



## Neuren Presentation to US Conferences

**4 April 2006:** The Chief Executive Officer of Neuren Pharmaceuticals Limited (ASX:NEU), Mr David Clarke, has been invited to speak at the Boston Bio-Relationships Conference, eG Capital's Australian Bio-Investment Forum in New York, and the Bio 2006 in Chicago in the coming week.

Attached is the presentation and update he will give. A copy of this presentation is also available to view on the Company's website: [www.neurenpharma.com](http://www.neurenpharma.com)

### About Neuren Pharmaceuticals

Neuren Pharmaceuticals (ASX: NEU) is a biotechnology company developing novel therapeutics in the fields of neurotherapy and metabolic disorders. The Neuren portfolio consists of six product families, targeting markets with large unmet needs and limited competition. Neuren has two lead candidates, Glypromate<sup>®</sup> and NNZ-2566, targeting a range of acute and chronic neurological conditions. Neuren has commercial and development partnerships, including Pfizer, the US Army's Walter Reed Army Institute of Research and Metabolic Pharmaceuticals.

For more information, please visit Neuren's website at [www.neurenpharma.com](http://www.neurenpharma.com)

### Contact details

Company	Media and investor relations
David Clarke CEO of Neuren T: 1800 259 181 (Australia) T: +64 9 3 367 7167 ext 82308(New Zealand) M: +64 21 988 052	Rebecca Piercy Buchan Consulting T: +61 2 9237 2800 M: +61 422 916 422

# Neuren Pharmaceuticals

**Update**  
**New York April 2006**



# Disclaimer

---

*This presentation includes forward-looking statements that are subject to risks and uncertainties. Such statements involve known and unknown risks and important factors that may cause the actual results, performance or achievements of Neuren to be materially different from the statements in this presentation.*

*Actual results could differ materially depending on factors such as the availability of resources, the results of clinical studies, the timing and effects of regulatory actions, the strength of competition and the effectiveness of patent protection*



# Neuren Pharmaceuticals

## *Corporate Overview*

---

# 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, with two NCE's in Human Trials (Phase 2 and Phase 1)

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

ASX code: NEU

Share price: \$0.58

Market cap: \$65m

Cash: \$11.4m (as at 31 December 2005)

Shares on issue: 112m (20m options)

### Recent Accolades:

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

## Register

Neuronz Ltd:	11.0%
NZ Seed Fund Management Ltd:	10.2%
Macquarie:	8.6%
Pfizer Inc:	7.2%
K One W One:	5.6%
Top Twenty:	71.4%

## Share Price Performance Since IPO

- 45% increase since listing ( Feb 05)

Register

Repairing brain damage from aging and injury

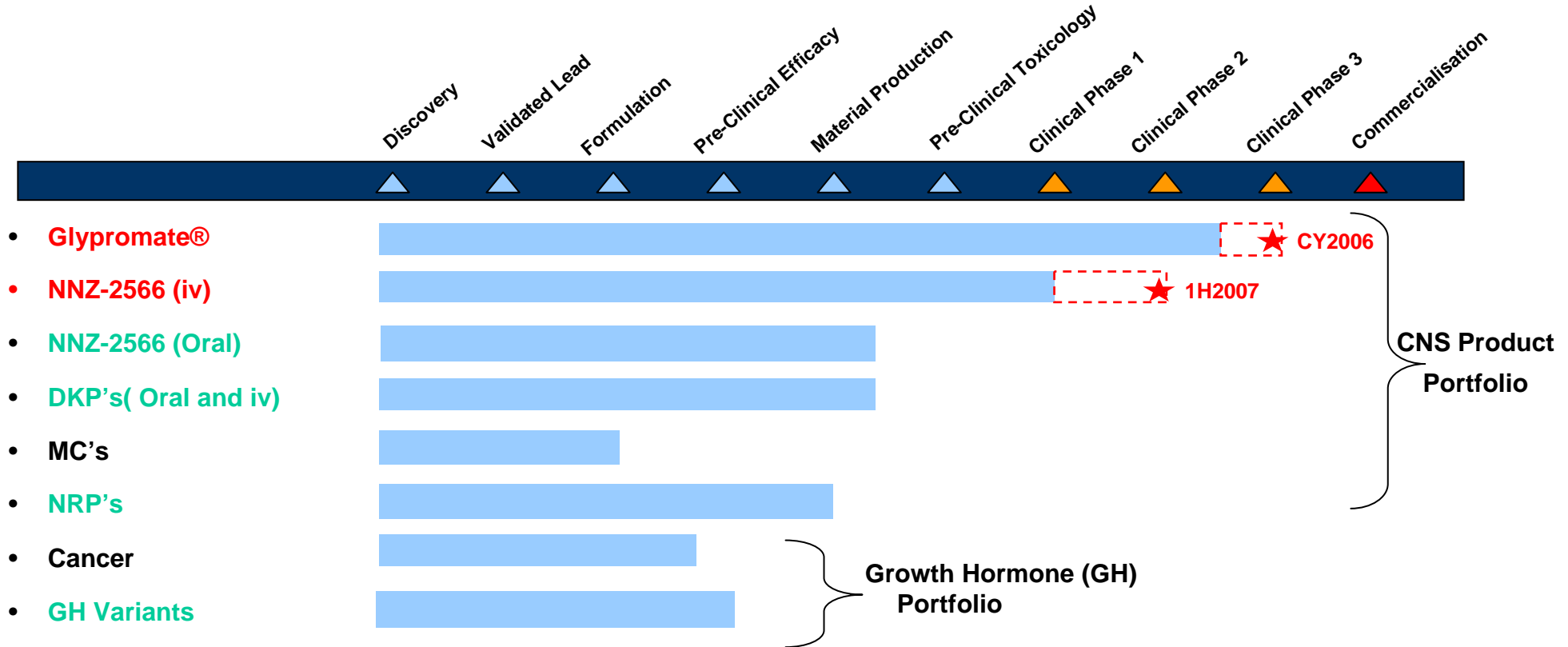
# Recent Events

---

- Strong cash position
- NEU has two ACUTE CNS trials underway
  - Pre-clinical **Glypromate** work for Phase 3 completed - Phase 2a report finalised
    - Glypromate Phase 3 on target
    - IND filing in September
  - Excellent pre-clinical results for IV administration of **NNZ-2566**
- NEU has two drug candidates for CHRONIC CNS markets
  - Successful pre-clinical results for oral administration of **NNZ-2566**
  - Pre-clinical results for oral administration of DKP, **NNZ-2591** - details to come
- Progress on the Growth Hormone (GH) portfolio
  - Cancer program moved from in-vitro to in-vivo
  - New version of GH now packaging for out-licensing
    - Unique molecule
    - No typical GH side effects

**NEU has met all milestones outlined in December 2005**

# Development Pipeline

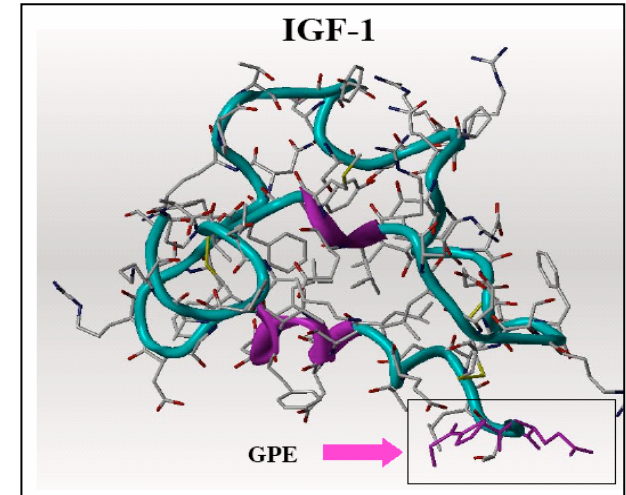


Two in clinic , four in pre-clinical, two discovery programmes

Extensive development portfolio offering several means of delivering value

# Glypromate®

- Glypromate® is derived from a naturally occurring peptide that is generated by the human brain.
- Glypromate® has the following significant neuroprotection characteristics:
  - Safe....maximum feasible dose ..no maximum tolerated dose
  - Crosses the blood brain barrier (BBB)
  - Multiple modes of action... Not single action
  - Long therapeutic window (highly effective when administered 7 – 11 hours after primary injury)
  - Highly effective in six different animal models
- Past major CNS drug issues.. 70% of failure...
  - BBB and toxicity
  - Chemistry, manufacturing and control and cost of goods
  - Single action.. ( Zoppo, NEJM, Feb 2006)
  - Short window
  - Poor trial design
- **NEUREN HAS ADDRESSED ALL OF THESE..**



In CY2005 pre-investigational new drug meeting with the US FDA accelerated Glypromate® development plan

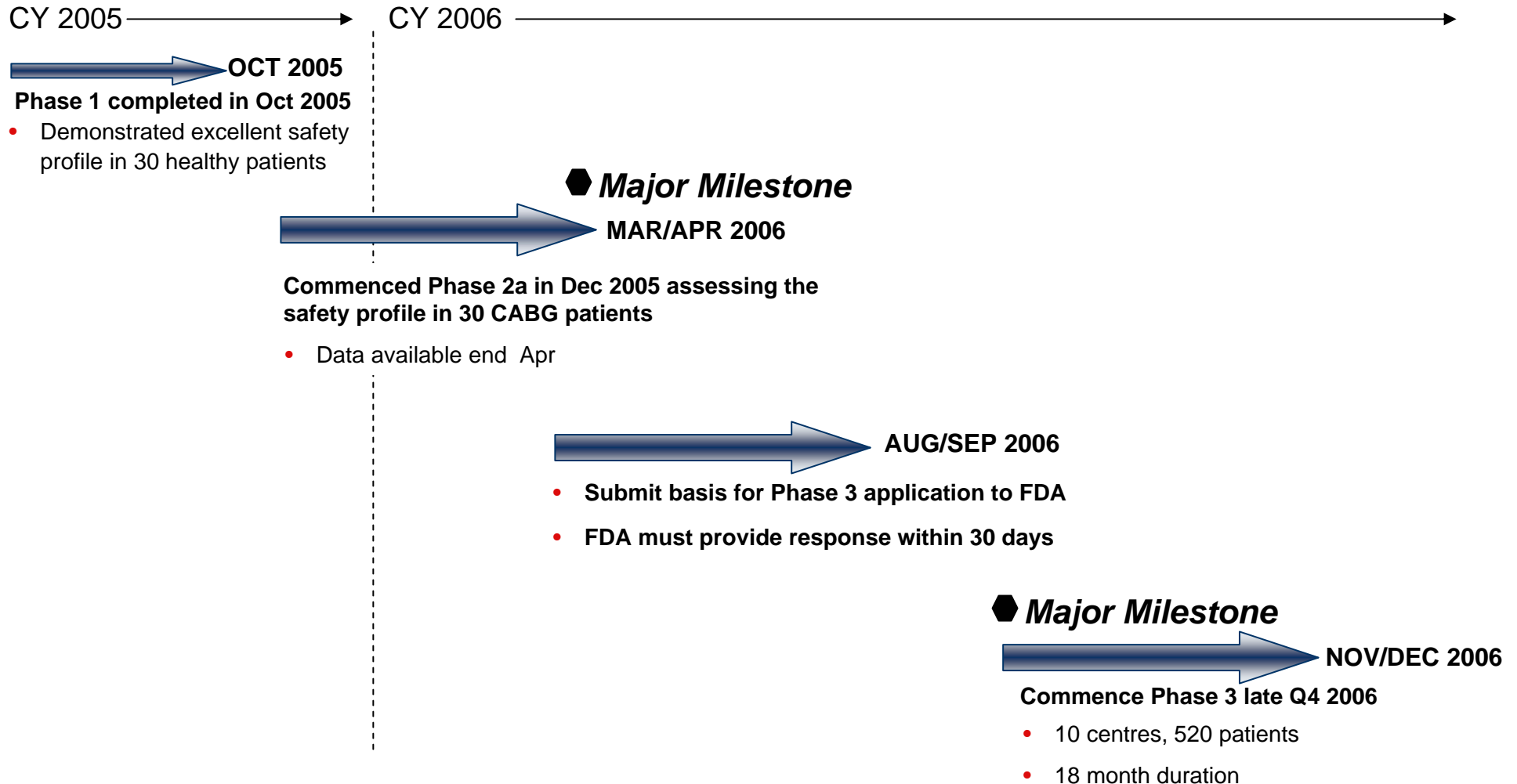


# Glypromate® - Neuroprotection in CABG Surgery

---

- Coronary Artery Bypass Graft (CABG) surgery was selected by Neuren because of its drug trial characteristics and excellent commercial prospects:
  1. Drug Trial Characteristics
    - CABG surgery scheduling is timed and known
      - Up to 70% of patients have a decline in cognitive function following CABG surgery
    - No ambiguity in diagnosis, base-line cognitive function can be tested
      - Phase 3 is 520 patients
    - Drug can be administered at optimal timing for maximal effect
    - Affordable trial, A\$10m
  2. Excellent Commercial Prospects
    - No drugs currently available, any efficacy demonstrated will likely result in rapid adoption for CABG... FDA recognized unmet need
    - Currently 400,000 CABG operations per year in the US alone
  3. Surrogate for Stroke
    - Demonstration of neuronal and other brain cell protection through CABG strongly correlates to stroke

# Glypromate® – Development Plan



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

# Glypromate® – Accelerated into Phase 3

---

- Safety is the key issue governing whether Glypromate® will successfully enter Phase 3 in 2006
- Safety considerations have been paramount in design and conduct of Phase 2a trial and preparation for Phase 3
- All the evidence to date suggests that Glypromate® is an extremely safe compound that is well tolerated in humans
  - Unable to generate any toxic response in animals
  - No drug related adverse events in Phase 1 trial
  - The FDA reviewed all data and on the basis of the safety profile was happy to accelerate the Glypromate® development program directly into Phase 3
- All FDA pre-clinical work completed successfully to Phase 3 standards

**NEU is poised in Q4 CY2006 to conduct a Phase 3 trial under FDA jurisdiction (unique in this market)**

# NNZ-2566 – First Indication is Traumatic Brain Injury

---

- Co-development with US Army (Walter Reed, Washington)
  - Share costs ..But NEUREN 99% market
  - 2566 domain is **completely partnerable**
- NNZ-2566 offers additional attractive characteristics including:
  1. Longer acting
  2. Oral bioavailability- chronic markets
- The first indication that NNZ-2566 is being tested for is traumatic brain injury (TBI)
- TBI is a large market with no currently approved therapies
  - 1 million treatable patients per year in US (2 million worldwide)
  - **70%** emergency department admissions / 30% hospital admissions
- Need for drug that can be safely administered at the scene or in the emergency room without need for sophisticated diagnostics (ie a very safe drug)
  - All previous compounds targeting TBI have received **FDA Fast-Track**

# NNZ-2566 has Delivered Excellent Results to Date

---

- Very successful pre-clinical program with Walter Reed
  - 70% reduction in neurological deficit at 72 hours
  - 50% reduction in activated microglia (key element of inflammation)
- Neuren and Walter Reed have identified a **new and effective** measure for assessing effectiveness of compound:
  - End Points: Non-convulsive seizures and cognition
  - Highly correlated with poor traumatic brain injury outcomes
  - Readily and objectively measured in an emergency medical setting
  - Subject of a new IP being filed by Neuren and Walter Reed
  - **Simplifies development path for NNZ-2566**

# NNZ 2566 Flexibility

---

- Toxicity package allows other acute iv markets
  - Hemorrhagic stroke
    - Market potential (US) US\$800 million
    - Similar pathology to TBI
      - » NNZ 2566 strong in-vivo results
  - Stroke recovery
    - Market est. US\$2 billion
      - » In hospital post stroke
      - » In vivo results Uni Texas
  
- And.....NNZ 2566 Oral
  - Chronic Markets. .Stage 2 of Neuren's plan
  - Orally available formulation ( 25%+)
    - Cognition
    - Memory and Learning

# NNZ 2566 Development Plan

CY 2005 → CY 2006 →

## Complete pre-clinical program with Walter Reed

- Demonstrated excellent results in all animal studies to date

## Delivered GMP for drug manufacturing

- Cost of goods reduced by 75%

## Major Milestone

### Commence Phase 1 in 1H 2006

- Alfred hospital (Melbourne)
- 30 patients
- Phase 1b under construction
- Results before end of year

*Note: Phase II protocol is already under development and summary has been submitted to Walter Reed for review and funding approval.*

Entering significant clinical development phase in next 6 months

## Pipeline

*Opportunity to out-license four product lines in near term*

---



# Four Near Term Out licensing Opportunities

- NEU does not have the resources to independently develop its entire pipeline
- NEU has focused on developing four product lines such that they are attractive near-term out-licensing opportunities
  - Stable compounds
  - Excellent manufacturing characteristics
  - Excellent in-vivo results

## NZ 2566 (oral)

- ♦ Confirmed oral bioavailability
- ♦ Highly protective in stroke (90%)
- ♦ Targeting Alzheimer's / Dementia
- ♦ Excellent IP position
- ♦ CY2006 Q2/3 in-vivo complete

## DKP: 2591

- ♦ Well known class: Unique analogue
- ♦ Parkinson's disease results confirmed
- ♦ Oral
- ♦ Parallel 2566 oral

## NRP: 4921

- ♦ In-vivo successful
- ♦ Peripheral Neuropathy - Unmet need
- ♦ Chemistry Manufacturing and Control / ADME underway
- ♦ Joint venture with Metabolic

## Cancer: 8000

- ♦ Breast cancer – Growth hormone mediated: 90% relevant
- ♦ Ab and small molecule
- ♦ Q2 milestone – Pab
- ♦ Q3 milestone - Mab

## Conclusion

*Poised for major milestones*

---

# Investment highlights- All on Track as per Dec 05

---

Stage of Development  
Poised for Major Milestones

- Glypromate® accelerated to **Phase 3** in CY2006
  - Preclinical package completed... **SAFE and STABLE**
- NNZ 2566 Phase 1 in 1H CY2006 and will deliver results before the end of the year
  - Conducted in collaboration with the US Department of Defence
- Major milestones that are expected to lead to significant re-rating of stock:
  - Poised to become one of very few Australian companies conducted a Phase 3 trial under **FDA jurisdiction**

Excellent Commercialisation  
Prospects  
Strategic Flexibility

- Option to secure **licensing deal for Lead Products** (Glypromate® and NNZ 2566 IV) in 2008
  - Pivotal Phase 3 efficacy trial completed for Glypromate®
    - Phase 3 in **fundable** by Neuren
- Opportunity to out-license **Four** product lines in near term (from Q1 2007)
  - NRPs, DKPs and NNZ 2566 Oral and Cancer
- Attractive margins and cost of goods

# Investment highlights

---

Uniquely positioned to fund its own Phase 3 Study

- 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

Significant Market Opportunities

- Large markets with unmet needs ,limited competition
  - Two Acute CNS drugs in humans 2006
  - Chronic CNS in humans 2007

Excellent Management Team

- Extensive international experience in drug development and commercialisation (100+ years; Filed 100 INDs )

Breadth and quality of portfolio

- Top calibre international partners: Pfizer, US Department of Defence
- Six families of products