP ) also potential candidates</li> </ul>

### Strong Competitive Position for Neuren's lead compounds

- Part of naturally occurring neuroprotective mechanisms
- Very low toxicity
- Able to provide protection for several hours after primary injury
- Tested in multiple animal models and consistently shown excellent results
- Multiple modes of action

